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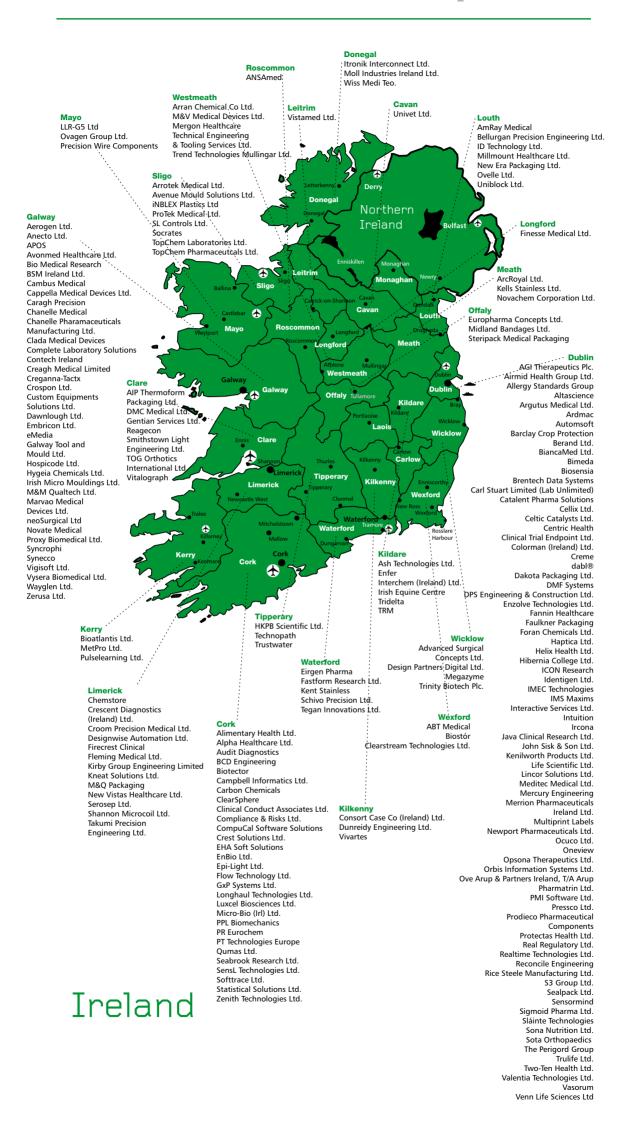
# IRISH LIFE SCIENCES

**Directory** 

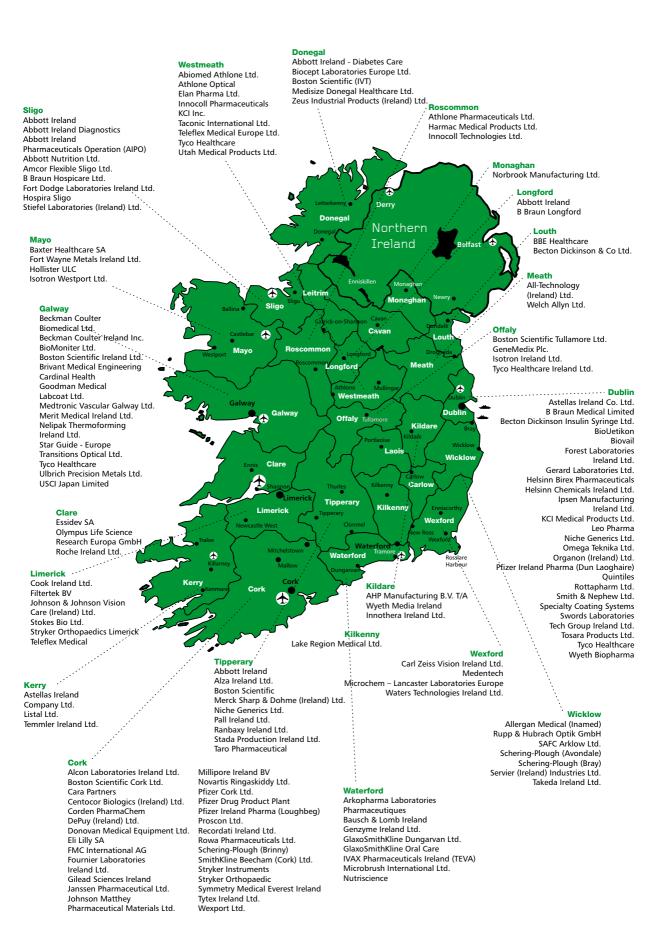


Ireland is a globally recognised centre of excellence in the Life Sciences industry.
This directory highlights the opportunities open to international companies to partner and do business with world-class Irish enterprises.

# **Irish Life Sciences Companies**



# Foreign Direct Investment Companies (FDI)



### Ireland

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#### TRELAND'S LIFE SCIENCES INDUSTRY AT A GLANCE

Ireland has secured a global leadership position in the life sciences industry and four decades of continuous investment has made Ireland the location of choice for international life sciences companies.

This industry now employs over 50,000 people directly and exports over €45 billion annually making Ireland the largest net exporter of pharmaceuticals in the world. Eighteen of the world's top 20 pharmaceutical companies have substantial operations in Ireland and six of the world's top 10 selling pharmaceutical products are exclusively produced here. Ireland is also home to Europe's leading medical technologies cluster and now has the highest per capita employment of medical technologies personnel across Europe. This cluster is comparable in scale to some of the world's leading clusters in Massachusetts and Minnesota and boasts nine of the top ten global medical technology companies.

A central feature of the Irish ecosystem is our dynamic, burgeoning and progressive indigenous company base. Irish companies are now competing in international markets throughout the world and are using the many competitive levers of price, cost, quality, speed, flexibility and innovation to secure a continually increasing share of the global market. From proprietary product developers, to technology intermediaries, to end product manufacturers and ancillary service providers, the indigenous company base is characterised by 'excellence' – on a global level.

Ireland's indigenous and multinational company base is complimented by a world-class research base (basic and applied), a highly evolved technology transfer and clinical infrastructure, a buoyant venture capital community, and an internationally renowned regulatory environment.

Through continued commitment and collaboration amongst all industry stakeholders, the sector continues to evolve and grow. We now offer a fully integrated, multi-disciplinary and cohesive value-chain in the lifesciences industry making Ireland the partner of choice for the global community.

This directory is a guide to finding you a world-class Irish partner.

#### Ireland's key State Agencies

The following Irish State Agencies work closely with the Life Sciences industry, ensuring that it continues to develop as a vibrant growth engine of the Irish economy.

#### **ENTERPRISE IRELAND**

Enterprise Ireland is the Irish Government agency responsible for the development and promotion of Irish enterprise. Our mission is to accelerate the development of world-class Irish companies to achieve strong positions in global markets, resulting in increased national and regional prosperity.

Innovation, leadership, competitiveness and growth are the core themes of the Enterprise Ireland strategy, driven by the overarching principle that growth in global markets through the internationalisation of Irish companies is the key to wealth and employment creation in Ireland.

Enterprise Ireland's priorities include driving innovation, stimulating the emergence and development of companies of global scale, consolidating existing growth in key sectors and markets, capitalising on emerging opportunities, and helping to realise sustained and balanced regional growth.

With 10 offices in Ireland and a network of over 30 international offices providing access to more than 60 countries around the world, Enterprise Ireland supports the internationalisation of Irish enterprises and helps international companies connect with and maintain profitable partnerships with businesses in Ireland.

#### www.enterprise-ireland.com

#### ENTERPRISE IRELAND, RESEARCH AND INDUSTRY

#### Using the best of Irish research for the benefit of industry

Enterprise Ireland is committed to the goals of the Irish Government's plan, **Building Ireland's Smart Economy**, which aims to drive growth in the Irish economy through innovation, research and technology application.

Enterprise Ireland has supported the development of a national technology transfer system to increase the flow of commercially viable research from higher educational institutes in Ireland into the marketplace, in the form of patents, technology licences and spin-out companies. Teams of highly experienced technology transfer personnel and commercialisation specialists are in place to specifically focus on identifying, capturing, protecting and translating research into new technologies that have the power to transform existing businesses, and in some cases, create new companies.

In addition to supporting in-house company R&D programmes, Enterprise Ireland continues to forge industry-academic linkages. Collaborative research projects between companies and research groups and industry-led research networks are underway throughout the country. This investment in Ireland's research infrastructure has created a flexible, responsive innovation eco-system, where companies can use cutting-edge Irish research and technology to gain competitive advantage.

For further information on the commercialisation of Irish research, please see www.enterprise-ireland.com/en/Research-Innovation/Researchers/ and www.biotechnologyireland.com.

#### IDA IRELAND

# IDA Ireland is the Irish Government enterprise agency responsible for securing Foreign Direct Investment for Ireland.

IDA also works with existing client companies, aiding the expansion of their Irish operations and their on going evolution to increase their strategic importance to their parent corporations. IDA plays a leadership role in the development of interdisciplinary collaborations between academia, Government and enterprise.

Over 1,000 overseas companies have chosen Ireland as their European base and are engaged in a range of activities across sectors as diverse as Life Sciences, Information Communications Technology, Globally Traded Business Services and International Financial Services.

IDA's focus is to attract high value Foreign Direct Investment requiring advanced skills and a professional business environment.

IDA works at securing High Value Manufacturing and Research, Development and Innovation projects in the following sectors;

- Life Sciences encompassing pharmaceuticals and medical technologies
- Information Communications Technology
- International Financial Services
- Business Services
- Consumer Products & Services
- Industrial Products & Services
- Clean Technology
- Entertainment and Media

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#### SCIENCE FOUNDATION IRELAND

Science Foundation Ireland is investing in world-class academic researchers and research teams who are not only excellent in the research they perform, but who are innovative and most likely to generate new knowledge, leading edge technologies and competitive enterprise.

Ireland is an exciting place to carry out research in the areas of bioscience and bioengineering across a broad range of disciplines that underpin the study of gene expression, protein synthesis and characterisation, protein signaling, neuroscience, immunology, DNA, RNA, genomics, chemistry, biosensors, drug delivery and bioremediation.

SFI has invested heavily in research of strategic importance to Ireland. SFI researchers collaborate with 300 companies, in particular the SFI Strategic Research Clusters (SRCs) and Centres for Science Engineering and Technology (CSETs) encourage collaboration with industry around strategic areas of research.

#### SFI Strategic Research Clusters (SRC's) - Life Sciences:

- Solid State Pharmaceuticals Cluster (SSPC), University of Limerick
- The Network of Excellence in Functional Biomaterials (NFB), NUI-Galway
- The Glycoscience Research Cluster, National University of Ireland, Galway
- The Irish Drug Delivery Network , University College Dublin
- The BioNanoInteract Cluster, University College Dublin
- Molecular Therapeutics for Cancer, Dublin City University
- Reproductive Biology Research Cluster, University College Dublin
- Immunology Research Centre (IRC), Trinity College Dublin
- Advanced Biomimetics for Solar Energy Conversion, University College Dublin
- Irish Separation Science Cluster, Dublin City University

#### SFI Centres for Science, Engineering and Technology (CSETs) - Life Sciences:

- Alimentary Pharmabiotic Centre (APC) at University College Cork
- Biomedical Diagnostics Institute (BDI), Dublin City University
- Regenerative Medicine Institute (REMEDI), National University of Ireland, Galway

#### For further information contact:

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# **CHEMICALS**



#### ARRAN CHEMICAL CO ITD



**Business Description** Arran Chemical Company is an independent fine chemical company manufacturing products for pharmaceutical and healthcare, personal care, and other specialised chemical and industrial applications. The manufacturing programme is supported by a strong process development capability and well-equipped laboratories on the same site.

#### **Products & Services**

- Arran offers pharmaceutical intermediates including alkylamines and hydrochlorides, Grignard-based chemistry, mandelic acid derivatives, a wide range of chiral substances, and are well equipped for, and experienced in, process development and custom synthesis. The chiral programme includes amines, aminoalcohols, and ligands and catalysts for asymmetric synthesis
- Arran's manufacturing programme also features a range of flavour/fragrance intermediates, based on aldehyde, oxipene and pentenone chemistry, with new products in development
- Total reactor capacity is approximately 50m3 with full support services and handling facilities for solids and liquids. Low temperature processing and short path distillation can also be offered as standard options

**Standards & Certifications** ISO 9001:2000, ISO 14001:2004, IPPC licence, Safety Management System, adheres to Responsible Care Programme.

Additional Languages Irish, French, German, Polish.

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#### BARCLAY CROP PROTECTION

**Business Description** Barclay develops and manufactures a broad range of post-patent crop protection products including herbicides, fungicides, plant growth regulators, insecticides and micronutrients. Key elements of Barclay's business strategy are: independence, product quality, operational excellence, value for money, reliability, customer responsiveness, and ease of doing business.

#### **Products & Services**

- Herbicides
- Fungicides
- Insecticides
- Micro-nutrients

**Key Customers** National and regional distributors and retailers in nineteen European countries. The distribution strategy and customer base is driven by local market and distribution structures.

**Standards & Certifications** Barclay operates to the highest EU pesticide standards and regulations and has a highly qualified and experienced registration team based at the Dublin office but operating in most European countries and beyond. A HACCP (hazard analysis and critical control points) quality assurance programme is applied, from sourcing right through to the manufacturing process.

Additional Languages French, Spanish, German.

Note Barclay has been awarded the standard of "Excellence Through People".

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#### CARBON CHEMICALS

**Business Description** Carbon Group was established in 1967 and has offices in Cork (HQ), Dublin & Belfast. Carbon Group offers a wide range of fine chemicals, solvents and natural ingredients from leading global producers for the pharmaceutical, medical, cosmetic, beverage and other industries. The company also supplies a wide range of industrial chemicals, sanitisers and detergents.

**Products & Services** Carbon Group has contract manufacturing capabilities and expertise to meet customer's specification, in addition to on-site facilities for blending (both wet & powder products), packaging and storage of chemical and solvent formulations. Its bulk solvent storage and drumming facility allows the delivery of various pack sizes in short lead times. Carbon Group recently launched its own HPLC range of solvents and high purity acids for analytical, laboratory and other applications to local and international markets.

Carbon Group has 3 business divisions;

- Chemicals/pharmachemicals
- Food ingredients
- Paint & equipment

Pharmachemical division product range includes: hydrocarbon solvents, glycol ethers/esters, fragrances and flavours, fats and waxes, acids and alkalis, petroleum jellies/white oils, antifreeze/glycols, pharmaceutical specialities, acetate esters, excipients, ethanol, glymes, ethanolamines, solvents.

**Key Customers** Pfizer Pharmaceuticals, GSK, Novartis, Millipore, Stryker, Eli Lilly, Jannsen, Recordati, Roche, Norbrook, BMS, Abbott, Corden, Pall Industries.

Standards & Certifications ISO 9001:2008 QMS, Responsible Care Award, member of REPAK and ESAD II

#### **Additional Languages French**

**Note** Carbon Group represents the following companies in the Irish Market – Sasol, Cepsa, Carbery, Novolyte Technologies, Robertet, Akzo Nobel, Helm and Darbox, thus bringing global knowledge and local expertise together.

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#### HYGETA CHEMICALS ITD

**Business Description** Hygeia Chemicals Ltd. manufactures and markets products for home and garden and agricultural consumers i.e. weed and moss control on hard surfaces and lawns, agricultural weedkillers, sheep dips, in Ireland and the UK. The company also markets seed dressing in the UK market for oilseed rape etc.

#### **Products & Services**

- Home and garden chemicals
- Amenity products
- Agri-chemicals
- Grassland weedkillers
- Seed dressings
- Animal husbandry products

**Key Customers** Home and garden distributors, Ireland and UK Agrochemicals, Ireland and UK Hardware and general merchants, Ireland and UK Vets and chemists, Ireland.

**Standards & Certifications** EPA (environmental protection agency) licensed, Basis registered, PCS Ireland compliant, PSD (UK) compliant, Health Service Executive (UK) compliant.

**Note** Hygeia Chemicals Ltd. is the marketer and formulator of products for the home and garden, domestic and agricultural sectors; weedkillers, fungicides and insecticides for cereals and grassland, and is the sole owner of a UK registered company, Agrichem International Limited, through which it develops, distributes and sells a unique range of seed dressings for non-cereal crops (www.agrichem.co.uk).

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#### METPRO LTD

**Business Description** MetPro is a global technology-based company that develops and manufactures corrosion protection additives for incorporation into packaging materials such as paper and plastics. This specialised packaging is used in the automotive, metal component and steel wrapping industries to prevent corrosion during storage and shipment.

**Products & Services** MetPro has established a reputation for invention and quality which has allowed the company to become a proven market leader and win critical approvals with many international organisations supplying OEM, Tier 1 and Tier 2 companies. MetPro's ability to supply and develop effective and innovative volatile anti-corrosion inhibitor technology, driven by market demands, is the platform on which they do business. The products are used widely in the following industry types: steel component manufacturers, machines parts and components, steel coil producers, wrapping of surgical blades and automatic wrapping of extruded profiles.

- VCI masterbatch
- VCI paper
- VCI film
- VCI steel coil wrap
- VCI woven raffia

Key Customers TRW, Bosch, Valeo, Siemens, Renault, Peugeot, VW, PMG Fussen, Ina, ZF, Volvo, SKF, Audi, Timken, Corus Steel, Eurosteel, Doktas, Ford, TATA, VW, Swann Morton, ALCOA.

Standards & Certifications ISO 9001:2000, US-MIL-PRF-22019E, German Mil-Spec TL 8135 0043/02, TRGS 615 – compliant, Reach Compliant 1907/2006/EG.

Additional Languages German, French, Spanish, Cantonese, Hindi.

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#### MICRO-BIO (IRL) LTD

**Business Description** Micro-Bio (Ire) Ltd. is a manufacturer of sodium hydroxide, hydrochloric acid, sodium hypochlorite, sulphuric acid, potassium hydroxide, as well as a toll manufacturer of detergents.

#### **Products & Services**

- Sodium hydroxide
- Hydrochloric acid
- · Sodium hypochlorite
- Sulphuric acid
- Potassium hydroxide
- Toll manufacturing
- Blending
- Storage and distribution of chemical products including bulk sea-fed storage tanks to warehousing

**Key Customers** The company supplies to manufacturing entities in the following industries: pharma-chem, bio-pharma, dairy processing, food and beverage, breweries, distilleries, and various niche industries. Micro-Bio has been supplying these sectors for over 30 years and is a well respected supplier for quality of product, service and support.

**Standards & Certifications** Micro-Bio's products are of the highest quality. Produced in an electrolytic cell membrane plant, products ranging from commercial to food grade are available, and complies with USP. The company also holds ISO 9001:2000 and Responsible Care certification.

#### **Additional Languages French**

**Note** The company is investigating GMP manufacturing of these products and would welcome enquiries from users worldwide who may require this level of assurance.

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#### PT TECHNOLOGIES EUROPE



**Business Description** PT Technologies develops and manufactures environmentally responsible solvents, wipes and lubricants for specification-driven industries such as power, telecom, aerospace, defence and marine. PT Technologies focusses on measurable work practice improvements via overall cost reduction through environmental and health and safety benefits.

#### **Products & Services**

- Surface cleaning and preparation products and wipe systems for aerospace, defence, utilities and other specification industries
- Bespoke surface cleaning programmes to reduce consumption VOC emissions, and health and safety exposure
- · Cable pulling and blowing lubricants
- Antibacterial hand cleaning wipes

**Key Customers** Airbus UK, Balfour Beatty, Bombardier Aerospace, British Airways, CAV Aerospace, CE Electric, Corning, EDF, EoN UK, ENSTO, GKN, Martin Baker, Pilatus, Prysmian Cavi, Safran Group, Scottish and Southern Energy, Scottish Power, United Utilities.

**Standards & Certifications** Accredited to MIL specs and aviation standards, Power industry specifications, Microbiological certifications and ISO 9001:2000.

Additional Languages French, German, Spanish, Dutch, Italian.

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# **DEVELOPMENT TECHNOLOGIES**



#### ALIMENTARY HEALTH ITD



**Business Description** Alimentary Health Ltd. is a specialty biotechnology company focussing on developing probiotic-based healthcare and prescription drug products for the management of inflammatory and infectious disease, as well as developing clinically proven bacterial strains founded on world-class scientific research.

#### **Products & Services**

- Strong pipeline fully underpinned by exclusive first negotiation option on probiotic-based technology generated by world-renowned Irish Government funded Alimentary Pharmabiotic Centre (APC). The APC is based on campus in University College Cork and has received additional funding of €17.3 million for the period 2008 to 2013
- Long-standing partnership with Procter and Gamble has resulted in the launch of a novel "over the counter" (OTC) product Align® for the management of digestive conditions. The active component of Align® is the AH proprietary strain Bif 35624
- Procter and Gamble Pet Care has launched Prostora™ Max, a new probiotic supplement for dogs, developed from AH proprietary pet care probiotic technology under license
- Well-defined collection of other bacterial candidates in clinical development for OTC & prescription indications

**Key Customers** Procter and Gamble Healthcare Division, Procter and Gamble Animal Healthcare, Mead Johnson, ConvaTec and General Mills.

**Standards & Certifications** Technology validated by extensive publication in leading industry journals. Robust IP strategy with significant number of patents filed in key Patent and Trademark Office (PTO) countries.

**Note** Article in Forbes magazine of 27 Oct 2008 at www.forbes.com/claytonchristensen/forbes/2008/1027/097. html. See also www.AlignGl.com

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#### ARROTEK MEDICAL ITD

**Business Description** Arrotek Medical is a highly skilled medical device engineering company offering a range of development and manufacturing services from initial product assessment through to the provision of sterile finished product.

Arrotek excels as an engineering resource for early stage companies or in product development for larger companies.

#### **Products & Services**

- Contract medical device design and development service
- Prototyping of concepts for product evaluation
- Compiling and submitting for CE and FDA regulatory approval
- Precision manufacture and supply of sterile product

**Key Customers** Start-up companies, University spin-outs and innovative medical professionals developing new medical products.

Standards & Certifications ISO 13485:2003

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#### **RFRANDITD**



**Business Description** Berand Ltd. provides high-value preclinical drug screening services and animal models of diseases to major pharma. The company is located in NovaUCD Business Park, and has access to core technologies at the UCD Conway Institute. R&D in Berand relates to autism and obesity.

**Products & Services** Berand's principal activity is the delivery of a high value service provision to meet the outsourcing needs of major multinational pharmaceutical companies and involves the characterisation, proof-of-concept studies and value enhancement of potential drug candidates at the preclinical/early clinical stage of development. Berand successfully operates in both the European and US markets. Berand has established and maintains unique animal models to determine therapeutic potential for the treatment of neurological and psychiatric disease. Research activity at Berand is focussed on employing these models together with in-house expertise to identify and develop novel therapeutic targets, specifically in the fields of autism and obesity.

**Key Customers** Partnering with or service provision to: major multinational pharmaceutical companies, biotechnology companies, SME's and research institutes.

**Standards & Certifications** Licenced by the Irish Department of Health and with experimental governance by University College Dublin.

Additional Languages German, Dutch, Irish.

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#### **BIOATLANTIS LTD**

**Business Description** BioAtlantis is a biotechnology company with products for two different market sectors at present: plant bio-stimulants and feed materials. Digestica™ based on soluble algal fibres is under development for human application.

#### **Products & Services**

- 1. Bio-stimulants: BioAtlantis currently supplies a range of speciality foliar feeds based on seaweed extract from Ascophyllum nodosum or Laminaria species for horticulture, vitaculture, agriculture and amenity
- 2. Feed material: GutCare™ has application in post weaning piglet diets where it improves performance, stimulates immunity and in general improves the health of the host in a stressful period of their life. A second product is for the lactating sow market where enormous benefits are gained by the producer through the maternal transfer of benefits from the sow directly to her piglets via breast-milk

#### **Key Customers**

- 1. Biostimulants: formulators or distributors of foliar feeds or direct to end-user
- 2. Feed material: pig feed compounders and home mixers

#### Standards & Certifications

- 1. Biostimulants: Organic Trust and OMRI (Organic Materials Review Institute) certification of pure seaweed extracts
- 2. Department of Agriculture approved for feed manufacture and feed retailing
- 3. HACCP

Additional Languages Spanish, Italian.

Note PCT has been filed and national applications have been completed for Europe and the US.

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#### CELTIC CATALYSTS



#### **Business Description**

Celtic Catalysts is a leading supplier of chiral products and manufacturing services to the pharmaceutical, fine chemical and biotechnology industries. The company has a strong and energetic management and scientific team who are focussed on providing customers and collaborators with products and services of the highest calibre.

#### **Products & Services**

Company chemists have a broad spectrum of experience in production, custom synthesis, contract research and process development and have on-site access to the full spectrum of analytical tools - NMR, MS, GC, HPLC and X-ray crystallography. Broadly speaking the core areas of competence can be categorised as follows:

- Contract research & manufacture
- Chiral chemistry
- Phosphorus chemistry
- Process R&D
- Unnatural amino acids
- Hydrogenation
- Gram, kilogram & ton scale

**Key customers:** Major pharma, biotech & fine chemical companies.

Additional Languages: German, Swedish, Polish.

**Note** The company actively seeks to work with partners to whom can be added the benefit of many years experience and expertise in the core focus areas (listed above).

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#### **EMBRICON ITD**

**Business Description** Embricon Ltd. was founded in 2005 to translate clinically identified opportunities into commercially available products for the improved treatment of endo- and peripheral vascular conditions. Based in the Business Innovation Centre at the National University of Ireland, Galway, the company's interests span clinical research to biomedical engineering.

Products & Services The strength of Embricon lies in its ability to access extensive medical research, identify product opportunities and translate those opportunities into commercially viable solutions for surgical and non-surgical use in the treatment of peripheral vascular disease. The technology platform spans multiple products currently in the planning and concept stage, demonstrating strong innovation and aggressive development activity. The first product addresses the globally extensive varicose vein treatment market. It combines innovative guide wire technology to perform a range of procedures currently executed in discrete surgical processes. The core values of global vision, strength of IP and management capability allows Embricon to address not only the scaleability of the first product but also the range of opportunities through the product pipeline.

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#### **ENRIO ITD**



**Business Description** EnBIO is a surface modification company that has developed a unique, market disruptive coating process for metallic medical implant devices. This patent pending 'active coating' technology improves the biocompatibility of medical implant devices.

#### **Products & Services**

- CoBlast: new and novel process for applying passive and active (drug-eluting) coatings to implantable metals at room temperature, without the need for a polymer carrier or a complex application process
- CoBlast: can be used to apply therapeutic agents of choice to a metallic medical implant surface (e.g. antibiotic, anti-thrombotic, bone morphogenic proteins, etc.)
- CoBlast: enables significantly enhanced surface-finish characteristics with superior end-product quality at a dramatically reduced application cost base with the elimination of infection and biofilm growth

**Key Customers** EnBIO's target customers are implant device manufacturers.

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#### FASTFORM RESEARCH LTD

**Business Description** FastForm Research focusses on the development and commercialisation of 'smart polymer' technologies and superior medical products for the healthcare industry, targeting a number of sectors particularly the orthopaedic market for fracture repair.

#### **Products & Services**

- Custom mouldable therapeutic solutions in the form of innovative custom mouldable splints; casts, braces and sterile support material for topical surgical applications such as brachytherapy
- Patient comfort is greatly enhanced while procedure times and associated costs are significantly reduced, thereby providing cost savings for healthcare organisations, payers and patients

**Key Customers** FastForm is strategically building market access through local bracing and soft-goods distributors in relevant markets worldwide.

**Standards & Certifications** All quality design and development work is carried out in accordance with ISO 13485 and FDA quality systems regulation CFR21 part 820. Products are CE-marked per MDD/93/42/EEC.

**Note** The company will enter strategic partnerships to co-develop and supply high value spinal bracing products and will achieve this by replicating its technology, know-how and capabilities and leveraging its strong relationships with orthopaedic professionals

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#### **IDENTIGEN ITD**



**Business Description** IdentiGEN is a leading provider of innovative DNA-based branding solutions for whole chain traceability to the agriculture and food industries. The core area of expertise, genetic identification, is being deployed to enhance consumer confidence in the safety and quality of food products. IdentiGEN has more than ten years experience in the commercialisation of DNA-based traceability solutions.

#### **Products & Services**

- Traceability of meat products from point of sale to animal of origin. Identigen's DNA TraceBack® system, www.DNAtraceback.com, provides retailers, meat processors, producers and local governments with the tools to unequivocally trace the identity of meat back to its source
- Authentication and validation of meat product attributes such as natural, organic or Angus. TraceBack is used
  to use to support consumer confidence in the fresh meat category. IdentiGEN's traceability is also used as a
  monitoring tool, ensuring that only meat from animals that meet customer specifications is sold in stores

Key Customers Meat packers, processors, grocery retailers and Government bodies.

Standards & Certifications ISO 9001:2000, USDA Process Verified Programme, ISO 17025.

Additional Languages Italian, French.

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#### MERRION PHARMACEUTICALS IRELAND LTD

**Business Description** Merrion Pharmaceuticals is a publicly listed product development company focussed on delivering innovation to the market by designing its own patented products and partnering to develop strategic products. Merrion is engaged in the development of oral forms (tablets) of drugs that have poor absorption and are generally given by injection.

#### **Products & Services**

#### **Partner Products**

Novo Nordisk: to develop oral insulin analogues and to develop and commercialise oral formulations of a Novo Nordisk proprietary GLP-1 receptor agonist, using Merrion's proprietary (GIPET®) technology Ferring: oral drug delivery research collaborative program with an undisclosed compound

#### **Merrion Products**

- Orazol (oncology): tablet form of blockbuster IV infusion for cancer bone metastases in Phase IIb (available for partnering)
- Almerol (osteoporosis): improved tablet form of blockbuster osteoporosis drug in Phase II (available for partnering)
- Acyline (fertility): tablet form of injectable hormone suppression drug in Phase I
- MER 102 (DVT): tablet form of injectable anticoagulant entering Phase I

Standards & Certifications Merrion has a GMP license to manufacture for human trials.

- 30,000ft<sup>2</sup> purpose-built
- 6,500ft<sup>2</sup> formulation process development area
- 21 processing rooms Class D clean room
- 4,000ft<sup>2</sup> analytical laboratories
- Development and feasibility

Additional Languages Polish, French, German and Cantonese.

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#### OPSONA THERAPEUTICS LTD



**Business Description** Opsona Therapeutics is a leading drug development company specialising in modulating the human innate immune system to treat autoimmune and inflammatory conditions, cancers and infectious diseases. Opsona's efforts are focussed on modulating Toll-Like Receptors (TLRs) and inflammasome signalling to treat diseases.

#### **Products & Services**

- OPN-305 fully humanised monoclonal antibody targeting TLR2 developed to reduce pro-inflammatory cytokine production associated with autoimmune and inflammatory diseases and expected to enter the clinic in 2011
- NALP3 Inflammasome small molecule programme aimed at inhibiting IL-1 production that is associated with a range of inflammatory diseases such as diabetes, gout and atherosclerosis
- OpsoVac<sup>™</sup>- novel TLR platform for increasing efficacy and antigen sparing of vaccines and immunotherapeutics. The technology is applicable to both cancer and infectious diseases

Key Customers Pfizer, CSL Ltd., Lonza, Merck, and Trinity College Dublin.

**Note** Opsona has raised a total of €28M in Venture Capital funding to date and has also received additional financing through partnering and grants to advance its research and development efforts.

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#### PHARMATRIN LTD

**Business Description** Pharmatrin Ltd. is a drug discovery and early drug development company, specialising in developing small-molecule new chemical entities (NCEs), with potential therapeutic applications in the areas of inflammation and auto-immune disease.

**Products & Services** Pharmatrin focusses on small molecule NCE synthesis in the discovery phase and has progressed a number of drug candidate molecules from discovery to lead optimisation and pre-clinical development. In addition, Pharmatrin has a developmental pipeline made up of additional therapeutic targets for lead compounds, as well as additional NCEs for use in the general therapeutic areas of inflammation and autoimmune disease. Ethnomedicine and natural product chemistry is used as a basis to give direction and lead to small molecule synthesis of NCEs with novel biological activity, together with an assessment on a variety of cell systems in vitro and animal models in vivo. Pharmatrin Ltd. also has an expanding patent portfolio.

Additional Languages German, Italian.

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#### SIGMOID PHARMA ITD



Business Description Sigmoid Pharma is a pharmaceutical specialty product and drug delivery development company with a portfolio of innovative products developed to treat gastrointestinal diseases, including orphan diseases. All products are enabled using the proprietary SmPill™ technology. SmPill enhances oral delivery of small molecules, peptides and vaccines.

#### **Products & Services**

- Ulcerative colitis in Phase II clinical study, available to license in early 2011
- Crohn's disease in pre-clinical study; Phase I / Open-label to complete in mid-2011
- Graft-versus-host disease in pre-clinical / Phase I study, US FDA Orphan designation

#### **Technology Offering**

- SmPill: enhances the solubility, permeability and release profile of poorly soluble APIs or to reposition drugs
- Oral peptide delivery enhanced oral bioavailability (10-20% absolute bioavailability)
- Oral vaccine delivery strong antibody response and viral protection

**Key Customers** Pharmaceutical and biopharmaceutical companies with strategically important discovery or in-market stage products that require enhanced solubility, permeability and controlled/targeted release formulations. SmPill is also applicable to improve delivery of functional food ingredients.

**Standards & Certifications** Sigmoid is licensed by the Irish Medicines Board. Sigmoid manufactures, tests and releases products for animal pre-clinical and human clinical studies at its Dublin GMP facility.

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#### VYSERA RIOMEDICAL ITD

**Business Description** Vysera is developing innovative solutions for the treatment of gastrointestinal disorders, including reflux control in palliative care, gastroesophageal reflux disease (GERD) and other applications including urology and drug delivery.

**Products & Services** The company is differentiated by its biomemetic material that can be applied in multiple medical specialities through minimally invasive solutions. In-house facilities include technology development, product design and development, biomaterials technology, chemical and pharmaceutical technology, product testing and regulatory approval.

**Key Customers** Clinical arrangements exist with Brigham and Women's Hospital (Boston), Mayo Clinic (Rochester, USA), Sahlengrenska University Hospital (Sweden), Aalborg Hospital (Denmark) and St. James's/Trinity College Dublin (Ireland).

Standards & Certifications ISO 13485:2003

Additional Languages French, Hindi, Japanese.

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#### XEOLAS PHARMACEUTICALS



**Business Description** Xeolas Pharmaceuticals is a speciality pharmaceutical company developing a portfolio of prescription pharmaceutical products. A particular focus of Xeolas Pharmaceuticals is to develop "patient friendly" medicines that better address the requirements of special patient groups, in particular medicines for children (paediatric medicines) and elderly patients.

**Products & Services** Xeolas' lead development project is a unique, patented product for the treatment of osteoporosis designed to improve patient compliance and adherence. The product has completed clinical trials and has been submitted to the European health authorities for pan-European marketing authorisations.

**Key Customers** Pharmaceutical companies with sales and marketing capabilities.

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# DIAGNOSTICS / INSTRUMENTS



#### ARGUTUS MEDICAL ITD



**Business Description** Argutus Medical Ltd. is an in vitro diagnostic biomarker company with a range of proprietary biomarker tests for the early identification of kidney injury. Argutus' biomarker discovery methodology has facilitated the identification and selection of biomarkers and the development of immunoassay tests which have unique tubular specificity.

Products & Services Argutus' kidney biomarkers leak into urine when tubular cells are damaged. Argutus' new 'Acute Kidney Injury' test is composed of three tests to detect injury to the proximal and distal tubules and to the collecting duct. Argutus' tests also reflect renal recovery. Argutus is the only company in the world with tests for distal tubule or collecting duct injury. The use of these tests in clinical studies reveals information about the site and course of the injury/recovery process. The tests are used by pharmaceutical companies and CROs in Phase I - IV trials and in clinical research.

**Key Customers** Pharmacutical companies, CROs, clinical researchers.

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#### AUDIT DIAGNOSTICS

**Business Description** Audit Diagnostics manufactures a complete line of liquid, ready-to-use, clinical reagents including immunoassay, TDM, Drugs of Abuse controls and calibrators. These are provided as dedicated, barcoded, system reagents for the Audit Sapphire range of automated analysers together with bar-coded, system reagents for Hitachi, Olympus and Automated Analysers.

#### **Products & Services**

- Audit's new point-of-care range, including the world's first true wet chemistry point-of-care system, Liqui-Stat®, together with the near patient testing for Hb-Stat®, provides for the first time laboratory quality results at near patient point-of-care locations
- The Audit CellSlide cytology Pap cervical cancer diagnostic screening system provides a cost-effective rapid preparation for cervical cancer diagnostics together with a range of non-gynaecological assays
- The Audit Sterl-Stat® unique range of sanitising products provides 100% protection against all bacteria, viruses, spores (including MRSA, C.diff, TB, Ecoli, Salmonella) on instant contact for a long period of up to seven days
- Future developments in unique point-of-care systems and dedicated immunoassay analysers will provide quality and innovative diagnostic solutions for the world healthcare market
- Audit's overall aim is to provide quality innovative healthcare solutions for the future

**Key Customers** Audit Diagnostics supplies its products to customers worldwide, through a network of distributors and OEM partners.

Standards & Certifications ISO 9001, ISO 13845, GMP, CE IVD.

Additional Langauges Chinese, German, French, Spanish.

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#### **RTOSENSTA**



**Business Description** Biosensia develops rapid, easy-to-use, multiplexing, quantitative, point-of-care in vitro diagnostics (IVD) platforms. Biosensia combines innovative in vitro diagnostic technologies to enable access to a broad range of diagnostic applications at the point-of-care.

# **Products & Services**

- RapiPlex: a multiplexing platform which can perform simultaneous diagnostic tests for a variety of different ailments from a single patient sample (blood, saliva, urine) at the point-of-care
- RapiPlex is also suitable for use in the detection of drugs of abuse, infectious disease and cardiac markers as well as in other markets such as environmental and food and beverage testing

Additional Langauges German, Irish.

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# CARL STUART LIMITED (Lab Unlimited)

**Business Description** The Carl Stuart Group is an established provider of services to quality control and process development laboratories, as well as manufacturing process areas in pharmachem and industrial sectors. The company has a highly trained workforce of 35 staff covering multiple disciplines. Their core capability is the distribution and after-sales support of products requiring a high degree of technical support.

**Products & Services** Carl Stuart maintains and calibrates a wide range of laboratory instrumentation, in addition to providing an independent validation services for third party equipment. A service orientated company, with a mission to provide a complete service to all customers. By adhering to core capability, Carl Stuart can fully support the client and all client requirments.

- Calibration and repair centre for Agilent and Alicat precision flow meters
- Extensive laboratory and chromatography consumable range, with almost 60000 products available online at www.labunlimited.com
- Personnel are extensively trained on an ongoing basis, in all aspects relevant to their position

**Key customers** Pfizer Ireland, Diageo, Gerard Labs, Glaxo Smithkline, Trinity College, University College Dublin, University College Cork, Pepsi Inc.

Standards ISO 9001:2008, ISO 17025:2005.

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#### CELLIX ITD

**Business Description** Cellix Ltd. is an instrumentation provider for the pharmaceutical and biotechnology industries in the area of drug discovery and drug screening, and produces a sophisticated in vivo drug screening tool that eliminates false leads earlier in the drug screening process and increases the success rate of clinical trials.

Products & Services The VenaFlux solution is the most popular of the Cellix range of products as it is simple to use, reduces costly layers of animal model studies, and delivers specific, accurate, and reproducible results, and is semi-automated. VenaFlux works 'out of the box' and brings the drug discovery process to a new level. The VenaFlux is the first semi-automated microfluidic in vivo platform capable of executing continuous flow cell based assays. Together with Cellix's biochips and cell analysis software, the VenaFlux measures cell adhesion to antibody-coated or endothelial cell cultured microcapillaries, producing IC50 curves under shear stress conditions mimicking physiological flow.

Key Customers Pfizer, AstraZeneca, Sanofi-Aventis and Servier.

Standards & Certifications CF Mark

Additional Langauges French, Mandarin, Russian.

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# CRESCENT DIAGNOSTICS (IRELAND) LTD

**Business Description** Crescent Diagnostics (Ireland) Ltd. is a diagnostics research and development company focussed on developing a new diagnostic test for osteoporosis fracture risk, based on analysing fingernail structure using a low-cost laser-based technique. This test offers a number of advantages over current diagnostic modalities.

Products & Services The company's focus is on developing expertise in the use of Raman spectroscopy to diagnose disease. Crescent has focussed initially on developing the intellectual property, clinical trial data, diagnostic algorithms, regulatory capability, medical and clinical Scientific Advisory Board to enable the company to develop a novel point-of-care diagnostic test for osteoporosis. Published clinical data to date indicates that the fingernail may be a suitable surrogate marker for bone quality and osteoporotic fracture risk. There is considerable need for new diagnostic tools for early stage osteoporosis diagnosis and Crescent is developing a product to fulfil the need.

- Novel PoC device for assessing bone quality and fracture risk using human nails
- Medical device clinical trials, Raman spectroscopy, IP management, in vitro diagnostics

**Note** Medical Futures 2005, runner-up Biomedical Research Innovation, in-house bone health assessment facility for contract research, three patents applied for in the area of bone quality, technology licensed from the University of Limerick.

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#### **ENFER**

**Business Description** Enfer develops and manufactures rapid diagnostic tests for a range of livestock diseases including transmissible spongiform encephalopathies (TSE), bovine viral diarrhoea virus (BVDV) and Johnes (ParaTB), and a breakthrough bovine TB diagnostic test.

**Products & Services** Enfer is committed to providing accurate, cost-effective diagnostics to improve the health and well-being of animals. The company is also engaged in an extensive R&D programme to develop a range of products for the large animal veterinary diagnostic sector, targeting a number of diseases which cause major economic losses and for which there are no commercially available rapid diagnostic tests. Diagnostic instrumentation is also provided.

Standards & Certifications ISO 9001:2000

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#### ENZOLVE TECHNOLOGIES LTD

**Business Description** Enzolve Technologies is engaged in the research and development, design and commercialisation of in vitro diagnostics using its own specialist, high-end, value proprietary enzymes. The company operates as a university research spin-out company with R&D facilities at NovaUCD and contract manufacturing in Clara, Co. Offaly.

Products & Services The Phenylketonuria (PKU) screening kit is Enzolve's first CE marked in vitro diagnostic product. This is part of the 'NeoScreenPak' single-format test-package which will be used to screen for seven of the eleven most commonly screened disorders affecting newborns. Enzolve's one-step tests are faster, more reliable, convenient and cost-effective than tests available on the market. The company plans to use its engineered enzymes in the further development of clinical diagnostics, and as "biocatalysts" in asymmetric synthesis. Enzolve's range of novel protein detection devices for electrophoresis gels are currently on the UK and Irish markets. The company also provides consultancy and biochemical services to diagnostic and pharmaceutical companies in enzyme research.

Standards & Certifications ISO 13485:2003, IVDD 98/79/EC.

**Additional Langauges** Armenian and Russian.

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#### LUXCEL BIOSCIENCES LTD



**Business Description** Luxcel Biosciences Ltd. is an award winning Irish biotechnology company developing highly innovative sensors and instrumentation for food safety, 'smart' packaging and pharmaceutical R&D. Luxcel sensors provide highly informative results faster, more easily and more cost effectively than competing technologies.

#### **Products & Services**

- Food Safety
  - Luxcel developed rapid food safety tests for 'same-day' detection of bacterial contamination by monitoring changes in oxygen and pH levels. They are faster, easier to use, with higher throughput capabilities than competing products. Results are available within hours when compared to standard tests, which take two or more days
- Packaging
   Luxcel developed sensors for high throughput, non-invasive monitoring of oxygen levels within food, beverage and pharmaceutical packaging. Improper oxygen composition in faulty packs may stimulate rapid deterioration of the product
- Drug Discovery
   Pharmaceutical companies use Luxcel sensors in developing new therapeutic drugs. These are used as a highly selective screen for drug toxicity. They are very sensitive and easy to use and provide results in days instead of the typical three months using standard methodology

Key Customers Large pharmaceutical and biotech companies, meat processing industry, research institutes and universities, R&D companies.

# **Additional Langauges Dutch**

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#### MFGA7YMF

**Business Description** Megazyme International Ireland Ltd. develops and supplies diagnostic test kits and reagents for the food, feed, fermentation, wine and dairy industries.

Products & Services Test kits for the measurements of components such as carbohydrates and enzymes in food, feed, beverages and dairy products. Kits include those for dietary fibre, starch, lactose, enzymes and a wide range of sugars, organic acids and alcohols in wine and other products. A range of other analytical reagents such as pure polysaccharides, oligosaccharides, enzymes and substrates for measurement of enzyme activity are also supplied.

Key Customers Most blue chip food, wine, enzyme and dairy companies including Kraft, Kellogg, Unilever, Proctor & Gamble, Heinz, Guinness, DSM, Danisco, Novozymes, Fosters, Hardys, Universities, research and analytical laboratories worldwide.

**Standards & Certifications** ISO 9001:2000. Eight of the Megazyme methods are official or recommended procedures of AOAC International and AACC International.

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# REAGECON

**Business Description** Reagecon is a manufacturer, distributor and service provider of complete business solutions to the laboratory, cleanroom, and personal protection industries in Ireland. A wide array of services combined with an innovative approach enables the company to guarantee availability, on-time delivery and product support.

Products & Services Reagecon is quality oriented, prides itself in its business excellence, and can deliver cost-effective solutions to customers through continuous focus on efficiencies. Its product portfolio offers more than 1,000 brands of chemicals and consumables, standards and calibrators, apparatus, instruments and equipment from over 350 global suppliers. In addition, a range of technical services including calibration, qualification, and preventative maintenance, training and sampling, and service and support are provided.

**Key Customers** All pharmaceutical, medical device, food, environmental, clinical and fourth level education in Ireland, as well as a wide range of users of standards and calibrators world wide.

Standards & Certifications ISO 9001:2000, ISO 17025.

Additional Langauges German, French, Polish.

Note Reagecon has in addition maintained the 'excellence through people' standard since 2004.

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# SENSL TECHNOLOGIES LTD

**Business Description** SensL is a leading technology innovator and manufacturer of photo-electronic detector systems used in low light sensing and photon counting applications. SensL technology and products enable customers to rapidly implement innovative, robust, compact and cost-effective solutions.

**Products & Services** SensL's proprietary Silicon Photomultiplier or SPM constitutes the core of its solutions portfolio. This versatile semiconductor device combines single photon sensitivity and proportional response with high internal signal gain. As such, it offers a compelling alternative to vacuum photomultiplier tubes and other low-light detectors. SensL provides best-of-kind sensor performance, OEM supply security and first rate engineering support at highly competitive pricing. The current product families include:

- Micro: discrete SPM sensors integrated in standard and custom packages
- Mini: turn-key, single channel photon detector and counting modules
- Array: large area SPM matrices and arrays
- Modules: plug & play photo multiplier substitutes
- HRM: high-resolution timing and pulse shaping solutions

Key Customers SensL offers stock, OEM and customised solutions to industrial and academic buyers world wide e.g. nuclear medical imaging (PET, SPECT and PET/MRI scanners); analytical instruments (flow cytometry, TCSPC, confocal microscopy, fluorescence detection and lifetime measurements); metrology (LIDAR); homeland security (hand-held and portal radiation detectors); industrial inspection (particulate counting, leak detection and spectroscopy).

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#### SEROSEP LTD

**Business Description** Serosep Ltd. is involved in the research, manufacture and distribution of laboratory diagnostic products in the clinical diagnostics and environmental areas.

#### **Products & Services**

Clinical Diagnostics

Serosep Ltd. has developed a molecular-based diagnostic test to screen for faecal pathogens within 24 hours in clinical microbiology laboratories. EntericBio detects Campylobacter, E. Coli 0157, Shigella and Salmonella. EntericBio is tipped to become the gold standard test for faecal pathogens

The company also developed the HistoPot range of pre-filled specimen containers. HistoPots are filled with fixatives such as formalin that are used for the preservation of tissues during transportation within the hospital.

Water Chemistry Reagents
 Serosep Ltd. manufactures Precision Reagents, a range of stabilised water chemistry reagents. These reagents are used in automatic chemistry analysers, and are stabilised for up to one year. The company prides itself on the extremely robust and reliable reagents that afford the laboratory a superior quality product

Key Customers Hospital laboratories such as microbiology, hisopathology and environmental laboratories.

Standards & Certifications ISO 9001 and ISO 13485.

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WEDSITE WWW

#### **TECHNOPATH**

**Business Description** Since its formation, Technopath has grown exponentially through its distribution business into the healthcare and biotechnology sectors. Following a three year R&D programme, Technopath opened a custom built manufacturing facility for the production of medical devices, which has facilitated expansion into new markets including US, Europe and Japan.

Products & Services Plasma components, quality controls, calibrators and proficiency sera for the clinical diagnostic and bioprocessing industries, with a particular expertise in the stabilisation of labile analytes and the production of human lipid extracts. Products are manufactured from fresh frozen, human plasma, using proprietary processing procedures, which have allowed the development of highly stable serum matrices. This has facilitated the production of a range of liquid stable, test consolidated QC material which closely mimic the patient sample and provide significant efficiency and cost savings to our customers. Particular emphasis is placed on manufacturing products to specific market and customer requirements, depending on batch size and analyte composition.

**Key Customers** NHS UK, Health Service Executive Ireland, clinical diagnostic manufacturers and multinational pharmaceutical bio-processors.

Standards & Certifications GMP, ISO 9000:2000 and CE Mark for IVD. ISO 13485 accredited for both design and manufacture.

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# **TRIDELTA**

**Business Description** Tridelta Development Limited is a veterinary diagnostic company based in Ireland. The company was formed in 1996 to identify, acquire, develop and rapidly commercialise novel proprietary technologies that have application in high margin, high growth segments of the veterinary diagnostic market.

**Products & Services** Tridelta markets an extensive range of assays for Acute Phase Proteins (APP), known as 'The Phase Range' which are used to indicate animal health status. The company is focussing on three main market sectors:

- Academic and industrial research: the assays have been used by academic research institutions and major pharmaceutical companies, as part of drug development and toxicity studies
- Mastitis: the company has discovered, and patented, a new Acute Phase Protein, MAA. The new protein has been shown to be a highly sensitive marker of bovine mastitis
- Animal Welfare: recent publications have shown the measurement of Acute Phase Proteins to be a major factor in improving animal welfare and food safety

**Key Customers** Leading pharmaceutical and research institutions world-wide.

**Note** The company currently has licence agreements for novel products with several leading research establishments in Europe and the USA, and is actively looking to expand its product range.

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#### TRINITY BIOTECH PLC

Business Description Trinity Biotech develops, acquires, manufactures and markets over 500 diagnostic products for the point-of-care and clinical laboratory segments of the diagnostic market.

Products & Services A broad line of test kits are used to detect infectious diseases, sexually transmitted diseases, blood coagulation disorders, clinical chemistry and autoimmune diseases. Trinity Biotech sells worldwide in over 80 countries through its own salesforce and a network of international distributors and strategic partners.

#### **Key Customers**

- Test kits: used to detect infectious diseases, sexually transmitted diseases, clinical chemistry and autoimmune
- Sells worldwide: present in over 80 countries through its own salesforce and a network of international distributors and strategic partners

Standards & Certifications ISO 13485:2003, ISO 9001:2000 and ISO 9001:2008, FDA PMA approved production facility in Bray, Ireland, FDA approved facilities for production of 510K cleared products, IMB approved facilities for production of CE marked products

Additional Langauges Spanish, French, German.

Note Other approved production facilities are located in Jamestown NY, Carlsbad CA, Kansas MO, USA.

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# HUMAN AND VETERINARY MANUFACTURE



#### AGI THERAPEUTICS PLC



**Business Description** AGI Therapeutics Plc. is a speciality pharmaceutical company focussed on the development and commercialisation of differentiated drug products for gastrointestinal (GI) diseases and disorders.

Products & Services AGI Therapeutics Plc. applies its KME™ model (known molecular entities) to identify existing drugs or "known molecular entities" with established safety profiles which can be developed and clinically differentiated for gastroenterological indications. KME™-based products offer distinct advantages in terms of the risk, cost and time associated with the development and regulatory process as compared to new molecular entities. AGI creates differentiated and proprietary products with novel uses and indications. AGI is developing a range of product candidates to treat a variety of prevalent GI diseases and disorders, including irritable bowel syndrome (IBS), gastroparesis, ulcerative colitis, gastro-esophageal reflux disease (GERD) and in particular nocturnal acid breakthrough (NAB) and diarrhoea-related conditions such as chemotherapy-induced diarrhoea (CID).

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The Irish Life Sciences Directory

Human and Veterinary

Manufacture

#### RIMEDA

**Business Description** Bimeda's primary focus is on the livestock and equine sectors; activities include R&D, manufacture, sale and distribution of veterinary pharmaceutical and animal health products.

Products & Services Bimeda's core business is development, gaining regulatory approval for, and manufacturing generic medicines. The company also has proven ability in original research of which the principle product has been a non-antibiotic intramammary seal which is sold globally by Pfizer Corp as Orbeseal®. A full range of sterile injectable solutions is available, including sterile metabolic fluids, injectable penicillins and (beta)-lactams. In addition, sterile intra-mammary infusions, insecticidal products (dips, sprays, pour-ons), oral liquids, disinfectants, equine anthelmintic pastes, soluble powders, tablets and pastes can be provided.

**Standards & Certifications** Operating plants are cGMP certified. Facilities within the group are EU and FDA approved. QC laboratories adhere to GLP guidelines.

Additional Languages French, German, Spanish.

# **Contact People for Overseas Markets:**

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# CHANELLE PHARAMACEUTICALS MANUFACTURING LTD CHANELLE MEDICAL



**Business Description** The Chanelle Group is involved in (a) development, registration and sale of generic registration dossiers; (b) contract manufacturing of generic and innovative products; (c) contract packaging; and (d) contract quality work including analytical testing to agreed specifications, Q.P. (quality product) release and stability.

**Products & Services** Human and veterinary (large animal and companion animal) pharmaceuticals: R&D, registration, Quality Product (Q.P.) release, manufacturing of tablets, capsules, liquids and powders. Chanelle also provides complete contract packaging facilities.

**Key Customers** Top 15 generic pharmaceutical companies in Europe.

Standards & Certifications ISO 9002, GMP for Europe.

#### **Contact People for Overseas Markets:**

Veterinary Pharmaceuticals: UK and Ireland: Fraser Hodgson / Michael Burke Veterinary Pharmaceuticals: Europe: Breda McCormack / Michael Burke

Veterinary and Human Pharmaceuticals: USA and Rest of World: Michael Burke, CEO

Human Pharmaceuticals: UK and Ireland: Michael Burke, CEO

Human Pharmaceuticals: France, Germany, Italy and Spain: Chanelle McCoy

Human Pharmaceuticals: Rest of Europe: Ciaran Burke

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#### **FANNIN HEAITHCARE**

The Irish Life Sciences Directory **Human & Veterinary Manufacture** 

**Business Description** Fannin reconstitutes a range of pharmaceutical products for use in Irish hospitals. These include chemotherapy, pain management and antibiotics. The company also prepares reconstituted total parenteral nutrition (TPN) for Irish hospitals, and provides a range of pre-filled products such as epidurals.

Products & Services Fannin's range of products includes reconstituted chemotherapy and antibiotics, paediatric TPN and pre-filled analgesia, and the company also provides customised pharmaceutical products for dispensing to patients' homes. Fannin's goal is to consistently manufacture, in accordance with EU GMP standards, pre-filled aseptic products that meet patients' requirements. The compounding facility is committed to providing quality validated products through our enhanced service offering. Patient safety is optimised and staff exposure to drugs is reduced, as products are individualised to match the prescriber's requirements. Fannin is continuously striving to expand this product range to meet the increasing complexities of the Irish health service.

**Key Customers** Health Service Executive and private hospitals.

Standards & Certifications GMP and licensed by the Irish Medicines Board.

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#### FORAN CHEMICALS ITD

**Business Description** Foran Chemicals is an established manufacturer and distributor of equine supplements and healthcare products with substantial market share in Ireland and other European markets, and continues to develop and update its comprehensive range of products as well as improving its international trading position.

Products & Services Foran manufactures, under its own laboratory control, a range of horse feed supplements and topical preparations typically used in the breeding, racing and the various equestrian sports. Foran is the official sponsor and preferred supplier to Eventing Ireland International Teams and sees itself as a partner in the race to perfection with all clients. Foran recently launched a novel hydrolysed protein of particular benefit to horses and will continue to roll out new improvements to the range which are non-doping.

**Key Customers** Foran has both wholesale and retail operations in Ireland and operates through a network of importing distributors elsewhere in the world and has established many key export client relationships.

**Standards & Certifications** Approved by The Department of Agriculture and Food under SI. No. 910 of 2005, European Communities Regulation No. 183/2005 of the European Parliament and of the council laying down requirements for Feed Hygiene Approval Number  $\alpha$  IED0000242.

**Note** The company regularly trades as Foran Equine Products and Foran Pet Care. It is best known around the world of racing, breeding and equestrian sports as Foran Equine Products but the company has recently expanded into the area of pet care.

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# The Irish Life Sciences Directory Human & Veterinary Manufacture

# INTERCHEM (IRELAND) LTD

**Business Description** Interchem (Ireland) Ltd. markets and distributes veterinary products to Irish veterinarians, and holds exclusive agreements with global veterinary companies, offering a turn-key approach. Strengths: ability to penetrate market segments and sustain market share for new products. Interchem carries its own brands.

Products & Services Distribution and marketing of veterinary products to veterinary surgeons. The company has strong relationships built up with the profession over a long number of years. The sales and marketing team is technically competent and offers a good alternative to pharma companies setting up their own subsidiaries in Ireland. The company is particularly strong in the companion animal area with this sector accounting for almost 60% of total business. The key product segments where Interchem currently operate are biologicals, antimicrobials, neurologicals, oral rehydration products, behavioural products, ecto-parasiticide, cardiology and prescription and lifestage diets.

Key Customers Veterinary surgeons, pharmacists, licensed merchants, licensed wholesalers.

**Standards & Certifications** Regulated by the Irish Department of Agriculture and Food, Irish Department of Health and Children, and The Irish Medicines Board.

Note Interchem (Ireland) Ltd. will explore joint venture options with interested parties.

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# LLR-G5 LTD



**Business Description** LLR-G5 Ltd. exclusively manufactures and distributes Organic Silicon G5® products, a silicon supplement for the consumer healthcare industry since 1999. LLR-G5 Ltd. is an internationally trading company and distributes worldwide to retail/private label and in bulk volumes for the healthcare, cosmetics and food industry.

**Products & Services** LLR-G5 Ltd. supplies and manufactures:

- Organic Silicon G5® Liquid: an aqueous solution of momomethylsilanetrol
- Organic Silicon G5® Gel: an aqueous based gel of momomethylsilanetrol

**Standards:** All procedures and materials used in the manufacturing and filling of G5® Solution are controlled by Quality Management Systems based on ISO 9002 Standards and HACCAP Standard Food Hygiene Procedures.

Additional Languages: French, Italian.

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# NEW VISTAS HEALTHCARE LTD

The Irish Life Sciences Directory

Human & Veterinary

Manufacture

**Business Description** New Vistas Healthcare manufactures a range of natural healthcare products. The company develops and produces homeopathic and herbal medicinal products, targeted at the chronic illness sector, in addition to providing a range of food supplement products that compliment its target market's needs.

Products & Services New Vistas Healthcare manufactures a range of herbal and homeopathic medical products. The range of products includes: xenobiotics for the detoxification of pathogens and foreign chemicals, liquescences which support and nourish stressed or damaged organs, and a variety of treatment remedies which stimulate the bodies own healing power. The products are designed with a therapeutic philosophy which addresses the practical challenges facing the masses of people wanting to remain healthy through preventative measures. The company is also actively involved in education and training, providing training to practitioners and other health professionals on health issues and nutritional medicine. The company has a strong reputation for quality, and operates good manufacturing practices and good distribution practices.

**Key Customers** The current sales channels are through practitioners (Ireland and UK) and retail sales through health stores and pharmacies.

**Standards & Certifications** Manufacturing authorisation and GMP certificate from the Irish Medicines Board, member of the Organic Trust, Ireland.

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#### NEWPORT PHARMACEUTICALS ITD



**Business Description** Newport markets innovative cost-effective therapies for the prevention and treatment of infectious disease and immunological disorders. The lead product is an immunopharmacologic agent, with both immunomodulatory and antiviral properties, that has been licensed for the treatment of cell mediated immune deficiencies associated with viral infection.

Products & Services The company's lead product is Inosine Acedoben Dimepranol (IAD) which is known under various trade names worldwide such as Isoprinosine, Imunovir, Delimmun and Viruxan. The IAD finished product has been registered for a number of therapeutic viral indications internationally, including the treatment of human papilloma virus (HPV), herpes simplex virus (HSV), varicella zoster virus (VZV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), measles virus infections and subacute sclerosing panencephalitis (SSPE). Newport Pharmaceuticals Ltd. has developed a worldwide network of licensees and distributors. The company also has sufficient capability to manage the development, manufacture and marketing of pharmaceutical drug products. The further clinical and pharmaceutical development of IAD is at the centre of the company's research and development programmes.

Key Customers IAD is exported worldwide through a network of licensees and distributors.

**Standards & Certifications** IAD is registered with the National Regulatory Agencies in many countries. The company operates to Good Manufacturing Practice (GMP) and its warehouse has been granted a wholesale license by the Irish Medicines Board.

**Additional Languages French** 

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# OVAGEN GROUP LTD

**Business Description** Ovagen is a biotechnology company which has developed a process for producing the world's first germ-free (GF) chicken eggs and GF birds in commercial quantities for use in the pharmaceutical industry. The company has worldwide patent protection for this process of producing GF eggs.

**Products & Services** Germ-free (GF) eggs and GF chickens. Ovagen also provides related research and development (R&D) support services to the pharmaceutical industry. Some of the applications of germ-free eggs/cells/tissues:

- 1. Conventional (prophylactic) vaccines
  - Whole egg
  - MVA-based (e.g. bioterrorism vaccines)
- 2. Therapeutic vaccines
  - Cancer vaccines (e.g. MVA-based cervical (HPV) vaccine, lung (NSC) vaccines)
- 3. Antibodies
  - Polyclonal (e.g. snake antivenom)
  - Therapeutic (cancer, rheumatoid arthritis)
  - Diagnostics

- Primary cell cultures
- Other pox virus based vaccines
- Infections agents (e.g. HIV)
- Monoclonal
- R&D (e.g. proteomics)
- Separation techniques (e.g. separation of stem cells from bone marrow)

- 4. Poultry Genetics (e.g. metacloning)
- 5. Pharmaceutical (e.g. hyaluronic acid, phospholipids)

**Key Customers** It is anticipated that GF eggs will be marketed to global pharmaceutical companies by Ovagen for high value/low volume applications as a superior, value-added replacement for specific pathogen free (SPF) eggs.

**Standards & Certifications** GF eggs are produced to GMP fully compliant with USDA Memo 800.65 and European Pharmacopoeia requirements.

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#### OVELLEITD



**Business Description** Ovelle Pharmaceuticals was founded in 1934 and are specialists in dermatology, developing skincare formulations and manufacturing both OTC and licensed skincare solutions.

**Products & Services** Available for partnership and co-operation in new markets:

- Ovelle Skincare portfolio of OTC skincare and licensed skincare, for the daily management of dry sensitive skin and skin conditions
- Elave Sensitive Skincare ranges: for the daily management of eczema, psoriasis, dermatitis and rosacea and proven to reduce skin irritation, redness and promote healthy skin.

**Standards & Certifications** Ovelle Pharmaceuticals is fully licensed to good manufacturing practice (GMP) by the Irish Medicines Board (IMB) to manufacture multi-dose liquid, semi-solid and solid pharmaceuticals.

Additional Languages Chinese, French, Hungarian, Polish.

Note Many of the company's brands and licenses are available for development and partnership.

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#### PR FUROCHEM

**Business Description** PR Eurochem Ltd. is a producer of low-volume pharmaceutical active ingredients, and supplier of forensic standards. The company also undertakes research and development for the fine chemicals and pharmaceutical intermediates markets.

#### **Products & Services**

- Chemical research
- Fine chemicals
- Prostaglandins intermediates
- · Organic synthesis
- Synthesis
- Purification and isolation of metabolites

Custom synthesis is also provided, as are controlled substances under licence.

**Key Customers** Large pharmachem industries in Europe.

**Standards & Certifications** PR Eurochem's full state-of-the-art R&D facilities complies with a high standard of quality control, supported by full analytical services.

**Additional Languages** French

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#### RICE STEELE MANUFACTURING LTD



**Business Description** Rice Steele manufactures its own proprietary brands of "over-the-counter" pharmaceutical products for human use (Rubex, Paralink, Dozol, Teedex, Pedamed and pharmacy brand) in tablet, liquid, powder and suppository formulations.

#### **Products & Services**

- Children's analgesic medicines such as Dozol, Teedex and Paralink in liquid form and Paralink suppositories in a number of dosage forms
- · Vitamin and multi-vitamin products in effervescent, liquid and solid form under the Rubex and Rescofer brands
- Footcare cream and powder which combats athlete's foot under the Pedamed brand
- A range of galenicals under the Pharmacy brand
- The company also distributes a range of additional products suitable for sale by pharmacy customers via its sales team

**Key Customers** Key customers are the Irish retail pharmacies and wholesalers for the local market. For the export market the company distributes through local distributors in each specific market.

**Standards & Certifications** Rice Steele manufactures all products to cGMP standards with on-site laboratory, OA and OC capabilites.

Additional Languages French, Czech, Polish.

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The Irish Life Sciences Directory

Human & Veterinary

Manufacture

#### SONA NUTRITION ITD

**Business Description** Sona Nutrition is the oldest established and largest Irish manufacturer and exporter of vitamin mineral supplements and herbal remedies. The company operates from purpose-built facilities in Dublin, and currently exports over 160 products to some 27 countries worldwide.

**Products & Services** Sona specialises in nutritional supplements and herbal remedies, from single vitamins to multivitamin formulations. Herbal remedies and dietetic products are produced in tablet, capsule, liquid, effervescent and sachet forms.

**Key Customers** All pharmacies and health stores in Ireland, with export agents in 22 countries, mostly in Europe and the Middle East.

**Standards & Certifications** Pharmaceutical manufacturing licence and GMP licence issued by the Irish Medicines Board. Food Safety Authority certified, Eastern Health Board certified.

Additional Languages Armenian, Arabic, French, Polish, Czech, Hindi.

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# TRM

**Business Description** TRM is Ireland's largest manufacturer and exporter of equine nutritional supplements. It has an EU licensed manufacturing plant and distributes its products in 48 countries around the world. TRM is currently diversifying into the canine nutraceutical market.

**Products & Services** TRM's sister company, Thoroughbred Remedies Ireland, is the leading provider of healthcare products for horses in Ireland. TRM provides:

- Equine feed supplements for enhanced mobility, breeding and performance
- Electrolyte products, vitamins and minerals
- Specialist equine disinfectant
- Equine gut nutrition formulae
- Canine nutraceuticals

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#### UNTRLOCK ITD

**Business Description** Uniblock's business is focussed on young animal health and nutrition. It is the largest developer and manufacturer of molassed mineral trace element blocks which allows farmers and horse owners to supplement their animal's diet with key trace elements, oil or proteins at grass or when housed.

**Products & Services** Uniblock has developed a range of feeds for the final weeks of pregnancy, which improves maternal colostrum and enhances the health of mother and young in cattle, sheep and horses. In addition, the company markets a range of milk-based feeds for calves, lambs and goat kids to ensure long-term animal health and also provides a broad range of molasses, mineral licks and supplements for cattle, sheep and horses.

Key Customers Dodson and Horrell, Origin, Glanbia.

**Standards & Certifications** All Uniblock products are manufactured to HACCP (hazard analysis and critical control points) and UFAS (uniform federal accessibility standards).

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#### **UNTVFT ITD**

**Business Description** Univet Ireland Ltd. is a leading veterinary pharmaceuticals manufacturer established to service a growing demand for animal health products in the Irish market. The company's product ranges are typically antibiotic treatments for large farm animals (e.g. Terrexine, for mastitis in lactating cows) and poultry.

**Products & Services** Univet has a continuous commitment to research and development and is actively developing new products. The company's constant and stringent vigilance on the quality, purity, potency and stability of all its products is just one facet of an all-embracing code of good manufacturing practice which quarantees the highest standard of each product. The company provides in a number of delivery formats:

- A broad range of antibiotic treatments for cattle, sheep, pigs, horses and poultry
- Intramammary mastitis treatment
- Fluke and worm drench for cattle and sheep
- Multivitamins/nutritional and mineral supplements

**Standards & Certifications** Univet's facility is licensed by the Irish Medicines Board (IMB) and operates under pharmaceutical GMP regulations.

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The Irish Life Sciences Directory **Human & Veterinary Manufacture** 

#### WESTGATE BIOLOGICAL ITD

**Business Description** Westgate licenses out its core technology, LactiSAL®, for topical applications. LactiSAL® is a patented broad spectrum natural antimicrobial agent that not only is effective against Gram positive and Gram negative bacteria, fungi, yeast and moulds, but also does not generate microbial resistance.

Products & Services Westgate's natural antimicrobial technology, LactiSAL®, is available for licensing in topical applications (gels, soaps, creams) for a wide range of fields including: hospital/healthcare acquired infections (HAI), feminine care, intestinal health, oral healthcare, animal health and wound care. LactiSAL® is composed of natural ingredients such as apo-proteins and fatty acids that have FDA GRAS status and it can be easily formulated into skin compatible topical formulations. LactiSAL® has broad spectrum antimicrobial efficacy (Gram positive and Gram negative bacteria, yeast, moulds and fungi). It is active against the antibiotic resistant bacteria (MRSA, VREF) and has the significant advantage that it does not generate microbial resistance.

**Standards & Certifications** Products containing LactiSAL® may be sold as cosmetics, medical devices or pharmaceuticals.

Note Westgate will consider opportunities for out-licensing with suitable partners for specific applications.

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# IT FOR HEALTH



# **AUTOMSOFT**

**Business Description** Automsoft International Ltd. offers data management solutions for process industries. With its US headquarters in New York and European headquarters in Ireland, Automsoft develops database applications that are designed to help customers improve the performance of their global manufacturing operations.

Products & Services RAPID by Automsoft operates from the heart of manufacturing facilities, and presents process industries with a powerful tool for turning raw data into 'intelligent information'. RAPID harnesses all production data and gives full visibility to each of the variables in the production process at a previously unattainable level of detail. RAPID's analysis tools identify process optimisation opportunities, which result in reduced costs of production, elimination of waste, increased speed to market and ultimately increased profitability. RAPID allows an organisation to:

- Gain a single and comprehensive view of the entire production process and all the variables that impact on the production process
- Reduce costs of production by eliminating waste
- Optimise the production process
- Reproduce the 'golden batch'
- · Meet and exceed regulatory requirements

**Key Customers** Genzyme, Baxter, Sanofi Pasteur, Pfizer.

Standards & Certifications Uses FDA approved 21 CFR part 11.

Additional Languages German, Polish.

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# **BIANCAMED LTD**

**Business Description** BiancaMed's mission is to transform personal health by providing the ultimate convenience in personal health monitoring. At the core of the product platform is a very sensitive motion sensor that wirelessly detects heart rate and respiration.

#### **Products & Services**

- · Patents awarded and pending for hardware and software technology
- Fitness software algorithm for congestive heart monitoring
- Baby monitor device with sleep monitoring function
- Sleep minder service for consumer/clinical trial
- Long term sleep monitoring devices for disease management

Standards & Certifications FDA (510K) submission for Sleepminder product.

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#### CAMPBELL INFORMATICS LTD



**Business Description** Campbell Informatics provides systems-based, codified compliance services, and technology to life sciences manufacturers, suppliers and regulators on an international basis.

#### **Products & Services**

The patented Avenio engine facilitates the definition and management of process technology systems and data throughout the engineering and operational life cycles, using proven quality by design methodologies.

Compliance consultancy and support in the following areas -

- · Quality risk management
- Life-cycle data management
- Structured protocol management

The company delivers and supports the Avenio compliance framework in the following formats;

- Site/corporate licences
- Project-specific rentals
- · Configurable class libraries

Key Customers Eli Lilly, Janssen, PIC Consulting, FDA.

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# CLINICAL TRIAL ENDPOINT LTD

**Business Description** CTEP provides software for patient data collection in clinical studies, made easy for doctors and study nurses. It can be set up in 4 weeks or a self-build option can be accessed over the web. CTEP is a member of global certification organisation CDISC.

**Products & Services** The company sells its services directly to pharma/biotech and also via European Contract Research Organisations (CRO's) with which it has established relationships.

- CTEP's Easy EDC system provides a web-based solution accessible at any time via a standard web browser and customised for every project
- A full service model means that CTEP experts are with the client every step of the way, from predesign to final delivery dataset. CTEP takes the onus of administering effective EDC off clients

Services include:

- Full project management
- · Study implementation and administration
- eCRF development and validation
- · Creation of customised clinical trial web site
- Full data management service and reporting service
- Surveys/questionnaires
- Support and helpdesk facilities

**Key Customers** Abbott, Servier, Novartis, Boehringer Ingleheim, Roche, Nycomed, and biotechnology companies as well as academic institutions, European and Irish CRO's (contract research organisations).

Standards & Certifications The company works within EU/USA frameworks and legislation including FDA 21.11, and ICH/GCP: EU Directive 2005/28/EC. CDISC's operational data model (ODM) v1.3 is at the product core.

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#### COMPUCAL SOFTWARE SOLUTIONS

**Business Description** CompuCal provides maintenance and calibration management solutions that ensures quality compliance with 21 CFR Part 11, GxP, ISO and PAT initiatives for regulated industries striving for quality and compliance.

Products & Services CompuCal provides the following services -

- Web-based online hosted solutions
- Mobile paperless solutions
- Reduces administration
- F-mail alerts
- Advanced interval analysis capabilities
- Download procedures to documenting calibrators
- 21 CFR Part 11 compliant calibration and maintenance software
- Automated deviation handling
- Flexible work flows
- Automated planning and scheduling
- Integration
- Calibration compliance audits

Key Customers GSK Roche, Stryker, Solvay, Heineken.

**Standards & Certifications** Certified to ISO 9000:2001 for the installation and support of software solutions for regulated industry.

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# CREME

**Business Description** Creme promotes health and wellness by enabling regulators, safety authorities, and food, personal care product and chemical manufacturers to easily and accurately evaluate food intake, nutrition and exposure levels of consumers.

**Products & Services** Creme uses the latest scientific data in combination with its leading web-based software tools and expertise to allow customers to obtain the most accurate nutrition and exposure information. Services include:

- Creme food
- Creme pesticides
- Creme cosmetics
- Creme consultancy

Key Customers Food Safety Authority of Ireland, Irish Pesticide Control Service, Unilever, EFSA – European Food Safety Authority, UK Food Standards Agency, ICPS – International Centre for Pesticides Control (Italy), ILSI Europe – International Life Sciences Institute (Belgium), Colipa - Cosmetics Industry Association of Europe.

Additional Languages Italian, French, Spanish.

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# dabl®



**Business Description** dabl® provides online cardiovascular disease management and research systems in collaboration with a number of international centres of excellence. These expert systems aid the prevention and management of high blood pressure, stroke, heart attack and a range of other cardiovascular conditions.

#### **Products & Services**

- dabl ABPM Range: the only expert online system for 24- hour ambulatory blood pressure measurement (ABPM) for hospitals, clinics and pharmacies
- dabl Research: a powerful on-line analytical system for centres and pharmaceutical companies involved in research and clinical trials
- dabl Anticoagulant: for the management of patients on warfarin
- dabl Cardiovascular & dabl Geriatric: a comprehensive hospital system for the management of cardiovascular patients

# **Key Benefits**

- · Guaranteed expert systems incorporating the latest research and guidelines
- Improve efficiencies while enhancing patient care and safety
- Ability for users to share patient data securely saving huge time and resources
- · Patient-friendly reports which aid patient compliance
- Enables chronic diseases to be diagnosed and managed in the community

Standards & Certifications Accredited by Irish Department of Health, ISO 9001:2000 certified, Tick IT certified.

Additional Languages Italian, French, Spanish, Russian.

# **Contact People for Overseas Markets**

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#### DESIGN PARTNERS DIGITAL LTD

**Business Description** Design Partners Digital produces multimedia videos, tutorials, tours and images for the medical device industry. These videos can communicate the exact function of the medical device. Design Partners Digital is a sister company of Design Partners – an award-winning Irish industrial design company.

**Products & Services** Design Partners Digital's services include interactive tutorials, product tours and powerful presentations. These can be used for internal product development presentations, key funding presentations and for marketing purposes on the web. The team specialises in communicating products and processes through easily understandable images and movies.

Key Customers Teva/Ivax, Mylan, Biancamed, HP, Palm, Logitech, Welch Allyn, Terraillon, Nypro.

Additional Languages French, Dutch, Polish.

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# **DMF SYSTEMS**



**Business Description** Since 1998, DMF Systems has been delivering highly functional and economical solutions to public and private healthcare institutions. These systems allow clients to manage departments, integrate disparate business systems and communicate securely with external entities.

#### **Products & Services**

- Pathology communications: Ireland's largest transmitter of electronic results
- PAS: ADT, bed management, scheduling, e-discharge summaries and billing
- · Allied health: dietetics, OT, social work, physio, speech therapy
- · Clinical systems: infection control, sleep lab and orthopaedics
- Project management, development to ISO9001 standards
- Full implementation and after-sales support and maintenance

#### **Key Benefits**

- · Cost effective, integrated, intuitive health software solutions
- Healthcare professionals involved throughout the product design process
- Turn-key solutions for rapid deployment and early benefits realisation

Key Customers St. Vincent's University Group, Mater Hospital, St. James's Hospital, Blackrock Clinic, Galway University Hospitals, Incorporated Orthopaedic Hospital, HSE South, HSE West, HSE Eastern, HSE North East, AMNCH, Children's University Hospital, University Hospital, Virus Reference Laboratory, Bon Secours Group, St Patrick's University Hospital, Coombe Women's Hospital, Irish Blood Transfusion Service, St John of God Hospital, National Maternity Hospital.

#### **Standards & Certifications**

ISO 9001:2008

Additional Languages Spanish, Russian, Polish.

Partners: Microsoft, MediBRIDGE, Claymon Laboratories. dbMotion, Stalis (UK).

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#### **EHA SOFT SOLUTIONS**

**Business Description** EHA Soft Solutions specialises in occupational health, safety, hygiene, and environmental risk management information systems. The company delivers a comprehensive software suite coupled with practical EHQS (environment, health, quality, safety) methodology and best practices to help clients minimise risk, improve employee safety, and reduce losses due to operational EHQS risk.

Products & Services EHA Soft Solutions has established a proven track record in companies that deploy effective EHQS programs, leveraging advanced integrated environmental management systems in support of current regulatory guidelines, including occupational health and safety, food safety, quality and the environment. Because of its methodology and best practices, the company helps clients to minimise risk, improve employee safety, reduce losses due to operational risk, improve quality, health, safety, environmental performance and productivity. mai™ is the choice of EHQS practitioners across the globe who seek effective risk management and control of environmental, health, and safety issues. EHA Soft Solution's comprehensive suite delivers powerful capabilities for analysis, continuous improvement and measurement of critical parameters for improved decision making.

Key Customers Boston Scientific, LEO Pharma, Pfizer, Bulmers, Millipore, Johnson & Johnson (DePuy), Britvic, Abbott Vascular

Additional Languages Portuguese, Spanish, Finnish, Malay, Tamil, Indonesian.

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# **EMEDIA**



**Business Description** eMedia is an award-winning interactive media design company, specialising in 3D medical animations and interactive technology enhanced learning. Solutions empower companies to effectively communicate and promote products and services at trade shows, the web, or by any other digital dissemination channel.

**Products & Services** Established in 2005 on Ireland's Atlantic coast, a hybrid creative team with multimedia, programming, paedagogic and medical expertise, has earned eMedia a reputation for quality and service within the lifescience community. eMedial can help bring science to life, whether the client is at the concept creation or product launch stage in a new product development life cycle.

- Product visualisation
- Highly illustrative animations to help clients develop awareness of medical technology and demonstrates their medical product's mechanism of action (MOA) to a variety of audiences e.g. boardroom (investor pitches/funding presentations), website (promotion via corporate website and email campaigns), conference (promotion of product launch)
- Interactive on-line training

These highly engaging and pedagogically sound eLearning training courses assist lifescience organisations in training employees, researchers, clinicians and sales teams in understanding the benefits of their medical technologies

**Key Customers** Private medical companies: 3D medical animations (marketing support for companies looking for a novel way of demonstrating the benefits of their medical technology), medical training institutions: medical eLearning courses (small and large scale projects, developing elearning, blended learning, and interactive media solutions to promote positive learning outcomes); medical education customers - under the brand of Pocket Anatomy, eMedia develops a range of medical education apps for the iPhone, iPad and iPod Touch.

**Standards** eMedia is a certified Apple developer and has award winning medical education applications avialable from the iTunes App Store.

Additional Languages French, Spanish, Irish.

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#### HAPTICA ITD

**Business Description** Haptica develops proprietary and customised simulators for minimally invasive surgery and has training modules in general surgery, MIS spine surgery and obstetrics/gynecology. Building on its patented augmented reality technology, the company is expanding into other surgical augmented reality products.

#### **Products & Services**

- Haptica develops custom simulators for specific procedures and devices works, largely for corporate customers – including MIS, spine surgery, ObGyn, hand-assisted surgery and single site surgery
- ProMIS: Haptica's proprietary surgical simulator is a complete solution for training in laparoscopic skills and procedures and is used for residency training at over 130 leading surgical skills centres globally

**Key Customers** Johnson & Johnson Ethicon Endo-Surgery, Covidien US Surgical Applied Medical, Cardinal Health Snowden Pencer; Microsulis. Medical schools and surgical providers include Emory University, Duke University, Harvard Medical School, Imperial College London, Royal College of Surgeons in Ireland, Stanford University and US Army Medical Centres.

**Standards & Certifications** CE Certification, TUV Certification, ISO9000 (for manufacturing), three awards for surgical and technology innovation.

**Additional Languages** French, Spanish, Portuguese.

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# HELIX HEALTH LTD



**Business Description** Helix Health is a leading provider of world-class healthcare software and IT solutions. The company's core competencies, developed over the last 20 years, are in areas such as practice management software, pharmacy management software, point-of-sale software, centralised electronic health records, transaction processing and messaging software.

#### **Products & Services**

- General practice software
- Retail and hospital pharmacy dispensing software
- · Point-of-sale software
- Chemotherapy dispensing software
- Head office solutions and business intelligence
- Private consultant software
- Health screening software
- Hardware, infrastructure and a range of pharmacy robotics
- On-line back-up and security solutions
- Self check-in and examination pods
- Care home management software

Key Customers The Mater Hospital, St. Vincents Hospital, Unicare, Bradleys, Nuffield Hospitals (UK Health Assessments), Pharmacy 2 U (UK Internet Pharmacy).

**Standards & Certifications** ISA member, Microsoft Gold Certified Partner, Intellect Partner, listed in the Deloitte Fast 50 since 2004.

Additional Languages Russian, Portugese, French, German, Punjabi, Hindi, Mandarin, Arabic.

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#### IMEC TECHNOLOGIES

**Business Description** IMEC develops and provides track and trace computer software, mainly to the regulated and healthcare industries using barcode and RFID technology. Company products track hazardous waste, products, people and assets.

**Products & Services** IMEC has developed a global system to identify, track and manage hazardous waste in the client's premises, providing the ability to reduce waste costs, provide regulatory documentation and aid compliance. Product range includes:

- Hazmat TandT hazardous waste tracking software
- Navigation enterprise labelling a label design, approval, control, printing and reconciliation system for life sciences companies
- Navigation material movements- a material tracking system integrated with a customer's ERP system
- Bespoke software solutions
- RFID systems

Key Customers GSK, UK NHS, Wyeth.

Standards & Certifications Microsoft Gold Partner, GAMP.

**Additional Languages** Polish

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#### TMS MAXIMS



**Business Description** IMS MAXIMS ground-breaking suite of advanced web-based clinical software transforms how healthcare institutions manage patient data and deliver effective healthcare. Designed and developed by IMS MAXIMS and clinicians, this is a zero-footprint application giving healthcare professionals instant access to a single patient record irrespective of location.

#### **Products & Services**

- PAS, patient management
- Order communications
- User defined assessments
- Correspondence
- Generic rich clinical functionality

# **Key Benefits**

- · Enhances clinical effectiveness and engagement
- Supports both existing HSE, NHS, independent sector IM&T systems and new NPfIT systems
- Gives in-depth support to NHS, independent sector and HSE priorities
- Can be implemented quickly and efficiently
- Supports joined-up healthcare and continuity of care
- Secure, reliable and interoperable. Web based system allowing users connectivity irrespective of location

**Key Customers** Health Service Executive, St. Vincent's, NTPF, Clatterbridge Centre for Oncology NHS Trust, Imperial College Healthcare NHS Trust, St. Helens and Knowsley NHS Trust, Stoke Mandeville Spinal Unit, Blackpool Victoria Hospital NHS Trust, HSC Trust, Great Ormiond Street Hospital for Children NHS Trust, Cornwall and Isles of Scilly Health Authority, Mid Western Regional, General Healthcare Group, Care UK, Turning Point, UK specialist hospitals.

**Standards & Certifications** IMS MAXIMS operates an Integrated Management System that covers the three related standard: ISO 9001, ISO 14000 and ISO 27001. IMS MAXIMS is IGSoC approved. IMS MAXIMS information security management system which includes information governance policy is ISO 27001 approved. Company is working towards ISO/IEC 27001 certification. The IMS MAXIMS Service Desk is ITIL conformant.

Additional Languages Irish, French.

Note IMS MAXIMS Plc. was founded in 1986 and floated on the London AIM market in 1999.

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#### LINCOR SOLUTIONS LTD

**Business Description** Lincor Solutions provides digital media solutions at the point of care with over 17,000 systems installed in 80 hospitals worldwide. This includes bedside patient entertainment services (TV, internet, VOD and phone) and also staff access to clinical applications.

### **Products & Services**

- Bedside multimedia touchscreen PC, Lincor's flagship solution, MEDIVista, delivers a complete range of
  multimedia services e.g. internet, TV digital radio, games, Skype, VOD etc. over IP to the bedside and allows
  clinicians and nurses to have real-time secure access to hospital applications such as electronic patient records
  and PACS (x-ray, mri images)
- Patient Entertainment Systems: digital triple play entertainment and information services

# Key benefits would include -

- Dramatic increase in patient satisfaction
- Enhanced patient safety
- Staff efficiency
- · Patient educational videos
- Rreal time medication management at bedside

Key Customers The Harley Street Clinic, Harley Street Clinic, London Bridge Hospital, Clinique Geoffrey Saint Hilaire (Paris), CHRA., St Vincent's Hospital, Dublin, Sports Surgery Clinic, Dublin, Bon Secours Cork, St. Pauls Hospital, Hong Kong, Holy Name Hospital, New Jersey, Mater Dei Hospital, Malta, University Medical Centre, Groningen., University College London Hospital.

Additional Languages French, German, Spanish, Italian, Catalan, Croatian, Mandarin, Dutch.

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#### OCUCO ITD

**Business Description** Ocuco develops off-the-shelf software solutions for ophthalmology, optical retail and optical lab businesses of all sizes, and is the leading independent supplier of practice management, lab management and business management systems to the optical sector outside of the US, with over 6,500 sites worldwide.

**Products & Services** The Acuitas Diabetic Retinopathy suite offers solutions for photography, grading and management services for DR screening programmes.

The Acuitas Clinical software is designed for ophthalmologists, with a strong clinical element along with robust patient management modules.

The flagship optical retail software suite, Acuitas, has been installed in independent stores and in chains across six countries including UK, Ireland, France, Spain, Switzerland and Mexico, with plans in place to localise the software for Italian, Canadian, American and Swedish markets. Solutions for independent practices and optical retail chains are available.

The Innovations Lab Management Software automates prescription lens processing. It manages both the process and business of lens manufacturing. Innovations is modular and can be custom configured to suit the specific needs of any size laboratory.

- · Feature rich, yet simple to use
- Acuitas integrates the patient journey, saving time on resources and equipment
- · Oracle reliability and security

**Key Customers** Royal Victoria Hospital Belfast, Moorfield's Eye Hospital, Vision Express, Mater Private Hospital, Mater Public Hospital, Waterford Eye Clinic, Blackrock Clinic, St James Hospital, Bon Secours Hospital Tralee and the Longford Westmeath General Hospital, for example.

Additional Languages French, Spanish, Italian, Swedish, Greek.

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# **ONEVIEW**

**Business Description** Oneview Ltd. is a software company specialising in converging clinical and patient information, communications and multimedia at the hospital bedside. Applications such as patient records, pharmacy orders, nurse call, ADT etc. in addition to the internet, movies, music and healthcare information, are streamed to the hedside

**Products & Services** Hospitals see a return on investment through the benefits or having access to critical patient records at the point of care, as well as reducing medical errors and improve work flow practices. Oneview Limited is one of the few dedicated software companies delivering the convergence of information, communication, and other hospital applications in the one place where it is required and matters most, at the bedside.

In addition, patients in hospitals have a greater expectation for comprehensive healthcare information, better multimedia experience from internet, movies, music, games, etc. Oneview Ltd. delivers all these and more right to the bedside.

The Oneview software can run on most PC's or terminals such as touch-screens or remote access, and can also be integrated with TV sets.

**Key Customers** National Maternity Hospital, Holles Street, Dublin, Methodist Hospital, Ohio, USA, Hospital, Hong Kong Sanatorium, Hong Kong.

Note Oneview Ltd. is seeking suitable partners to integrate and deliver the software to every part of the world

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#### ORRIS INFORMATION SYSTEMS ITD

**Business Description** Orbis Information Systems Ltd. is a leading systems integrator with particular skills in the implementation and support of laboratory informatics and manufacturing execution systems.

**Products & Services** Orbis was founded in 1998 to bring integrated laboratory informatics and manufacturing solutions to the local and international market. Orbis specialises in laboratory informatics and enterprise manufacturing intelligence software solutions, services and support. The company solutions have satisfied the most comprehensive regulatory standards, and are designed to advance laboratory automation through instruments data capture and systems integration.

**Key Customers** BMS, Abbott Laboratories, Elan, Eli Lilly, Schering Plough, Servier Industries, Helsinn Birex, Noven Pharma, Millipore.

Standards & Certifications ISO 9001:2000

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# PMI SOFTWARE LTD

**Business Description** PMI Software is an engineering software solutions company specialising in software for engineering, facilities and health and safety. The company is a Microsoft Certified Partner for Dynamics CRM and custom development. All company staff are Microsoft Certified Professionals.

**Products & Services** The PEMAC family of products provides solutions for maintenance management, facilities management, permit to work, risk assessment and contractor management. Designed in collaboration with end-sers, the software products evolve with the customer in a user-friendly but effective way. PMI specialises in Dynamics CRM, .NET, SQL Server 2005, Forms Server 2007 and Sharepoint 2007.

Key Customers 400+ clients across all sectors: Pharma, Food, Public Sector, Financial, Medical, Facilities.

Standards & Certifications ISO 2000 and Microsoft Gold Certified Partner

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#### PULSEL FARNING LTD

**Business Description** PulseLearning creates learning solutions that bring measurable business value to its clients, and achieves this through a high-energy, client-centric approach that combines excellence in people, process, partners, technology, and innovation.

**Products & Services** Products and services include eLearning (self-paced, web-based multimedia instruction), instructor-led (face-to-face) training, social and informal learning, Learning Management Systems (LMS), and Employee Performance Support Systems. The company also offers expert consultancy and staff augmentation for instructional design, multimedia development, strategic enterprise learning plans, and the conversion of ILT to eLearning.

PulseLearning uses a rigorous yet flexible method of analysing, designing, developing, implementing, and evaluating the effectiveness of training. All learning services and products created by PulseLearning are expertly engineered to maximise learner engagement and retention. Learning produced by PulseLearning is SCORM-conformant so it will work with the client LMS to track and report on learner performance – a critical component in proving compliance with regulations.

**Key Customers** CA Technologies, Bank of America, BP, Citigroup, HP, InterContinental Hotels Group, Merck, UnitedHealth Group, NASA, Pfizer, LexisNexis, The Princeton Review.

Additional Languages French, German, Italian, Spanish, Dutch, Danish, Greek, Russian, Polish, Arabic, Hebrew, Japanese, Cantonese, Korean, Portuguese.

Awards Ernst & Young Entrepreneur of the Year, Deloitte Technology Fast 50, Chief Learning Officer, Learning in Practice Awards, Gold Award, Bersin & Associates Learning Leaders

Locations Offices and teams are located in the United States, Canada, United Kingdom, Ireland, Europe, and Australia, serving clients worldwide.

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# S3 GROUP LTD

**Business Description** S3 Group is a leading provider of telehealth consultancy services to healthcare providers and medical device vendors, enabling clients to develop and implement patient-centric telehealth/telecare products and services that meet the needs of patients, their carers, clinical professionals and the wider healthcare system.

**Products & Services** S3's telehealth development services for medical device vendor clients enables development of next generation telehealth/telecare products:

- Concept & requirements
- Telehealth enterprise system development
- Personal health device product realisation

Services for health and social care providers enable the implementation and deployment of telehealth and telecare systems that improve health outcomes, are compelling to patients, and support clinical staff with data-driven safe and efficient workflows which reduce the cost of care delivery.

To provide solutions that scale beyond pilots, S3 ensures that the telehealth/telecare system is integrated with the wider healthcare IT system while addressing the issues of privacy, confidentiality and data governance.

#### Provider solutions:

- Bespoke telehealth solution implementation
- Health IT System integration EMR's, GP systems

**Standards & Certifications** ISO 9001:2000, CMMI Level 3 (standards applied, but not certified). ISO 13485 pending.

Key customers Tunstall, Fold, Philips, Toshiba, IBM, Intel, Xilinx, ST Microelectronics, OpenTV.

Additional Languages French, German, Dutch, Polish, Czech, Portuguese, Cantonese, Mandarin.

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#### SEARROOK RESEARCH LTD.



**Business Description** Seabrook Research Limited is a life sciences specialist integration company, providing automated device and batch history data collection systems along with SCADA (supervisory control and data acquisition), automation and validation services. The company has developed significant expertise in drug eluting stent manufacture, and knowledge of manufacturing quality systems is at the highest level.

**Products & Services** Seabrook is the European Partner for Camstar Enterprise Quality Solutions and electronic batch record (EBR) systems, and has implemented integrated manufacturing systems for Boston Scientific, Cordis JandJ, Biotronik Germany etc. An experienced team has skill sets ranging from project management, integration services, return on investment programmes, new product introduction as well as automation and validation services.

Key Customers Boston Scientific, Cordis J&J., Stirling Medical, Biotronik GmbH.

**Standards & Certifications** Seabrook Research has helped companies achieve successful FDA and IMB audits and Seabrook's processes are ISO 9001:2000 compliant. The company's consultants undertake a rigorous certification programme with Camstar before achieving fully certification.

Additional Languages French.

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# SENSORMIND

**Business Description** Sensormind is an Irish SME, which has developed and markets unique technology to support independent living through a range of products, centrered around an innovative web-based system. The modular system was designed to empower older or vulnerable people to remain living at home independently for as long as possible. At the same time, it offers peace of mind to family members, carers and health professionals.

#### **Products & Services**

- Sensormind Alert: a wireless personal alert system
- · Sensormind Independent Living System: a wireless automated monitoring and alert system
- Sensormind Care Monitor: a proactive automated system for managing home care/community care visits.

All systems are accessible through a secure web interface, are wireless, ideal for retrofit situations, and are flexible, modular and interoperable with other Sensormind components.

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# SLÁINTE TECHNOLOGIES



**Business Description** Sláinte Technologies provides web-based software solutions that deliver substantial efficiency and financial improvements in the health sector. Claimsure delivers sophisticated revenue cycle management for public/private healthcare. Formsure enables paperless workflows with full systems integration. SlainteVault brokerage service delivers scalable secure transfer of sensitive information.

#### **Products & Services**

- Claimsure electronic health insurance revenue cycle management solution, fully integrated with hospital systems for rapid collation submission and payment of patient claims
- Formsure document automation solution to allow hospitals rapidly move to ward-based bedside datacapture due to its integrated template wizard. Contains workflow and high volume scanning capabilities
- Billsure configurable billing solution for physicians and hospitals
- Tele-radiology integrated solution facilitating ad-hoc or high-volume DiCom radiology images to be rerouted to third party for reporting, with reports reconciled to originating site
- SlainteVault secure brokerage system to facilitate exchange of sensitive clinical and demographic information and files from multiple sources to hospital systems and vice versa
- Iguana highly flexible, highly scalable HL7 integration engine for co-ordinating and rationalising intrahospital systems integration

**Key Customers** St. James' Hospital, Mater Misercoridiae University Hospital, Cork University Hospital, Galway Clinic, Aut Even Hospital, Mt. Carmel Medical Group, Euromedic Group, St. John of Gods Hospitallers, Aviva Insurance.

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# SOFTTRACE LTD

**Business Description** Softtrace Ltd. is a leading developer of cost-effective traceability and quality management software solutions for a wide range of industries, including dairy, beverage, pharmaceutical, healthcare and independent laboratories.

**Products & Services** Products include quality management software applications, LIMS (laboratory information quality management systems), manufacturing and inventory systems, and bespoke software design.

**Key Customers** FMC BioPolymer (Irl & USA), Wyeth, Boston Scientific, Bodycote, Glanbia, Dairygold, Lakeland Dairies, Tipperary Co-op, Wexford Creameries, Arrabawn Co-op, Connacht Gold, Carbery Group, Bandon Co-op, Town Of Monaghan and Independent Analytical Services, for example.

**Standards & Certifications** All applications conform to EU and FDA regulations.

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#### STATISTICAL SOLUTIONS LTD



**Business Description** Statistical Solutions Ltd. designs, develops and distributes unique statistical software applications for statisticians, clinical researchers and data analysts. Each application addresses specific critical issues that arise in the design and statistical analysis of clinical trials, research surveys and other scientific investigations.

#### **Products & Services**

- nQuery Advisor: the world's leading sample size and power determination software is used by major pharmaceutical and biotechnology companies, FDA and other regulatory agencies
- SOLAS for Missing Data Analysis: provides researchers with different data imputation techniques in an easyto-use, validated software application
- EquivTest: provides tests and confidence intervals for equivalence testing and pharmacokinetic calculations
- BMDP: a general statistical analysis application used to analyze data from any field of study
- Comprehensive Meta Analysis: meta analysis is the statistical procedure for combining data from multiple studies and is an increasingly popular technique in all areas of research
- NCSS: a comprehensive, accurate, and easy-to-learn statistical analysis and graphics system

**Key Customers** Novartis Pharma, Sanofi Aventis, AstraZeneca, Amgen, Bristol Myers Squibb, Genentech, Eli Lilly, Parexel, Covance, FDA.

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# **SYNCROPHI**

**Business Description** Syncrophi Systems develops and markets advanced wireless ambulatory patient-monitoring systems for use in hospitals and related healthcare settings. The products enhance patient welfare, support clinical review, reduce nursing workload and speed the pull-through from ICU/CCU to step-down care settings.

#### **Products & Services**

- Wireless Monitoring Systems: fully integrated and easy-to-install
- The systems are scaleable, comprising modules which are simple to deploy, with negligible facility/ infrastructure disruption and which can be used either as a stand-alone or integrated with existing systems
- The patient's vital-signs (ECG, BPM and SPO2) are simple to monitor and review using an intuitive graphical user interface and archiving systems
- Roaming facility allows patient location to be known at all times
- Syncrophi provides demonstrable continuity-of-care through its archival records

**Key Customers** The system will appeal to clinical users, economic buyers and senior hospital and community-care centre administrators. The patient, of course, is the ultimate beneficiary.

**Standards & Certifications** Syncrophi is ISO EN 13485 certified. The KOSMOS ambulatory patient monitoring system is CE-marked and available for sale.

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#### THE PERIGORD GROUP

**Business Description** The Perigord Group provides artwork management systems (AMS) and artwork services to large pharmaceutical companies (from creation through to digital delivery), providing a secure and validated environment.

**Products & Services** GLAMS is a web-based artwork management system that tracks, manages and centrally stores artwork and graphics providing significant benefits to the pharma industry:

- Gain the benefits of total visibility, full control, audit trails, all of which ensures client timelines are achieved
- Gain total control of valuable assets locally, nationally and globally
- Gives each stakeholder in the client organisation real-time access to all content, approvals, and status
- Ensure better regulatory, organisational and GxP compliance

Key Customers Mylan, Pfizer, GSK, Teva, Microsoft, Symantec.

**Standards:** ISO 9001:2000 Quality Management System, FDA CFR Part 11 compliant and operating to GAMP 4 and 5 standards.

**Additional Languages:** All

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#### TWO-TEN HEAITH ITD

**Business Description** Two-Ten Health is the leading supplier of dental hospital clinical software internationally, recently winning the first National Programme for Dental Hospitals with the award of the English Framework Contract. The product Salud was designed specifically for this teaching/treating environment and is used in four continents.

**Products & Services** Salud for Dental Schools / Hospitals - comprehensive Dental School / Hospital Clinical Information System providing: Electronic Dental Record (EDR), treatment planning and treatments, patient management, billing, student supervision, grading and progress monitoring, administration, appointment scheduling, reporting, security and data-protection.

- Salud for dental outreach clinics
- Salud for dental hygiene education
- · Salud ASK (auditable shared knowledge) for data mining
- Salud alumni portal for dental schools
- Professional services include: business analysis, implementation and consultancy

# **Key Benefits**

- Better patient experience
- Improved record keeping and real time access to information
- Enhanced student education
- · Clinical performance measurement, quality and compliance
- Easier reporting and accreditation
- · Tighter financial controls
- Resource and revenue optimisation

**Key Customers** Live clients include the Dublin Dental School & Hospital, Ireland, University Oslo Dental School, Norway, University Complutense Madrid, Spain, Boston University, USA, University of Alabama at Birmingham, USA, for example.

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#### VALENTIA TECHNOLOGIES LTD



**Business Description** Valentia Technologies is an international healthcare software company focussed on the development of enterprise-level mobile systems for public and private healthcare providers with an incommunity service focus.

# **Products & Services**

Valentia's systems address the dramatic shift that is occurring in the provision of healthcare services away from traditional hospital and clinic settings to their provision in the community and at home. The emphasis of Valentia's systems is on directly improving health and social care management and outcomes by facilitating proactive intervention, care management, condition monitoring, data aggregation and analysis, and quality assurance.

- Pre-hospital EMS
- In-community healthcare
- Call taking/resource deployment management (including CAD)
- Location-based services
- Point-of-care data recording
- Full cycle hospital-to-home therapy management by visiting clinicians

- Managed care pathways
- Patient messaging
- Hi-Tec medications supply chain and home delivery management
- Telecare/telehealth management
- · Healthcare staff rostering
- · Healthcare staff HR management and credentialing
- Complex healthcare billing

**Key Customers** Isle of Wight NHS Trust, Pre-Hospital Emergency Care Council of Ireland, United Drug plc, Falck Group Europe, Falck Group UAE, Dubai Ambulance Service, Czech Ambulance Service, Croatian Ambulance Service and the Isle of Man Ambulance Service, for example.

Standards & Certifications ISO 9001:2000, Microsoft Gold Partner.

Additional Languages French, German, Polish, Spanish, Czech, Turkish, Dutch, Arabic, Urdu.

#### **Contact Name / Title**

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# VIGISOFT LTD

**Business Description** Vigisoft is a leading provider of web-based quality management systems for small, medium and large organisations. The flagship product provides an integrated and cost effective solution for enterprise quality and compliance management typically in preparation for regulatory activities in the form of audits and inspections.

**Products & Services** Web-based quality management solutions incorporating - Workload management, workflow, document management and changes, assurance management, non-conformance management, CAPA, governance, SOP management, audit management, reports/dashboards. Benefits include:

- Single enterprise-wide repository accessible to all users
- Improved adherence to Company SOP's and processes
- Maximum transparency of QMS for management and audit purposes
- Version controlled, secure access providing information on a need-to-know basis
- Ability to author, change, review, approve QMS content
- Supports closed-loop activity chain for quality non-conformances
- Time stamped audit trail for all QMS activities
- Audit management and reporting
- Timely QMS updates following changes in regulatory or quality requirements
- · Clearly articulated strategy and goals, communicated across the enterprise
- Improved business alignment through monitoring of KPI's

Standards & Certifications ISO 9001

**Additional Languages French** 

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# **VIVARTES**

**Business Description** Vivartes is a health care media provider and software developer based in Kilkenny. A team of professionals is committed to developing solutions that help hospitals and healthcare organisations transform the patient experience for those in protective isolation, palliative care, or long-term residential care facilities.

Products & Services Open Window is a unique interactive patient care solution for patients and residents of long term care facilities, enabling hospitals and healthcare institutions to achieve breakthrough results in the areas of improved patient satisfaction. Connecting patients to the outside world through a number of portals, Open Window is delivered through an interactive over-the-web platform designed specifically for medical care environments. The subject of a five year clinical trial in St.James Hospital, Dublin, Open Window is the only interactive patient care solution that has been clinically shown to significantly reduce patient anxiety and improve overall patient experience. Patients using Open Window can choose from a range of curated art works, renderings of scenes of nature, and live video links and images from important family events.

**Key customers** St.James Hospital Dublin, Blackrock Hospice, Carlow County Arts Office, Kildare County Arts Office.

#### **Contact Name / Title**

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# MEDICAL AIDS/ FINISHED PRODUCTS



# The Irish Life Sciences Directory Medical Aids/ Finished Products

#### ART MEDICAL



**Business Description** ABT Medical supplies the Irish and international medical device industry with OEM customised angioplasty balloons. Its team manufactures specialised products that cover the complete spectrum of interventional treatments from coronary special products to valvuloplasty products.

**Products & Services** ABT Medical offers the design, development and manufacture of angioplasty balloons, and can work from a concept through to a prototype and then into production.

# **Product Range:**

- Diameters range from 0.5 to 50mm
- Lengths from 5-495mm

#### Materials (not limited to)

- Pebax
- PET
- PU
- Nylons (11 & 12)
- Various compositions
- Custom and special projects
- Diagnostic balloons
- Ancillary balloon equipment

**Key Customers** Key customers range from small start-up medical device companies through to large multinationals covering USA, Asia and Europe.

Standards & Certifications Working towards ISO 13485 with expected certification Q4 2010.

# **Additional Languages Mandarin**

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# ADVANCED SURGICAL CONCEPTS LTD.

**Business Description** Advanced Surgical Concepts Ltd. is a medical device design company established in 1998 to increase the number of abdominal surgeries performed endoscopically though the development of novel access technologies.

# **Products & Services**

- ASC QuadPort for single port surgery
- · ASC TriPort for single port surgery

**Key Customers** Key clients include Olympus Winter and Ibe GmbH (part of Olympus Corporation) and Davol Inc. (part of CR Bard).

**Standards & Certifications** ASC is registered with NSAI to ISO 13485:2003. The quality system also includes suitable controls to address the requirements of the FDA Quality System Regulation (QSR 21 CFR part 820).

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# AFROGEN ITD



**Business Description** Aerogen is a specialty medical device and drug delivery company. Aerogen's unique market position is based on its strongly patented OnQ™ vibrating mesh technology. Aerogen has invested in excess of \$50m in developing its OnQ™ aerosol generator which is leveraged into many different commercial areas.

## **Products & Services**

- The Aeroneb® Pro nebuliser: specifically developed for ventilated acute care patients, the Aeroneb® Pro
  produces a fine particle, low velocity aerosol optimised for deep lung drug deposition
- The Aeroneb® Solo nebuliser: designed for use with ventilated patients, the Aeroneb® Solo is a single patient use device. It does not affect ventilator parameters and can be left in line for up to 28 days intermittently or seven days continuously
- The Aeroneb® Go nebuliser: provides fast, simple and efficient therapy for patients who require daily
  nebuliser therapy in and away from home. It is simple to operate and works with either an AC mains adaptor
  or a battery pack which uses three AA disposable batteries

**Key Customers** Critical care units, hospitals, patients with respiratory conditions such as CF and asthma, ventilation companies, and medical device distributors.

**Standards & Certifications** All product design and development work is carried out in accordance with ISO 13485, CMDCAS and FDA quality systems.

## **Contact Name / Title**

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# ALTASCIENCE

The Irish Life Sciences Directory

Medical Aids/

Finished Products

**Business Description** AltaScience is developing a novel implant to provide permanent female contraception. AltaSealTM is placed in the fallopian tubes by a gynaecologist without the need for surgery. The procedure can be carried out in the doctor's surgery rather than having to use an operating theatre. It will be easy to use, inexpensive to manufacture and will provide immediate contraception.

Products & Services The market for devices that enable permanent female contraception without the need for surgery is estimated at greater than \$1 billion annually, of which the United States accounts for ca. 80%. Unlike other devices on the market, AltaSeal™ will provide immediate closure of the tubes and it will not require confirmatory procedures at a follow-up visit. AltaScience has recently initiated clinical testing of AltaSeal™ and results show that the device is easy to place and immediately occlude the fallopian tubes. The next phase of development will involve clinical trials to test its effectiveness as a permanent contraceptive device. The device will be marketed in the EU under CE mark and requires a PMA (pre-market approval) from the FDA for US marketing.

Standards & Certifications Working to IS EN ISO 13485 standards.

Additional Languages German.

## **Contact Name / Title**

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# APOS

**Business Description** APOS supplies and manufactures prosthetic and orthotic medical devices for the private sector and the Western, Midland and Mid Western Health Service Executive.

Products & Services APOS Ltd. caters for all upper and lower limb prosthetic needs; assessment, prescription, casting, manufacturing, fitting and reviews. All limbs made are individually customised to restore maximum function. APOS aims to use the latest technology available to provide the best restoration of function possible. The orthotic service covers all custom-made externally applied devices. The company also specialises in extra wide and deep footwear, as well as custom made footwear, and has a large variety of suppliers who can adapt footwear to suit the patients individual requirements. Alterations such as flares, raises and wedges are carried out in APOS's workshop.

Key Customers Private sector and the Western, Midland and Mid Western Health Service Executives, Ireland.

**Standards & Certifications** ISO 9001:2000 certification, APOS LTD is registered with the Irish Medicines Board, British Association of Prosthetists and Orthotists (BAPO), International Society for Prosthetists and Orthotists (ISPO).

**Additional Languages Irish** 

# **Contact Name / Title**

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**Business Description** ArcRoyal is involved in the full development cycle of acute care and original equipment manufacturer (OEM) medical products. It specialises in the manufacture of custom procedure packs (CPT's) for single-use in hospital operating rooms and cardiac catheterisation labs.

# **Products & Services**

- Custom procedure kits, for use in operating rooms, angiography and ophthalmic procedures
- Sterile accessories: angiography and endovascular accessories, surgical and medical accessories, temperature monitoring products, surgical suction systems and waste management systems
- Advanced wound care products
- Bulk non-sterile medical products custom procedure tray accessories, angiography accessories for further processing

**Key Customers** Corporate distribution partners, independent national distributors, CPT assembly companies, hospitals and clinics.

## **Contact Name / Title**

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# ASH TECHNOLOGIES LTD



**Business Description** Ash Technologies designs, manufactures and distributes a range of innovative electronic magnification solutions for the global low vision community.

**Products & Services** Core expertise is innovating through technology and design integration to develop a range of electronic magnification products that provide portability, mobility and independence to those with low vision. Specific product lines include:

- TVi
- Prisma range
- Quicklook range
- Fusion
- Liberty Solo
- Presto
- Eclipse
- Opti
- Horizon
- Agilo

**Key Customers** Eye care professionals, low vision organisations, low vision distributors and dealers and the optical consumer and trade catalogues.

Standards & Certifications CE certification for all products, ISO 9002 accredited.

**Note** Ash has been acknowledged nationally with year-on-year recognition in the Deloitte Fast 50 category and also as DHL Exporter of the Year in 2004. Internationally it has received two prestigious iF design awards; the Quicklook product in 2005, the Fusion product in 2007, and a red dot design award in 2010.

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# AVONMED HEALTHCARE ITD

**Business Description** Avonmed Healthcare Ltd. specialises in clinical research, physician concept development, product design, device manufacture, validations and marketing of single-use, disposable medical devices.

**Products & Services** Avonmed Healthcare Ltd. has developed the most technologically advanced coupling for inter-connecting flexible tubes.

- Avonseal systems deliver a secure, leak-proof connection method, appropriate for use in a broad range
  of fluid delivery and life sciences applications. These precision systems incorporate an advanced sealing
  technology and combine both fixed self-sealing and quick-disconnect couplings. These features enable
  Avonseal to connect to unlimited connectors
- Typical applications include fluid administration, oxygen delivery, urology drainage, cardio-thoracic, enteral feeding and surgical drains

Standards & Certifications Annex V. 93/42/EEC Medical Devices.

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# BIO MEDICAL RESEARCH



**Business Description** BMR is a privately owned Irish company with over 40 years experience in the research, design, manufacture and marketing of medical grade products for both muscle conditioning and pain relief. Two divisions exist; Slendertone (consumer health and fitness) and Neurotech (pain management and rehabilitation).

#### **Products & Services**

- Slendertone: a world leader in providing products that improve muscle tone and body shape, supported by clinical research on effectiveness
- Neurotech: produces NMES, TENS and orthotic devices to treat common conditions such as back pain, osteoarthritis, post-surgical knee rehabilitation, labour pain, incontinence
- All BMR Products: approved under the European Medical Device Directive

Key Customers Argos (UK), Boots (UK), ECI (Spain), Decathlon (France), Go Sport (France), Next, Oaklawn (Japan), Otto, Quelle, United Drug, hospitals, GP's and physiotherapists.

Standards & Certifications ISO 13485:2003 certification, MDD93/42/EEC.

Additional Languages Irish, French, German.

## **Contact Name / Title**

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# CLEARSTREAM TECHNOLOGIES LTD

**Business Description** ClearStream specialises in the design, manufacture and supply of angioplasty products for treatment of blockages in coronary and peripheral arteries, with a specific focus on the treatment of chronic total occlusions, critical limb ischaemia and diabetic foot.

Products & Services Products are used by cardiologists, radiologists, angiologists and vascular surgeons performing interventional procedures. Channels to market include distributors of medical devices (to sell ClearStream branded devices), JandJ (Cordis) who distribute certain products on a "co-labelled" basis to a world-wide customer base, and business-to-business (OEM) customers who purchase unbranded devices for stent delivery, PTCA and PTA. Products include balloon catheters for both angioplasty of peripheral arteries and angioplasty of coronary arteries, in addition to coronary stents including bare metal, cobalt chromium and drug eluting (Trapidil).

Key Customers A range of distributors of ClearStream branded devices in Europe, South America, Middle East and Asia. J&J (Cordis) on a world-wide basis. OEM customers in Europe, USA, India and China.

Standards & Certifications EN ISO 13485:2003, MD93/142/EEC, Consolidated Canadian Medical Devices Regulations, SOR/98-282, FDA: CFR 21 QSR 820.

Additional Languages French, German.

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# CREAGH MEDICAL LIMITED



**Business Description** Creagh Medical is a finished goods/original equipment manufacturer (OEM) that specialises in the design, development and manufacture of percutaneous transluminal angioplasty (PTA) balloon dilatation catheters, with specific focus on designs for peripheral vascular indications.

# **Products & Services**

Creagh Medical has developed a range of catheters that address the entire periphery from general vascular PTA and lower extremity disease to dialysis access speciality products. A fully integrated operation includes on-site extrusion, balloon and catheter design, manufacture and test capabilities. Validation and regulatory capabilities exist on-site and our products have received CE, FDA and Japan MHLW approvals. Contract product design and commercialisation services are also provided. The manufacturing facility was purpose built in 2006 and is currently scaled for high volume production and has further expansion capability. Strategic consulting services to clients seeking to enter angioplasty markets are also available.

**Key Customers** Leading medical device companies worldwide, and start-up medical device companies.

Standards & Certifications EN ISO 13485:2003, MD93/42/EEC, Japan MHLW, FDA: 21 CFR Part 820, Canadian Medical Devices Regulation.

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# CROSPON ITD

**Business Description** Crospon designs and manufactures medical devices that measure the dimensions and provide images of hollow body organs. The company has a strong competency in the design and manufacture of electro-mechanical medical devices. In addition to designing its own products, it also provides contract design services to third parties. The company's design capability includes embedded software development for critical care devices.

#### **Products & Services**

Crospon's first product, EndoFLIP® (endolumenal functional lumen imaging probe) is a platform technology with potential applications to address a variety of unmet medical needs. EndoFLIP® uses unique patented technologies for monitoring dimensions of hollow body organs. Crospon's initial focus for EndoFLIP® is on applications in the gastroenterology and upper gastrointestinal surgery markets. In particular the first product is intended

- to assist in the diagnosis of gastroesophageal reflux disease (GERD), and for use in the GERD surgery market
- to assist bariatric surgeons in measuring pouches and stomas created during a variety of bariatric surgery procedures

The company believes that EndoFLIP® will have potential value in a number of other applications, in particular for assessing sphincter performance in the treatment of incontinence or for other lumen measurements in the cardiology area, for instance when treating defects in PFO.

**Key Customers** Medical Management Systems (MMS) was recently appointed as the worldwide distributor for EndoFLIP® in the GERD market.

Standards & Certifications ISO 13485, CE Mark for EndoFLIP hollow organ imaging technology.

**Note** Crospon, founded in late 2006, has received a number of awards in the past year including the 2009 Frost & Sullivan European Gastroenterology Technology Implementation of the Year award, the Overall Medical Technology Excellence Award, Gold Award for Innovation and Research and Development at the 2009 Irish Medical Device Association Awards and, most recently, the 2010 Innovator of the Year Award at the Irish Small Firms Association National Business Awards.

#### **Contact Name / Title**

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# DMC MEDICAL ITD



**Business Description** DMC Medical Ltd. carries out R&D, manufacturing & distribution of a range of cardiovascular devices, custom polycarbonate syringes, wound care dressings and general surgical supplies. DMC is dedicated to bringing innovative devices to market through three distinct avenues: direct hospital sales, subdistributors and custom kit packers.

**Products & Services** DMC Medical exports over 95% of its products worldwide. Logistics, regulatory and customer service functions are based in both Ireland and the USA. DMC has an in-depth knowledge of manufacturing in China. Cardiovascular accessories:

- SVDS saphenous vein distention system used during open-heart surgery
- CIP cardiac insulation pad protects the phrenic nerve while topically cooling the heart
- HeartNet heart positioning device
- VIC and BIC bevelled and blunt vein irrigation cannula

# **General Surgical:**

- Polycarbonate syringes colour coded luer lock PC syringes in 94 variations
- BioTrap fluid collection device used in radiology for the collection of biohazardous waste
- Connectors various sized polycarbonate connectors

#### Wound Care:

- SupraGel amorphous wound care gel
- SupraCel wound care dressing

**Key Customers** Cardinal Health Inc., Medline Industries Inc., Owens and Minor Inc., PHS Inc., ACP Ltd/Getz Bros., AMSC LLC., Palex Ltd., Luke Medical LLC.

Standards & Certifications Operates to EN ISO 13485:2003 + AC:2007

# **Additional Languages Spanish**

## **Contact Name / Title**

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# FLEMING MEDICAL ITD

**Business Description** Fleming Medical is an OEM provider of a wide range of medical and pharmacy consumables. The company has 25 years of expertise is in the development of innovative medical diagnostic and consumable products for the primary and pharmacy markets which offer key points of difference and a clear value proposition.

# **Products & Services**

Medical equipment, including defibrillators, cardiology, general diagnostics and emergency equipment.

Medical consumables, including:

- Wound care
- · Bandages & compression
- Plasters & tapes
- Burn care
- First Aid
- Infection control & gloves
- Incontinence
- · Protective clothing
- Patient care & hygiene care

**Key Customers** The main export markets are Northern Ireland and the United Kingdom, with a growing presence in Europe, Caribbean and Asia. Pharmacies, hospitals, doctors, nursing homes, physiotherapists, medical distributors.

Standards & Certifications ISO 9001:2008 and ISO 13485:2003.

Additional Languages French, German.

#### **Contact Name / Title**

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# TTRONTK INTERCONNECT LTD



**Business Description** Itronik Limited was founded in 2004 as a provider of electronic design and prototyping services, primarily in the healthcare sector. Itronik has identified a gap in the market for a system which automates the control of hand hygiene by way of monitoring, recording and reporting hand washing activity.

**Products & Services** Itronik has now successfully completed the design of an RFID technology-based system called HigenX which will provide management tools and information to ensure the adoption of best hygiene practice, while producing a verifiable audit of compliance for risk management purposes.

- Itronik believes that HigenX is the first product worldwide to provide an effective solution to control the problems associated with poor hand hygiene, and that therefore the potential of the product is enormous
- Itronik is in discussions with Irish, UK and European hospitals that want to introduce the HigenX products. The company is currently selling in Ireland through an appointed distributor (Spray-Chem)
- Itronik has also supplied the HigenX product to the food industry and is in the process of supplying a major fast food chain

# Standards & Certifications ISO 9001

Note The company is willing to source and negotiate with distribution partners in other countries.

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# LONGHAUL TECHNOLOGIES LTD

**Business Description** Longhaul Technologies Ltd. is a manufacturer of the Medicore brand of pressure distributing air cushions and mattresses. The company has made its reputation in the highly regulated aerospace industry.

**Products & Services** Successful R&D in the area of longhaul aircraft seat cushioning saw its LongRest brand take off in 2002 with top world airlines. With a technology based on polyurethane open cell foam, air and valves within give greater and more efficient pressure distribution and hence long-term comfort. The Medicore brand has inherited all the benefits from this experience and research.

- Stand-alone seat bottom air cushions for hospitals and nursing homes bedside seating
- Pressure distributing air mattresses for long-term care: single and multi-zone
- Portable ultra-lightweight air cushions for back support for use in transportation seating
- Portable ultra-lightweight air cushions for seating pressure distribution in transportation seating
- Contract design services for companies involved in manufacture of equipment needing cushioning features for the disabled

Standards & Certifications ISO 9000:2011

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# MEDITEC MEDICAL ITD



**Business Description** Meditec Medical designs, manufactures and delivers cutting edge technology in the area of pressure relief mattresses and patient support surfaces. Meditec Medical is committed to enhancing patient care through its products, services and adding value for clients through its education and training packages.

#### **Products & Services**

- Distributor: range of patient aids and appliances such as patient transfer systems, patient lifting hoists, beds and bariatric equipment
- Added value offering: distributed items includes education on the prevention and treatment of pressure ulcers and product training

# Meditec Medical Ltd. has three divisions:

- Sale: pressure relieving mattresses, aids and appliances to the healthcare industry and private institutions
- Rental: pressure relieving mattresses and aids and applicances to the healthcare industry and private institutions
- Maintenance and decontamination: capital equipment within the healthcare industry

**Key Customers** Irish Health Service Executive, NHS (UK), private institutions.

Standards & Certifications CE Mark, ISO pending.

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# MIDLAND BANDAGES LTD

**Business Description** Midland Bandages manufactures bandages and distributes related medical consumables. In 2007 MBL became part of Lynch Medical Supplies (LMS) Ltd., specialists in orthopaedic surgical equipment and supplies.

# **Products & Services**

- Bandages
- Dressings
- Cotton wool
- Gauze
- First aid kits
- · Tapes and strapping
- First aid consumables
- Medical disposables

Key Customers Irish Health Service Executive, private hospital, pharmacy distributors, veterinary distributors.

Standards & Certifications ISO 13485:2003

# **Contact Name / Title**

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# NEOSURGICAL ITD



**Business Description** neoSurgical Ltd. is an emerging medical devices R&D company, developing a range of surgeon enabling devices in minimally invasive abdominal surgery. These devices will drive market development by facilitating rapid penetration of newer modalities such 'Single Incision' and by expanding the existing laparoscopic market.

**Products & Services** neoSurgical's innovative devices are designed to give the laparoscopic surgeon greater control of the operative procedure thereby achieving neoSurgical's vision of safer, simpler, superior surgery. neoSurgical currently has four devices in development and IP protection is in process.

Key customers Laparoscopic/keyhole general surgeons.

# **Contact Name / Title**

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# NOVATE MEDICAL

The Irish Life Sciences Directory

Medical Aids/

Finished Products

**Business Description** Novate Medical Ltd. is a developer and manufacturer of novel treatments for pulmonary embolism. The company was founded in 2006 and has established R&D and QA/RA capabilities to bring its products to market.

**Products & Services** Implantable vena cava filters. Novate Medical is developing a unique bioresorbable vena cava filter which addresses significant unmet clinical needs.

Standards & Certifications ISO 13485

# **Contact Name / Title**

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# PPL BIOMECHANICS



**Business Description** Podiatry Products Ltd. (PPL) is a company which manufactures and supplies biomechanical and rehabilitation devices and associated products, predominantly orthotic devices for the foot. The company was established in 1996 by two podiatrists who still own and manage the company.

**Products & Services** PPL supplies a wide variety of products, ranging from manufactured and stock devices plus associated products such as special footwear, splints and braces. Key manufactured products are custom-made foot orthotic devices. These are one-offs, designed and manufactured for each individual end-user. Employing qualified practitioners as part of the technical support team, skills are in place to help practitioners construct complex prescriptions for their most complicated cases, and also help with the selection of the correct type of device for their patient. The company runs multiple highly respected training courses throughout the year in biomechanics and orthotic device prescription.

**Key Customers** Healthcare professionals, predominantly physiotherapists and podiatrists, in both the private and public sector, Ireland and the UK.

Standards & Certifications CE approved – registered with Irish Medicines Board.

## **Contact Name / Title**

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# PROXY BIOMEDICAL ITD

**Business Description** Proxy Biomedical is a leading innovator in the research, design, development and manufacture of finished medical devices and tissue engineering biomaterials for the life sciences industry. Experienced medical device professionals and project managers work with patented technologies in a quality-controlled environment.

**Products & Services** Advanced surgical implants, tissue engineering biomaterials, and combination devices for soft tissue and orthopaedic repair have been developed using state-of-the-art absorbable and non-absorbable materials and micro-machining processes. A design and development service is available to custom build tissue engineering biomaterial solutions, and to provide support from concept development through to manufacturing and commercialisation.

Standards & Certifications ISO 13485:2003, FDA registered.

**Additional Languages** Irish

**Contact Name / Title** 

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# SOTA ORTHOPAEDICS

Business Description R&D and manufacture of trauma orthopaedic devices.

**Products & Services** The X-Bolt® is an expanding bolt akin to a masonry rawl plug, which anchors with significantly better holding capacity in osteoporotic bone compared to a traditional bone screw. Trochanteric nailing and dynamic plating systems are designed for comprehensive hip fracture fixation, with clinical trials commencing 2011. The O-Jig™ accurately guides metal or bioabsorbable pins for the operative fixation of olecranon fractures, thus ensuring better patient comfort and virtually eliminating the need for second surgery.

**Key Customers** Trauma surgeons and hospital purchasers in the US and Europe.

#### Standards & Certifications ISO 13485

**Note** Founder and CEO has successful medical device design with the TightRope® family of suture-button anchors, www.ankletightrope.com.

# **Contact Name / Title**

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# TOG ORTHOTICS INTERNATIONAL LTD.

**Business Description** TOG Orthotics is Europe's largest custom made orthotic supplier. The company's Gaitscan system has an industry high 4096 sensors and scans at a rate of over 300 Hz per second. This allows TOG to capture very valuable and clinically relevant biomechanical information, allowing for very accurate and detailed orthotic prescriptions.

Products & Services As biomechanics specialists, the company supplies both the TOG Gaitscan system and the custom-made orthotics, and holds annual research-based lectures in each territory with Continuing Professional Development (CPD) points awarded. TOG has leading medical expertise available in-house, and leads the industry in product and in clinical support and expertise, and offers on-site corporate scanning at a convenient time for the customer's workforce with a minimum of disruption. TOG Orthotics has a full team of other healthcare practitioners in the allied health domains including chartered physiotherapists, chiropractors, osteopaths, and podiatrists.

Key Customers NHS, UK; all leading hospital groups and all leading healthcare practitioners internationally.

Standards & Certifications Irish Medicines Board approval registration number, IE/CA01/R/OS/0867.

Additional Languages Danish, Norwegian, Swedish, French, German.

Note TOG Orthotics won The Ulster Bank Awards for Business Going International for 2008.

#### **Contact Name / Title**

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# TRUITEF ITD



**Business Description** Trulife is an Irish owned and internationally-based group of companies engaged in the creation, development, manufacture and marketing of niche class I medical device products. The company has a long and distinguished history as a market leading innovator in the fields of orthopaedics, prosthetics, breastcare & pressure-care products.

#### **Products & Services**

- Orthopaedic, Prosthetic and Physical Rehabilitation: products with proven designs that meet or exceed industry standards
- Naturalwear Breast Forms and Speciality Bra Ranges: offers the widest selection of styles, shapes and sizes to suit different surgeries, lifestyles and needs
- Fusion, Azure, Oasis and Oasis Elite: extensive range of silicone gel pads and positioners, providing effective protection against pressure sores and nerve damage during and after surgical procedures
- Relax Wheelchair Cushion Range: provides choice in the solution for pressure relief and positioning
- Full range of walking aids, sticks and crutches
- · Hospital equipment
- Trulife, through the NHS, provides orthopaedic clinical services throughout the UK

**Key Customers** Product ranges are marketed worldwide by a network of distributors and are sold to medical supply facilities and women's healthcare specialty boutiques. The company also provides orthotic services to the NHS in the UK.

Standards & Certifications ISO 13485:2003 certification in Dublin, Sheffield, Birmingham and Washington.

Additional Languages German, French.

**Note** Trulife maintains a core group of dedicated R&D professionals who have gained vast expertise over the last 20 years. Trulife commits significant resources towards enhancing its knowledge and capabilities in new materials, products, technology and process improvements.

## **Contact Name / Title**

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# VASORUM

The Irish Life Sciences Directory

Medical Aids/

Finished Products

**Business Description** Vasorum is developing medical devices for the interventional cardiology and radiology markets. It has developed Celt ACD<sup>TM</sup>, a 316LVM biocompatible stainless steel implant used to close an arterial puncture site after percutaneous catheter-based vascular interventions. It is set to commercialise the product in early 2011.

Products & Services Celt ACD™ affects the closure of the arterial puncture by applying the implant to both the inside and the outside of the puncture site in the femoral artery at the level of the arterial wall. Vasorum has successfully completed CE Mark clinical trials. The Company is currently scaling up manufacturing capability both in-house and through sub-contractors which will allow it launch Celt ACD™ in Europe in early 2011, US launch in expected in 2012. Sales will be achieved in collaboration with an international company with the sales and marketing infrastructure to extract the full market potential from the product.

It is estimated that 8.6 million catheter-based procedures involving arterial punctures are carried out annually with half carried out in the US. The average selling price of ACD's is US\$200 in the US, suggesting a potential market of approximately US\$860 million. With a selling price of €100 in Europe the potential market is worth €430 million. In 2009 the leading product in the market, St. Jude's AngioSeal, generated sales of \$380 million and an estimated market share of close to 65%.

Standards & Certifications EN ISO 13485 Approved

**Additional Languages** German

**Contact Name / Title** 

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# VITALOGRAPH



**Business Description** Vitalograph is a global leader in the design and manufacture of pulmonary function medical devices and software. Products include spirometers and software, asthma and COPD monitors, consumables and products and systems for clinical trials. Target markets include primary and secondary care, CROs, telemedicine and pharmaceutical companies.

#### **Products & Services**

- Spirometers of all types such as volumetric, desktop, office and handheld
- Asthma and COPD monitors including peak flow meters and lung monitors
- Aspiration and resuscitation products
- Spirometry and respiratory consumables such as bacterial/viral filters and noseclips
- · Clinical drug trial software, systems, equipment and project and data management

**Key Customers** Pulmonary function labs in hospitals, surgeries, occupational health screening, and clinical trial applications for pharmaceutical companies and CROs. Telemedicine companies, individual health screening and pharma marketing departments.

Standards & Certifications All European applicable standards including EN ISO 13485 2003, IEC 601 2005 -1 -2 and -4, FDA cfr820, CMDR and JPAL Medical Devices 93/42/EEC 1993, ATS/ERS 2005 and EN 13826.

Additional Languages German, French.

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# ZERUSA LTD

**Business Description** Zerusa Ltd. designs, develops and delivers less-invasive medical devices. The company comprises a team of seasoned medical device experts covering areas including computer-aided design, polymer processing, and metal-working. The next generation Guardian II device will be available from Q4 2009 in all international markets.

**Products & Services** The Guardian and Guardian II haemostasis valves are easy-to-use devices with the following key advantages:

- · Significant reduction in blood loss from the patient and less blood in the procedural field
- Excellent management of multiple devices
- Simple, intuitive, time-saving operation

Zerusa's Guardian™ range of haemostasis valves has both CE mark and FDA clearance to market.

Key Customers Vascular Solutions Inc. – sole distributor for Zerusa's products in the USA.

**Standards & Certifications** The next generation Guardian II device will be available from Q4 2009 in all international markets supporting the CE Mark. For all other regulatory timelines, please consult the company directly.

Additional Languages German, French.

# **Contact Name / Title**

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# MEDICAL SUB-SUPPLY



# **ANSAmed**



**Business Description** ANSAmed provides advanced extrusions and catheter solutions to the global medical device industry. The company also provides contract design services and manufacturing of medical device systems/components using a broad range of process technologies.

#### **Products & Services**

#### Advanced Extrusions:

Operating 6 Sigma processes, ANSAmed's extrusion products and components conform to the tightest possible tolerances. Extrusions are available across a wide range of materials in the following configurations:

MultilayerThin wall

- Microbore (< 0.5 mm) Bump/tapered
  - Single & multilumen

- Profiles
- Co-extrusionStriped tubing

Lead times of 2 weeks are achievable for prototypes.

## Catheter Solutions:

With competencies in design and manufacturing of catheters, ANSAmed is in a position to provide timely solutions, with proven technologies in extrusion, braiding and catheter manufacturing to benefit devices used in minimally invasive procedures in many clinical areas. ANSAmed's technical core competencies are established in the following areas:

Braiding

- Moulding
- Printing

- Heat Forming
- Extrusion
- Porting, Skiving
- Welding (multi-durometer materials)
- Vertical lamination
   Assembly
- · Grinding tipping and shaping, bending, stretching, flaring

**Key Customers** Broad range of medical device multinational and leading OEM customers.

**Standards & Certifications** ISO 13485:2003, 21 CFR 820 FDA compliance.

**Additional Languages** German

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# ARROTEK MEDICAL LTD

**Business Description** Arrotek Medical is a highly skilled medical device engineering company offering a range of development and manufacturing services from initial product assessment through to the provision of sterile finished product.

Arrotek excels as an engineering resource for early stage companies or in product development for larger companies.

# **Products & Services**

- Contract medical device design and development service
- Prototyping of concepts for product evaluation
- Compiling and submitting for CE and FDA regulatory approval
- Precision manufacture and supply of sterile product

**Key Customers** Start-up companies, University spin-outs and Innovative medical professionals developing new medical products.

Standards & Certifications ISO 13485:2003

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# AVENUE MOULD SOLUTIONS LTD.

**Business Description** Avenue Mould Solutions specialises in the design, manufacture and validation of multicavity injection moulds.

**Products & Services** The company makes extensive use of Moldflow™ technology and robotised 24/7 machining capabilities, in addition to mould validation equipped to meet FDA and GHTF validation guidance requirements. This leads to:

- Greater control over lead times from start to finish
- Products that are fully compliant with FDA and other regulatory requirements
- On-time delivery
- Reduced time-to-market
- Effective and efficient production lines, leading to competitive pricing

**Key Customers** Abbott Laboratories, Bausch & Lomb, Becton Dickinson, Covidien, Glaxosmithkline, Honeywell/Allied Signal, Medisize, Millipore, Novo Nordisk, Owen Mumford, Pfizer, Smiths Medical, Tech Group Europe.

Standards & Certifications ISO 9001, ISO 13485.

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# BELLURGAN PRECISION ENGINEERING LTD

**Business Description** Experienced engineers and machinists at Bellurgan Medical help in the development and machining of precision components and assemblies for the medical device sector. Projects to date include pump delivery systems, drug delivery systems, hand held diagnostic devices, acute care ventilators/respirators, oxygen regulators and surgical implants.

**Products & Services** Bellurgan Medical has been machining precision components for over 30 years, with manufacturing carried out in 30,000 sq ft facility:

- 7-12 axis multi-spindle /sliding head lathes
- 3-5 axis high speed CNC machining
- Tolerances within 5 microns
- Pro E workstations, Gibbs CAM and Esprit CAD CAM offline programming software
- 30+ years manufacturing experience operating from a 30,000 sq ft facility

- Bellurgan offer a wide range of finishing services: ultrasonic cleaning, passivation, plating, heat treatment, anodising, electro polishing and hardening
- Process capabilities include broaching, thread whirling, burnishing, burr-free machining, mill turn and lapping

Taking advantage of the supply base, Bellurgan can offer a wide range of finishing services: plating, heat treatment, anodising, electro polishing and hardening.

Additional Process Capabilities:

- Broaching Thread whirling Burnishing
- Burr free machining
   Mill turn
   Lapping

**Key Customers** Leading life science companies in Europe and the US.

Standards & Certifications ISO 9001:2008

## **Contact Name / Title**

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# CAMBUS MEDICAL



**Business Description** Cambus Medical was established to develop and manufacture technologically advanced hypotubes and micro-component solutions for minimally invasive devices. The Cambus team has over 30 years combined experience in providing precision solutions to the medical device industry.

Products & Services A highly experienced team will provide turn-key manufacturing solutions for all hypotube and micro-component needs; from product development, to high volume manufacturing. Cambus Medical's range of highly innovative processes include; electro-chemical machining, passivation, PTFE coating, electro-discharge machining, laser cutting, laser marking, laser welding, over-moulding, bonding and product testing. Custom products are produced in a range of metals including stainless steel, Nitinol and other exotic alloys. Features include, but are not limited to, skives, laser cut spirals (and other geometric profiles), laser welded core-wires and complete sub-assemblies.

**Key Customers** From global OEMs and niche device manufactures, to professors and researchers at universities and hospitals. The company has contacts in over 40 companies in 20 countries around the world.

# Standards & Certifications ISO 13485:2003

# **Contact People for Overseas Markets:**

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- Name John Farragher (Commercial Director)
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# CAPPELLA MEDICAL DEVICES LTD.

**Business Description** Cappella has developed a novel solution to treat complex coronary artery disease, specifically bifurcation vascular disease. Cappella's initial product, the Sideguard® Coronary Sidebranch Stent, offers interventional cardiologists a straightforward, effective solution to treat the sidebranch of diseased coronary arteries first, rather than the main vessel.

Products & Services The Sideguard® Coronary Sidebranch Stent is an anatomically-shaped, self-expanding coronary stent that utilises a unique split-sheath delivery system. Both the stent and this delivery system were developed by Cappella Medical Devices Ltd. The novel, low-profile delivery system of Sideguard® enables straightforward, rapid-exchange delivery and precise stent placement at the sidebranch ostium. The proprietary split-sheath technology prevents the Nitinol stent jumping at delivery and ensures accurate deployment. The self-expanding Nitinol design conforms to the anatomy of the sidebranch ostium while the mechanical properties of Nitinol sustain continuous wall apposition and scaffolding.

**Key Customers** Interventional Cardiologists

**Standards & Certifications** CE 0123, ISO 13485:2003, EC Certificate Full Quality Assurance System, EC Design Examination Certificate

## **Contact Name / Title**

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Vice President of Finance and Administration

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# CARAGH PRECISION



**Business Description** Caragh Precision is a provider of precision engineered metal and plastic products to medical device industry, specialising in products and assemblies for orthopaedics, cardiovascular, oncology and minimally invasive devices.

# **Products & Services**

- Innovation centre: provides design and project management support to the medical device sector from concept, through prototyping to production
- Extensive medical device experience: collaborates on the development of cardiovascular devices and orthopaedic instruments with OEM manufacturers and institutions
- Capability to deliver complete products including sterile barrier packaging and sterilisation
- Full supply chain support
- Process design & development

Extensive knowledge, equipment and skills in the areas of:

- Contract manufacture and assembly, contract measurement and certification
- Multi-axis CNC machining, CNC turning & wire EDM
- Laser marking, laser welding
- · Cleaning, passivation and finishing

**Key Customers** Leading multinational OEMs.

Standards & Certifications ISO 9001:2008, ISO 13485:2009, Japanese Ministry of Health.

# **Contact Name / Title**

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## CLADA MEDICAL DEVICES

**Business Description** Clada Medical Devices provides design, research and development, testing, and full manufacturing services in the production of medical devices and components. Included in its capabilities are the following: catheter balloon design and catheter manufacture; needle design and specialist suture systems.

**Products & Services** Clada has the in-house expertise, equipment and design software to provide solutions to the most challenging of medical device problems and components. The company's capabilities in these areas are as follows:

Advanced Balloon Capabilities: specialised in-house capabilities for the design and manufacture of complex balloon designs to meet the most challenging of requirements. This is achieved through in-house balloon mould manufacture using state-of-the-art design and machining software and 4-axis CNC machining capabilities.

Catheter Design and Manufacture capabilities: in-house capabilities to take a custom balloon/catheter design from initial concept to final manufacture and launch. Clada carries out PTA, PTCA catheter design and manufacture, including catheter sub-assembly manufacture, full assembly, packaging and testing.

Standards & Certifications ISO 13485

**Additional Languages** Irish

## **Contact Name / Title**

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# CONSORT CASE CO (IRELAND) LTD

**Business Description** Consort Case is one of Ireland's and the UK's leading manufacturers of customised cases and vacuum-formed products, with over thirty years experience in the industry. The company's strength is in its diversity and ability to find solutions to almost every thermoplastic and casing need.

**Products & Services** With over 15,000 square feet of floor space and six operating machines any job, big or small, can be accommodated. Consort has developed trusted relationships with some of Europe's largest medical and electronics companies. Consort designs, develops and manufactures a wide range of carrying cases and thermoformed plastic products for the medical, electrical, point-of-sale, aerospace, contract packaging and many other market sectors. Consort also has the ability to modify and customise the insides of a range of waterproof flight cases and polypropylene cases that are stocked on site. The company produces vacuum formed parts ranging from light gauge blister packs and clamshells, to heavy gauge transport and procedure trays, and machine parts and covers.

#### **Contact Name / Title**

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## **CONTECH IRELAND**

**Business Description** Founded in 1993, Contech Medical International Ltd. Ireland continues to provide OEM Medical Device companies with optimum outsourcing solutions.

#### **Products & Services**

Through key supply chain alliances Contech Ireland has the ability to service many sectors of this industry throughout the world, such as: cardiovascular & peripheral device companies, vascular access/implantable port manufacturers, disposable products for orthopaedics, urology, gastroenterology and ENT. A 35,800 sq ft facility is equipped with both Class 7 and 8 clean rooms.

- · Catheter & guide wire packaging
- Device assembly
- · Stent & balloon protection
- Flexible packaging (loading and sealing pouches, FFS)
- · Rigid packaging (loading & sealing trays)
- Injection mould design and manufacture expertise (solid works)
- Engineering support (project management, DFM, problem solving)
- Process development & optimisation
- Custom flaring
- UV/CA adhesive bonding expertise
- Heat welding
- RF welding
- Supply chain management, SMI, ship to line, supply data

**Key Customers** Customer base varies from major medical device multi-national companies to many small to medium-sized companies throughout the world.

Standards & Certifications FDA registered and ISO 13485:2003.

Additional Languages German, French.

#### **Contact Name / Title**

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## CREGANNA-TACTX MEDICAL



**Business Description** Creganna-Tactx Medical provides a complete range of solutions to assist medical device and lifescience companies take products from concept to production. The company specialises in design and manufacturing of delivery devices for minimally and less invasive therapies.

## **Products & Services**

Creganna-Tactx Medical creates innovative medical technologies for advanced catheter and specialty needle applications. A contract design and development service is provided for out-sourced product development. Components and sub-assemblies from prototype quantities to full scale manufacturing are provided including metal hypotube shafts, medical balloons, extruded tubing, braided tubing and micro-molded components.

**Key Customers** Creganna-Tactx Medical supplies a range of customers worldwide. Customers vary from the world's leading medical device and lifescience companies to emerging, start-up medical technology companies. Creganna-Tactx Medical serve 7 of the world's top 10 medical device organisations.

**Standards & Certifications** FDA Registered Contract Manufacturer, ISO 13485, Japan MHLW, accredited foreign manufacturer (Article 13-3 PAL).

**Note** Manufacturing facilities are located in Ireland and MA, USA.

## **Contact details for other Markets:**

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## CROOM PRECISION MEDICAL LTD.

**Business Description** Croom Precision Medical was established in 1995 for the purpose of providing a high-precision subcontract machining service to the medical device industry. The company specialises in the provision of services to the orthopaedic implant sector.

**Products & Services** Croom Precision Medical manufactures a range of orthopaedic implants and surgical instruments for the world's leading orthopaedic companies. Croom's products include:

- Hip and shoulder joints
- Knee implants
- Ankle implants and special one-off custom implants.
- A rapid prototyping and design service is also offered to customers

The company's manufacturing technology includes the following:

• Swiss Auto Turning, 3-,4-, and 5-axis milling, CNC grinding, CNC turning, electro discharge machining, WDM, laser technology, bead blasting, super finishing, robotic finishing, CMM, hardness testing, surface finish testing, ultrasonic cleaning. Materials worked on include titanium, cobalt chrome, stainless steels and plastics

Standards & Certifications ISO 9002, ISO 14001, ISO 13485.

**Additional Languages French** 

## **Contact Name / Title**

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## CUSTOM EQUIPMENT SOLUTIONS LTD



**Business Description** Custom Equipment Solutions Ltd. designs and fabricates customised manufacturing and testing equipment, primarily targeted at the medical device assembly sector. CES Ltd. will work with the customer to brainstorm ideas and assist in the initial concept phase of a given project.

**Products & Services** With over 13 years of experience in medical device design and assembly and with inhouse expertise in the area of polymer technology and machine design, CES Ltd. is ideally suited to understand the needs of R&D and manufacturing engineers, and can provide a unique service to R&D, pilot manufacturing and mainstream manufacturing departments, within medical device companies.

Machines built to date include, balloon neck welding, tube flaring and tip forming, tube necking, catheter coating & UV curing, balloon heat-setting, Rx port welding, stent fatigue testing, a markerband swager auto-feed unit, FEP heat-shrink removal fixture, multiple trimming fixtures and a number of bespoke process machines.

CES Ltd. provides innovative process solutions which improve process control and repeatability, reduces operator skill set requirements and head-count and reduces time to market for new product introduction.

Key customers Abbott Vascular (Galway & US), Accellent (Galway), BioInteractions (UK), Cook Medical (Limerick), Creganna–Tactx (Galway), Marvao Medical (Galway), Medtronic Vascular (Galway), National University of Ireland (Galway), Novate Medical (Galway), Proxy Biomedical (Galway), Stryker Instruments (US), Theta Chemicals (Mayo), USCI Ireland (Galway), Veryan Medical (Galway), Vistamed Ltd. (Leitrim), Vysera Biomedical (Galway).

Standards & Certifications All equipment built to meet EU regulations and CE marked.

Additional Languages English, Spanish.

#### **Contact Name / Title**

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## DAWNLOUGH LTD

**Business Description** Dawnlough Ltd. is a precision engineering company, designing, developing and manufacturing jigs and fixtures for leading medical device companies in Ireland and abroad. The company also manufactures high volume precision machined components for the medical, electronics and related industries.

## **Products & Services**

- Dawnlough offers a design and development service, from concept through first off to full production run, for client companies
- Jigs and fixtures are manufactured and assembled from either client companies design or in-house design and development
- The company is actively engaged in the development of overseas markets for its goods and services, mainly in the United States
- Dawnlough is highly customer focussed

**Key Customers** Medical device companies, electronics, food manufacturers.

Standards & Certifications ISO 9001:2000, ISO 9001:2008 (pending).

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# DESIGNWISE AUTOMATION LTD



**Business Description** Designwise Automation designs, develops, and manufactures automation and process equipment for the automotive, healthcare, medical devices, and life sciences sectors. In partnership with FT Automation GmbH and Co. KG, Designwise delivers turn-key automation projects, material handling and inspection systems. From the earlier stages of the product development cycle through to high volume manufacture the company has the expertise to help.

**Products & Services** Designwise Automation designs, develops, and manufactures automation and process equipment for the automation, healthcare, medical devices, and life sciences sectors.

- · Mechanical design and consultancy services
- Jigs, fixtures and precision tools
- Process development and pilot production
- Special purpose machines
- · Material handling and component feeding technologies
- Turn-key automation systems

**Key Customers** Analog Devices, Boston Scientific, Bausch & Lomb, Cook Medical, Proctor & Gamble, Tyco, Johnson & Johnson.

Standards & Certifications ISO 9001:2001

**Additional Languages** German

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## DUNRETDY ENGINEERING ITD

Business Description Dunreidy Engineering Ltd. provides mechanical and electrical turn-key products to the pharmaceutical/food industry. The company is a manufacturer of a patented conduit system called HYCON.

## **Products & Services**

- Mechanical, electrical and instrumentation installations
- Fabricated steel items
- HYCON (hygienic stainless steel cable containment system)

Key Customers Wyeth, Pfizer, Novartis, Eli Lilly, Merck, Glanbia, Medimmune, Henkel Loctite.

Standards & Certifications UL - EN - BS.

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www.hycon-irl.com

## EUROPHARMA CONCEPTS LTD



**Business Description** Europharma Concepts is a contract formulator and manufacturer of pastes, creams, gels and liquids for the cosmetic and medical device industries. The company specialises in the oral hygiene sector and currently formulates and manufactures a number of well-know toothpaste brands.

**Products & Services** Europharma Concepts will formulate, trial and develop pastes, creams, gels and liquid for the cosmetic and medical device industries. The company carries out R&D, stability and toxicological studies for new and existing products. Europharma Concepts has the capability to develop products from first principles, including laboratory batches, stability, toxicological studies, pilot batches and validation batches etc. Europharma Concepts offers customers flexibility in terms of production runs – from large runs, one-off runs to small runs and batch manufacturing sizes. Europharma Concepts can also provide overseas companies access to the European market within the cream, paste, gel and liquid cosmetic and medical device arena. R&D and manufacturing are carried out in a class 100,000 ppm clean room environment at the plant.

Standards & Certifications ISO 9001 and ISO 13485 Medical Device including design control.

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## FINESSE MEDICAL LTD

**Business Description** Finesse Medical specialises in the development, manufacture and marketing of a range of advanced technologies used in the management of a variety of wound and skin conditions. Finesse provides outsourcing solutions in the area of contract manufacturing, including tube and bottle filling, RF welding, die cutting, lamination, packaging and sterilisation.

#### **Products & Services**

- Wound Care Products, including polyurethane foam/film, silicones, amorphous hydrogels, barrier film, hydrocolloids, alginates and anti-microbial products
- Skin Care Products, including barrier creams, moisturisers, incontinence care and enzyme-enhanced products
- Sub-Contract Manufacturing, in the areas of tube and bottle filling, dressing conversion, RF welding, lamination and packaging

Standards & Certifications ISO 13485:2003, MDD 93/42/EEEC, FDA registered.

#### **Contact Name / Title**

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Marketing and Business Development Directorr

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## GALWAY TOOL AND MOULD LTD



**Business Description** GTandM Ltd. specialises in the design and manufacture of injection mould tools and micro moulds, multi-cavity hot and cold runner moulds. Established in 1990, the company has a long history of cooperating with multinational companies involved in the design, development and production of precision plastic components.

**Products & Services** Full design service for plastic components, full design and manufacturing service for injection mould tooling and micro mould tooling. Individual components, or full projects can be developed by the design team right through, from initial concept to validated, production ready tooling with a proven process. GTandM also offers a micro manufacturing service, in both wire and sink EDM and also high-speed milling. Tolerances of  $\pm$  0.001mm can be achieved in its controlled manufacturing environment. The company offers wire EDM down to 30 micron wire diameter and HSM using cutting tools as small as 0.06mm diameter.

Key Customers Covidien, Creganna Medical Devices, Boston Scientific Irl Ltd., Alps Electric Ireland.

Standards & Certifications ISO 9001:2000

**Additional Languages** Irish

## **Contact Name / Title**

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Website www.galwaytoolandmould.com

## GENTIAN SERVICES ITD

**Business Description** Gentian provides an outsourced develop source and supply service to companies in the medical and industrial sectors. Gentian's core areas of expertise are:

- Design and supply of monitoring and control equipment
- Supply chain development and full turnkey supply for customised clinical consumable products and kits

**Products & Services** Full turnkey design and supply of monitoring and control instrumentation for the medical and industrial sectors. This includes:

- Electronic and mechanical design and development
- Prototype and demonstration unit build
- Design for manufacturing
- Low volume manufacture
- Transition to full manufacturing and full turnkey follow on supply

Customised clinical consumables manufacturing and supply chain solutions, these include

- New product supply base development and ramp up
- · Customised products requiring a combination of metal and plastic parts
- · Supply and manufacturing solutions for customised kits requiring packing and sterilisation

**Key Customers** Gentians customers are medical product and device OEMs in Ireland and the UK with a requirement for customised clinical consumable supply solutions as well as product design and supply solutions for complimentary monitoring and control instrumentation.

**Standards & Certifications** All design develop and supply work is carried in accordance with ISO 9001 and ISO 13485 standards. Products developed and supplied by Gentian have been certified to various appropriate standards including CE, UL and FDA.

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## HKPB SCIENTIFIC LTD



**Business Description** HKPB is an innovative company with the capacity to manufacture and supply custom biomaterials for orthopaedic medicine, particularly calcium phosphates for use in bone cement formulations and orthopaedic coatings. The company also supplies surface coating drug delivery solutions for implantable medical devices.

## **Products & Services**

- Hydroxyapatite and other calcium phosphate salts supplied in customer specified quantities and with a specified range of properties
- Rapid turn around provided by a novel patented process for their manufacture
- · Custom ceramic biomaterials supply on request
- A surface modification solution that facilitates the delivery of a broad spectrum of therapeutic agents within a range of carrier matrices from custom coated medical devices

HKPB has strong links with Irish universities and a team of 6 PhD's in-house encompassing engineering and the physical and biological sciences to provide research and development consultancy to customers.

Standards & Certifications The company is in the process of securing ISO 13485 certification.

Additional Languages Russian, German, French.

# **Contact Name / Title**

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## INBLEX PLASTICS LTD

**Business Description** iNBLEX PLASTICS specialises in the manufacture of injection moulded and blow moulded packaging solutions for the medical devices, pharmaceuticals, diagnostics, veterinary, chemicals, and nutrition sectors in Ireland, the U.K. and Europe.

#### **Products & Services**

- Mainly bespoke products with a small range of stock items
- Injection moulded closures, vials, caps, nozzles etc.
- Extrusion blow moulding and injection blowmoulding of bottles, containers, jars, tubs, flexible liners, floats and hollow components in sizes ranging from 10ml to 10 litres
- Cleanroom and non-cleanroom manufacturing
- Materials processed include in HDPE, LDPE, ULDPE and PP
- A full product design through to full production service is offered
- Highly flexible with a very customer focussed approach

**Key customers** Wide portfolio of customers ranging from SMEs to large multinationals.

#### **Contact Name / Title**

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## TRISH MICRO MOULDINGS LTD



**Business Description** Irish Micro Mouldings Ltd. is a developer and producer of product and services mainly for the medical health care, pharma and lifesciences industries. IMM is also a finisher of moulded parts including assembly, welding, decorating, printing, painting, EMI/RFI shielding.

### **Products & Services**

- Product design design for manufacture
- Product design design for manufacture, mould and tool design
- Injection moulding
- Service micro-moulding
- Tool building
- Project management, assembly, finishing, printing, painting, welding, logistics, ship-to-stock, just-in-time
- The company also provides medical devices product development services
- Specialist ability to develop devices like stent catheters and other medical deployment catheters

Standards & Certifications ISO 9001:2000

**Additional Languages** Irish

## **Contact Name / Title**

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# M&M QUALTECH LTD

**Business Description** M&M Qualtech Ltd. is a solutions provider to the electronics, telecommunications and medical device manufacturing industry sectors. The company's focus on low to medium volume business guarantees dedicated customer service and customised supply chain architecture.

Products & Services As a sub-contract manufacturer, Qualtech offers a one-stop shop, flexible and cost effective suite of services covering the following areas:

- Full service, product life cycle manufacturing partner
- Design services, prototype development, manufacturing, sourcing/procurement, materials management, logistics/order fulfillment, end-of-life management and repair
- Print-on-demand facility for documentation and manuals
- Products include: cable and harness, printed circuit board assemblies, box build
- Medical device assembly including respirators, ventilators, nebulisers, muscle stimulants

Key Customers Aerogen, eVent, Respironics, Blue Tree Systems, Nortel, Thermo King, Tyco, APC, Crospon, Kosran.

Standards & Certifications EN 9001:2000, EN 13485:2003, TUV, CSA, UL.

Additional Languages Irish, French, Polish, Hungarian, Latvian, Czech, Bangladeshi, Urdu.

## **Contact Name / Title**

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## M&V MEDICAL DEVICES LTD



**Business Description** M&V Medical is an indigenous Irish manufacturing company which was established in 1980. The company offers a range of services including CNC turning, polishing and lustering and ultrasonic cleaning. M&V operates in the areas of cardiovascular, orthopedic, all Airway products and tool room supplies for the medical device industry.

**Products & Services** The company specialises in the manufacture of prototypes, special tooling, jigs and fixtures. Its CNC multi-axis turning machines have cross-drilling and milling capabilities, allowing the manufacture of precision engineered parts. The company has experience of working with all commonly used metals and plastics and is capable of producing complex, high precision turned parts and devices for the medical sector, operating from small batch runs to full turn-key production. Other services include polishing, lustring, de-burring and ultrasonic cleaning. From the outset, M&V discusses client needs and tailors design services to suit. Ship-to-stock arrangements with all major clients have been established, affording them more than 80% stock reductions with deliveries on request in less than 24 hours.

Standards & Certifications ISO 9001:2008 and working towards ISO 13485.

Additional Languages French.

## **Contact Name / Title**

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## PRECISION WIRE COMPONENTS

**Business Description** Precision Wire Components manufactures wire components for the medical device industry, and provide a complete service from packaging or moulding mandrels to finished guidewires. Utilising custom built machines and using proprietary processes, Precision Wire fulfils all the requirements for the end-user.

**Products & Services** With highly skilled operators, Precision Wire Components has the ability to take on high volume as well as prototyping jobs. Working with the company's R&D department, the client can take a concept from prototype to finished product. Precision Wire's short run centre guarantees a 7–10 day lead time, invaluable for design engineers. The company also offers:

- wire straightening
- grinding
- quidewire component manufacture and assembly
- Nitinol forming and straightening, with PTFE, Parylene, silicone and hydrophilic coatings

#### Standards & Certifications ISO 13485

Additional Languages Spanish, German, French.

## **Contact Name / Title**

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## PRESSCO ITD



**Business Description** Pressco Ltd. supplies precision components and fully certified electro-mechanical assemblies to the medical device industry. The life sciences division machines LSG polymers in a dedicated white room facility. Assembly takes place in an ESD protected assembly plant and all piece parts are fully traceable.

## **Products & Services**

- CNC-milling (5-axis 3D)
- CNC-turning
- Swiss turning (13-axis)
- Surface finishing and heat treatment
- High level fully certified electro-mechanical assemblies
- White-room LSG plastics machining
- Supply chain management
- Design and development

**Key Customers** Multinationals in the life sciences and high-tech sectors.

**Standards & Certifications** I.S. EN ISO 9001:2008, I.S. EN ISO 13485:2003.

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## PROTEK MEDICAL LTD

**Business Description** ProTek Medical is a full service outsourcing partner to the global medical device industry. With world class operations in the USA, Europe and Asia, the customer benefits from decades of design and manufacturing expertise. Advanced product innovations are possible, leveraging off a comprehensive portfolio of injection moulding and manufacturing technologies.

#### **Products & Services**

- Research (materials research, injection moulding technologies)
- Design (clinical investigation, user studies, exploration, design and development, design for manufacturing and assembly, on-line prototyping database development, design verification and validation, rapid tooling, production tooling)
- Cleanroom moulding (thermoplastic, micro, multi shot, LSR, over and insert moulding, metal, ceramic, magnesium, bio absorbable)
- Cleanroom manufacturing (automated assembly, drug repackaging, metal forming, fine wire welding, pilot production, testing)

Key Customers Boston Scientific, Covidien, Stryker Howmedica, Smith Medical, Micrel Medical Devices.

Standards & Certifications ISO 13485, FDA ~ 21 CFR Part 820 and CFR (Parts 210 and 211).

Additional Languages German, French and Dutch.

#### **Contact Person for Overseas Markets:**

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#### **Contact Name / Title**

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## REALTIME TECHNOLOGIES LTD



**Business Description** The company consists of two distinct divisions: (1) Realtime Technologies offers ISO certified sub-contract manufacturing and design services to the non-invasive medical electronics device sector, while (2) SHIMMER Research designs, manufactures, markets, sells and distributes SHIMMER™, a hardware research platform designed explicitly for wearable health sensing.

Products & Services Realtime has a wealth of engineering knowledge accumulated from many years of industry experience which ensures products are introduced in a swift and structured fashion. Realtime is rated as an A supplier by several customers based on quality, delivery and service. The company provides prototyping and automated printed circuit board assembly, AOI, ICT and functional testing, burn-in and environmental stress screening, configure to order, unit assembly, supply chain management, design and development, DFM. The SHIMMER™ platform enables researchers to reduce the time spent on developing foundational technologies for health sensing – its TinyOS based open platform coupled with low power consumption, dual radio and MicroSD storage facilitate wearable wireless sensing in both connected and disconnected modes.

**Key Customers** The company's portfolio is drawn from the life sciences and high-tech sectors including multinational OEMs, institutional and academic customers, and Realtime currently ships to over 20 countries.

Standards & Certifications ISO EN 9001:2000, ISO EN 13485:2003, UL listed.

**Note** The company has also received the 'excellence through people' award.

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www.shimmer-research.com

## SHANNON MICROCOIL LTD

**Business Description** Shannon Microcoil Ltd. provides guidewires, endoscope coil pipes and assemblies, and complex wireforming for the medical device industry.

## **Products & Services**

- Fast response, prototyping and small batch service as well as full production runs
- Full product development and certification support
- · Custom coiling and guidewire manufacture
- Endoscope assemblies and coil pipes
- High precision wire forming with accuracies to 2.5 micron
- Materials include SS, PtW, PtIr, Pd, PTFE coated
- Wire sizes to 25 micron

## Standards & Certifications ISO 13485

## **Additional Languages** Spanish

## **Contact People for Overseas Markets:**

**Eamonn Barrett** 

## **Contact Name / Title**

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## SMITHSTOWN LIGHT ENGINEERING LTD



**Business Description** Smithstown Light Engineering is a precision engineering company offering services in design, manufacturing and inspection capabilities. Quality is the cornerstone of everything the company does, the focus is primarily on the medical industry, specifically orthopaedics and the medical devices sector, including manufacture of paediatric filter and check valve moulds.

Products & Services A company policy of investment in new technology every year means that the most modern and technologically advanced services are always available. This, combined with top-class staff and continuous re-training, ensures that a design and manufacturing solution to suit client needs will be found. A full range of manufacturing services are available, including all manner of CNC-milling, including 5-axis, CNC-turning including mill/turn, CNC-grinding, OD/ID-grinding, wire-EDM, spark-EDM, CMM-inspection, laser-welding, and high-speed milling. Full design capability using Unigraphics is available, enabling compatibility with all design systems and formats. The company also has a dedicated inspection department utilising two Zeiss CMM's and a Smartscope, along with various types of inspection equipment.

Standards & Certifications ISO 9001:2000 and ISO 13485:2003.

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## TAKUMI PRECISION ENGINEERING LTD

**Business Description** Takumi Precision Engineering is a sub contract precision engineering company which manufactures medical implants, surgical instruments, production aids and a variety of specialised tooling. The company has grown its business through delivering unrivaled customer service and by constantly exceeding customer expectation.

**Products & Services** From initial concept through prototyping and into production, Takumi is a proactive partner, facilitating faster time-to-market. The company has an innovative and committed team of engineers and all of its operatives are skilled programmers. The ever changing world of sub contract manufacture has honed skills in new product introduction and implementation of new processes.

- Takumi is skilled in machining and finishing orthopaedic instruments and implants, and has a dedicated air conditioned area for the dry machining of polyethylene bearing inserts and other plastic components
- Takumi provides assembly aids and specialised tooling for the cardiovascular industry. These include balloon forming moulds and related tooling, complex wire shaping mandrels and micro-wire forming devices
- Takumi collaborates with customers to produce innovative solutions to engineering problems
- Takumi's ability to develop and maintain stable manufacturing processes is the company's greatest strength

**Key Customers** Abbott, Boston Scientific, Clearstream, Creganna, Cook, Cordis, Vistakon, Depew, Endosence, Stryker, Symmetry, Lake Region, Medtronic, Merit Medical, Tornier.

**Standards & Certifications** ISO 9001:2000, ISO 14001, ISO 13485.

Additional Languages Polish, German, Japanese.

#### **Contact Name / Title**

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## TECHNICAL ENGINEERING & TOOLING SERVICES LTD.



**Business Description** Technical Engineering specialises in providing engineering services to the pharmaceutical, aviation and medical device industries. These services include design, precision engineering, mould tooling and automation and machine building. A particular strength of the company is its ability to respond rapidly to customer requests.

#### **Products & Services**

- Automatic robotic necking machine, for use in the manufacture of balloon catheters
- · Revolutionary hub for multi-lumen catheter
- Washer/dryer for brushes, used in the pharmaceutical industry
- The company has highly skilled designers, toolmakers and mould toolmakers using high specifications hardware and software capable of bringing products from design to final assembly
- Fast delivery service as a result of operating 24 hours per day with three shifts

**Key Customers** Wyeth, Glaxo SmithKline, Akzo Nobel (Organon), Medtronic, Abbott, Tyco, Eli Lilly, Hewlett Packard, Servier, Boston Scientific.

**Standards** ISO 9001:2008, AS 91000 REV B (aerospace certification), EASA Part 21(G) Approved Production Organisation (Aviation Certification).

Additional Languages German, Polish, French. Sales Offices in Germany, France and Switzerland.

# **Contact People for Overseas Markets:**

Germany - Bastian Theisen, btheisen@techengtool.com UK - Ray Kirby, rkirby@techengtool.com France - Karen Ryan-Guyot, krguyot@techengtool.com

**Note** The company is actively seeking partners for each of the projects mentioned, all give a very consistent and uniform product.

## **Contact Name / Title**

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## TEGAN INNOVATIONS ITD

**Business Description** Tegan Innovations Ltd. specialises in the design and build of special purpose equipment, predominantly for the medical device industry. All research, development and manufacturing are carried out in in-house.

## **Products & Services**

- Typical projects include: assembly machines for the medical industry, specialised fixturing, packaging systems and component feeding and handling systems
- Tegan has developed the following expertise: 3D design, PLC and PC controls, vision systems, Scada, GAMP and CE marking of own equipment
- Tegan has the following capabilities: 3D solid modelling (4 sets of SolidWorks), rapid prototyping (3D printing), two seats of CAM, two 4-axis CNC-milling machines, CNC-lathe, wire machine and AutoCAD electrical

**Standards & Certifications** All equipment is built to meet CE regulations. For the medical and applicable industries the company works to good automated manufacturing practice (GAMP) and standards.

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**Business Description** Trend Technologies is a manufacturer of complex injection moulded components and assemblies and offers design, development, engineering and manufacturing services to the medical device, diagnostics and pharmaceutical industries.

## **Products & Services**

- Products manufactured include finished devices, surgical device components, printed syringes, wound care products, respiratory components and pharmaceutical packaging products
- Injection moulding technologies: including multi-component moulding, insert moulding, overmoulding, and IML/IMD
- Downstream services including pad printing, painting, ultrasonic welding, manual and automated assembly, are also available
- All aspects of the project are managed: including design, tooling, finishing, assembly, testing, packaging, vendor management and logistics
- Manufacturing activities are carried out within Trend's large class 10,000 (Class 8) cleanroom facility

**Key Customers** Covidien, KCI Medical, Schering-Plough, Gyrus Medical, Waters Technologies, and Johnson & Johnson.

Standards & Certifications ISO 9001, ISO 13485, ISO 14001.

#### **Contact Name / Title**

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## **TRUSTWATER**

**Business Description** Trustwater is a leading manufacturer of "green-chemistry" hygiene systems. Trustwater's on-site generating technology replaces traditional chemicals in a wide variety of cleaning and disinfection applications. Applications include biofilm control, water disinfection, environmental decontamination, aseptic manufacturing, food and beverage process hygiene, healthcare infection control, and more.

**Products & Services** Trustwater's on-site generator range produces two solutions simultaneously. One solution is a powerful detergent known as Aversol™. The second solution is a very effective disinfectant and branded Ecasol™. Trustwater systems have been successfully installed worldwide in applications such as:

- Clean-in-Place in food and beverage processing
- Food industry and industrial process water treatment and biofilm removal
- Legionella prevention in water systems and cooling towers
- Dental waterline disinfection
- Environmental decontamination

Trustwater solutions are more effective than advanced oxidant techniques such as chlorine dioxide and ozone, and far more effective than conventional biocidal chemicals. Yet, Trustwater is completely harmless to the environment and offers significant efficacy, health and safety and environmental advantages over conventional disinfection methods.

**Key Customers** Health Service Executive, Mercy Hospital Group, Dublin Dental Hospital, Queally Group, local authorities, Coca Cola, Abbott, Roche, NHS UK, Shell Chemicals, Planmeca, Bibby Line.

Standards & Certifications All Trustwater systems are CE listed, UL and TÜV certified.

## **Contact for Overseas Market**

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# **Contact Name / Title**

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## VISTAMED ITD



**Business Description** VistaMed has positioned itself as a leading provider of complex extrusions and finished medical devices. The company provides novel catheter solutions to its customers, enabling them to deliver leading edge technologies to the marketplace. Products include steerable guiding catheters, micro perfusion pain management catheters, and balloon catheters.

**Products & Services** VistaMed offers a comprehensive package in medical device innovation, from design concept to device assembly and packaging. As all key processes are carried out in-house fast project turnarounds can be achieved. Internal capabilities include:

- · A comprehensive range of extrusions
- · Moulding and insert moulding
- Tip forming and welding
- · Laser machining of catheter tubing
- Balloon blowing, Nylon and thermoplastic polyurethane (PUR) balloons
- Complete assembly and packaging
- Assistance with technical files for CE or 510K submissions

Standards & Certifications ISO 13485:2003

**Additional Languages** German

Note: VistaMed are pleased to announce that they have recently entered into a joint venture with Helix Medical.

## **Contact Name / Title**

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## WAYGLENITD

**Business Description** Wayglen is a design and manufacturing company that provides product development services to bring concepts to market. The company specialises in idea development, project management, CAD design and production. Wayglen's design and manufacturing expertise as a dedicated single-source solution provider can quickly bring customer's ideas to life.

**Products & Services** Full design, re-engineering, tooling, rapid prototyping and high-volume moulding of plastic products in the following areas:

- Medical devices, catheter components, pharmaceutical, veterinary, agua culture
- Automotive, electronic, consumer goods, architectural

Standards & Certifications ISO 13485; Class 100,000 cleanroom.

**Additional Languages** Irish

## **Contact Name / Title**

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## WISS MEDITED



**Business Description** Wiss Medi Teo. is a contract manufacturer for interventional medical devices within a cleanroom environment. The company has a proven new product introduction (NPI) track record, and provides a very competitive cost base by combining its interconnect and medical device business activities within a single facility.

**Products & Services** Manufacturer of catheter devices, plastic injection moulding, overmolding cannula, device assembly and device packaging – Form, Fill and Seal. Extensive final product testing.

Key Customers Customer base are USA healthcare companies, details available upon request.

**Standards & Certifications** ISO 13485:2003, ISO 9001:2000.

**Additional Languages** Irish

## **Contact Name / Title**

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# PHARMA AND MEDICAL DEVICE SERVICES



## ATP THERMOFORM PACKAGING ITD

**Business Description** AiP Thermoforming Packaging has over 10 years experience in the Irish medical device market, and is focussed on the design and manufacture of "technical packaging solutions" using the principal technology of thermoforming. AiP provides a quality product on time at a competitive price.

**Products & Services** Core activity is the manufacture of thermoform packaging. Typical examples of products supplied are rigid form procedural trays and rigid form tubing for device protective packaging. Additional services include acting as the Irish sales agent for Atlas Vac USA sealing machines, and exclusive Irish licensee holder for UK patented Vituweld clamshell design.

Key Customers Medical, electronic and retail sectors. A list of customers is available on request.

Standards & Certifications ISO 9001:2000

## **Contact Name / Title**

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## AIRMID HEALTH GROUP LTD

Business Description Airmid Health Group is a multi-disciplinary team of medical specialists, occupational health and hygiene professionals and scientists whose mission is to prevent ill health caused by exposure to indoor air contaminants. AHG provides indoor air testing services and carries out scientific testing of consumer products that may impact on the quality of indoor air.

## **Products & Services**

- Indoor air quality testing
- Ventilation system hygiene assessments with biological sampling
- Air and surface sampling for mould, bacteria and allergens
- Chemical risk assessments and exposure monitoring for dusts, fumes, gases and vapours
- Noise and light assessments

 Environmental chamber testing facility - providing data for product claims where micro-organisms are concerned

health of building occupants

- Other laboratory services:
- Immunoassay testing
- Passive allergen transfer studies
- Modified dust trap

- Simulated use testing
- · Identification of fungi, viruses and bacteria
- Conventional PCR capability/real-time PCR capability

Advanced scientific testing on consumer products

indoor bioaerosol load of indoor spaces and so the

to ensure they reduce or do not impact on the

Standards The Airmid Health Laboratory is currently in the application process to achieve formal recognition from the Irish National Accreditation Board (INAB) of competence to perform tests to ISO/IEC 17025. Therefore, the Airmid Health Laboratory AHL has a framework of set policies and procedures that are implemented and detect nonconformities when they occur.

# **Additional Languages French**

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## ALLERGY STANDARDS GROUP



**Business Description** Allergy Standards is a physician-led, global certification company that prepares independent standards for testing consumer products to determine their suitability for asthmatics and individuals with associated allergies.

Products & Services A product that is certified asthma & allergy friendly™ has been scientifically tested to show that it is more suitable for those suffering from asthma and allergies, and qualifies to display the asthma & allergy friendly™ certification mark. This mark empowers consumers to make informed decisions. Testing protocols used for asthma & allergy friendly™ certification are independently validated by experts to ensure impartiality and confidence in the product certified. Products are tested against stringent international criteria to ensure that only best-in-class products are recommended to those suffering from asthma and allergies.

Key Customers The asthma & allergy friendly™ Certification Programme has a range of certified products with the world's leading companies, including Disney, LG, Dyson, Sara Lee, Hollander bedding & Forbo flooring. Certified products can be purchased in Wal-Mart, Target, JC Penneys, Target, Bed, Bath & Beyond & Lowes as examples.

Standards Allergy Standards Limited tests and certifies products in a range of sectors, including vacuum cleaners, washing machines, flooring, paint, plush toys, bedding, air cleaners & cleaning products.

Note The global asthma & allergy friendly<sup>™</sup> certification programme was launched in North America in 2005, in partnership with premier not-for-profit, patient-oriented asthma & allergy foundations, the Asthma & Allergy Foundation of America and the Asthma Society of Canada, and has recently expanded to the UK in partnership with Asthma UK.

## **Contact Name / Title**

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## ALPHA HEALTHCARE LTD

Business Description Alpha Healthcare Ltd. provides management and administrative support to GP's and other healthcare professionals. The company's expertise is in the development and delivery of primary care centres and in the provision of practice management services.

**Products & Services** Alpha Healthcare implements the "gold standard" in primary care centre management and is a provider of shared management services support to GP's and healthcare professionals.

- The company takes basic management principles, quality standards and suitable industrial techniques and applies them appropriately to a healthcare environment
- Offers a very personalised and confidential management service to medical centres working in collaboration with GP's, to address their administrative and management needs
- Offers a complete support service to GP's and healthcare professionals in all areas of primary care centre development, inlcuding an unrivalled set of project management, administrative and system skills focussed exclusively on GP practices and primary care centres

**Key Customers** GP's and groups developing primary care centres, other primary healthcare professionals, the Irish Health Service Executive.

Standards & Certifications ISO 9001:2000 accreditation.

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### AMRAY MEDICAL

**Business Description** AmRay Medical is one of Europe's leading manufacturers of x-ray and nuclear medicine radiation protective products and accessories. The company's commitment to quality and customer service has ensured the AmRay brand is now recognised world wide.

Products & Services Amray Medical offers a wide range of accessories and support equipment encompassing personal protection, shielding rooms for x-ray/mri (glass, walls and medical doors), mobile screens, together with a full range of associated products including lead and lead free aprons, protective eyewear and gloves. The range of nuclear medicine products includes metabolic treatments units, dose calibrator VDC 304, gamma barrier Ls-200, syringe shields, pet shielding, chromatograph VCS -103, wall meters, detector of feet and hands VLB-202, medical doors etc.

# **Key Customers**

X-Ray Department - EU and Middle East Cardiac Cath. Labs - EU and Middle East PET Department - EU and Middle East Nuclear Medicine - EU and Middle East

Standards & Certifications ISO 9001, CE Mark certification.

Additional Languages Italian, French, German, Spanish, Polish.

## **Contact Name / Title**

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### ANECTO ITD

Business Description Anecto is an accredited test laboratory and test development company, which provides testing services to product designers, developers and manufacturers in the life sciences sector. Anecto is strategically positioned to support companies requiring FDA and CE approvals for electronic products and sterile packaged devices.

Products & Services The scope of the test laboratory is growing and reponsive to customers needs. It is currently accredited for 40 different standards as defined by ASTM, CEN, EN, ISO, ISTA, MIL standards bodies. The laboratory is equipped to deliver temperature, humidity, thermal shock, vibration, tensile, compression, drop and mechanical shock, salt spray, water and dust ingress test stimuli.

- ISO 11607 testing for terminally sterilised medical devices
- Stability and cold chain testing
- · Transportation and package testing
- Design and manufacture of test systems
- Product and process validation
- Environmental testing
- HALT (highly accelerated life testing)

**Standards & Certifications** ISO 17025:2005 Scope registered. No 175T, ISO 9001:2000 (Certificate number 19.3304), ISTA (international safe transit association).

**Additional Languages Danish** 

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### ARDMAC

Business Description Ardmac is a long established leader in the construction of cleanroom and controlled environment solutions for the pharmaceutical, biotechnology, medical device, institutional, micromanufacturing and healthcare sectors.

**Products & Services** Having worked in the technology sector for over 30 years, ardmac offers turnkey and architectural performance envelope solutions for cleanrooms and other controlled environments. ardmac's expertise in the delivery of architectural solutions and in-house engineering capabilities offers unique ability to interpret clients' requirements thus providing them with the best technical and value engineered solution for their project.

ardmac's knowledge of client applications and experience in the co-ordination of complex processes and services provides a high quality environment. A strict adherence to DQ, IQ, OQ together with robust construction management procedures also ensures certainty of performance and a safe, compliant on time validated facility. ardmac's cleanroom product range includes modular partitioning in steel or HPL finish, glass wall systems, sliding and rapid roll doors and walk on ceilings to suit various applications, furniture and associated accessories for presentation of utilities.

Key Customers GSK Biologicals, Janssen, Centocor, Pfizer, Novartis, Allergan Pharmaceuticals, Abbott, Boston Scientific, Lilly, Baxter, Teva, Merck, Roche, Bristol Myers Squibb, Millipore, Wyeth, Nypro, Niche and many more.

Standards International accreditations: quality - ISO 9001:2008; environment - ISO 14001:2004; Safety - BS-OHSAS 18001:2007

Note In addition to serving clients across Ireland, UK and Belgium, ardmac operates throughout Europe and in international markets.

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### BCD ENGINEERING

Business Description BCD delivers high purity liquid processing systems worldwide to the pharmaceutical, biotechnology, food & beverage and chemical industries. The company specialises in delivering turnkey innovative process, mechanical & automation solutions which are delivered as modular skids and process vessels from BCD's workshops, or built at site by an experienced installation team.

#### **Products & Services**

- Chemical process reactors & bulk storage vessels manufactured in stainless steel and related alloys such as hastelloy
- Integrated modular process systems including clean-in-place, filtration, chromatography, heating/cooling transfer, designed, built and fully tested in company workshops
- Market leaders in the supply of biowaste effluent treatment systems for the highest level containment facilities working with Class III and Class IV pathogens
- · High purity process piping installations on site, including purified water, water for injection, medical gases
- Complete design capability from concept through to detailed engineering with development of process flow diagrams, equipment specifications, 3D models, piping layouts
- Comprehensive qualification documentation, including commissioning and validation

Key Customers Novartis, Pfizer, GSK, Allergan, Eli Lilly, Elan, Patheon, Reckitt Benckiser, Sanofi-Aventis, Merck, Intervet.

Standards & Certifications ISO 9001

# **Additional Languages Irish**

Note BCD is rapidly increasing market penetration internationally, with direct sales representation in Belgium, Egypt, Singapore and China. BCD is continually seeking new regions to supply into.

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# BIOSTÓR



Business Description Biostór Ireland Ltd. is the leading independent biorepository in Ireland for temperature-critical storage of biomaterials from accelerated temperatures to room temperature to refrigerated (-20°C, -80°C, -196°C). The repository provides fully controlled and monitored conditions and caters for a wide range of sample types.

#### **Products & Services**

- Biomaterial storage and distribution including; clinical trial samples, APIs, laboratory samples, product retains, manufacturing trials
- Storage of human tissues and cells (accredited tissue establishment) including; stem cells, bone marrow etc.
- Stability studies for pharmaceutical and medical devices industries
- Sample management, formatting, processing, archiving and backup services, GMP safe deposit boxes, freezer inventory consolidation, stock taking, cataloguing and barcode labelling

Key Customers Pharmaceutical companies, CROs, tissue establishments, hospitals, clinics, universities, research institutes.

Standards & Certifications Irish Medicines Board (IMB) accredited tissue establishment. The quality management system complies with directives 2004/23/EC, 2006/17/EC and 2006/86/EC, US regulations; 21 CFR Parts 11, 16, 210, 211, 820, 1270, 1271 and international standard ISO 13485:2003.

Additional Languages German, Italian.

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## BIOTECTOR ANALYTICAL SYSTEMS LIMITED

Business Description BioTector Analytical Systems Limited manufactures an innovative range of on-line liquid analysers for environmental monitoring, process control and waste minimisation across both the industrial and municipal markets. Guaranteed to handle the most demanding applications, BioTector analysers are specifically developed for continuous analysis in the harsh on-line environment.

Products & Services A unique self-cleaning oxidation technology enables BioTector analysers to easily handle difficult samples and significantly reduce the maintenance schedule and costs associated with traditional on-line measurement. BioTector analysers eliminate build up issues from salts, particulates, fats, oils and greases that lead to drift and high maintenance. With reliable, continuous environmental monitoring and real-time process control, BioTector analysers allow plants to optimise processes by decreasing chemical dosing, minimizing waste, reducing sample processes and lowering overall plant operating costs. For over 15 years BioTector products have proven to be the most advanced in their class, achieving precise results from the simplest to the most demanding applications.

Key Customers Pfizer, Novartis, DOW Chemicals, BASF, Shell Chemicals, Glaxo SmithKline Pharmaceutical, Exxon, Huntsman.

Standards & Certifications ISO 9001:2000, ETL Certification (Class 1 Division 2), TUV Certification (EExp Group II Category 3).

Additional Languages French, Turkish, Polish, Czech.

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## BRENTECH DATA SYSTEMS LTD



**Business Description** Brentech's supply chain management application, AWARDS-BA<sup>3</sup>, addresses the needs of the healthcare distribution sector where customer service, tight inventory management and accurate information is fundamental to business success. Customers range from single site operations to larger businesses dispatching over 130,000 fully traceable order lines every day.

### **Products & Services**

AWARDS-BA<sup>3</sup>: Brentech's flagship application is designed to maximise the efficiency and profitability of companies operating in the wholesale distribution markets.

The company also provides:

- Consultancy
- Implementation
- Training
- On-going support services

Key Customers Co-Operative Healthcare, Mawdsley-Brooks Ltd, United Drug Plc.

**Additional Languages French** 

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### **BSM TRFLAND ITD**

Business Description BSM helps the world's leading life sciences manufacturing companies in the pursuit of operational excellence. The company's focus on the application of the 'real lean' techniques of levelling and flow is unique in the sector.

Products & Services BSM implement Levelling and Flow throughout life sciences value streams. However, BSM has developed a particular focus on radically improving the performance of analytical laboratories. The terms 'train' and 'rhythm wheel' were introduced by BSM and are now widely used throughout North America and Europe, in particular. The rhythm wheel term is also widely used in pharmaceutical and food manufacturing. BSM's deep understanding of the life sciences environment also enables the provision of support to companies in the area of information systems strategy.

Key Customers BSM works with many of the world's best known life sciences manufacturing companies, e.g. Wyeth/Pfizer, Schering Plough/Merck, Baxter, Pfizer, Millipore, Stryker, Astellas, Syngenta, Abbott, Elan, Aptuit, Almac, Stiefel/GSK, Medtronic.

Additional Languages Irish, French, Spanish, German, Dutch, Italian.

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### CATALENT PHARMA SOLUTIONS

Business Description Catalent Ireland is part of Catalent Pharma Solutions, a large pharmaceutical contract manufacturer. Catalent's Dublin site is a specialist supplier of printed components to the pharmaceutical, healthcare, medical device, biotech and animal health sectors, as well as these markets in the UK, Germany, France and Belgium.

Products & Services With four print plants in the US and Puerto Rico the group also supports transatlantic projects and launches. Due to the network of Catalent Pharma Solutions sites throughout Europe the company can offer many local contacts through its global sales team. In addition to traditional print products, the company offers a suite of compliance packaging as well as solutions for track and trace requirements. The Dublin plant is undergoing significant investment and expansion in order to support current and new customers with the benefit of the latest technologies. Products include:

- Printed solid board cartons
- E flute and F flute laminated cartons
- Blister cards
- · Shelf ready trays
- Leaflets
- · Carton, label and leaflet fulfilment
- Compliance packaging
- Anti-counterfeit
- Track and trace

**Key Customers** Prescription pharmaceuticals, OTC pharmaceuticals, medical device companies, other sectors include healthcare, cosmetic, biotech and IT.

**Standards & Certifications** ISO 9001:2000, accredited to the pharmaceutical code of practice. ISO 15378 primary packaging certification.

Additional Languages French, German, Mandarin.

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### CENTRIC HEALTH

Business Description Centric Health provides a new and innovative approach to the provision of quality primary healthcare services in Ireland, the UK and Australia. The company has an established record of providing quality out-of-hospital care which are easily accessible, proactive and responsive to local needs and include the provision of radiology services, community medical services, urgent care services, health screening and the treatment of chronic medical conditions including diabetes.

# **Products & Services** Some of Centric Health's services:

- Radiology and teleradiology services and providing support to private and public hospitals to help meet radiology reporting requirements
- Operation and development of community GP practices
- Provision of occupational medical services to corporate clients and executive medical health screening services to private individuals and corporate clients
- Chronic disease management in the community
- Medical recruitment, including the provision of locum doctors to GP practices and HSE and private hospitals across Ireland and Australia

**Key Customers** Patients, corporate clients and other healthcare providers.

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### CHEMSTORE

**Business Description** Chemstore Ltd. is a designer and manufacturer of hazardous material storage systems for all industries including customised storage systems to suit customer's particular needs, in order to comply with environmental regulations and health and safety legislation.

Products & Services Safety storage for flammables and hazardous chemicals, gas cylinder stores, waste management compounds, warehouse and racking, fire rated safety sabinets, temperature control stores, bunded oil tanks, spill protection kits, personal protective equipment, drum handling, safety sans, stainless steel cabinets and lockers, safety showers, drain protection, flood barriers, waste balers and compactors, safety signage, chemical awareness and spill response training, laboratory training, bund testing, safety audits, refurb/trade-in hazardous storage equipment, storage solutions rentals. As part of the customer service policy a free site survey is also available to all of Chemstore's customers.

Key Customers Pharmaceuticals and Healthcare: Wyeth, Allergan, Leo Pharma, Alza, Schering Plough, Astellas, Glaxo, Stryker, Manufacturing: Analog, Smurfit, Unilever, Food and Beverages: Dawn Foods, Green Isle Foods, Diageo Group, Also many sectors, including: hospitals and the public sector.

Standards & Certifications'Ex' Ratings, CE, IS EN 14470-1, IS EN 14470-2.

Additional Languages Spanish, Polish, Hungarian, French.

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## CLEARSPHERE

Business Description ClearSphere is a single-source specialist in controlled environment technology, with over twenty years experience delivering the highest standards to the Irish, UK and European markets. The company takes pride in its reputation for excellence as a one-stop-shop for clean operations.

#### **Products & Services**

- ClearSphere is committed to exceeding its customers expectations by providing solutions based on the highest international standards of quality and excellence
- ClearSphere's single-source solutions allow its clients to get all products & services installed, validated and up and running more guickly and at a lower overall cost

Some of these solutions are as follows:

- · Cleanroom solutions: design and installation of cleanroom systems
- Containment solutions: sampling and solvent booths, isolators and lab containment stations
- Validation and maintenance: CTCB (cleanroom testing and certification board) certified engineers
- Product solutions: laboratory furniture and safety cabinets

Key Customers Alcon, Baxter healthcare, Centocor, Genzyme, Gilead, GSK, Jacobs, Johnson & Johnson, Merck Sharp Dohme, Pfizer, PM Group, Servier, Wyeth, some Irish universities.

Standards ClearSphere is a certified ISO 9001:2008 organisation. ClearSphere validation engineers are CTCB certified.

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# CLINICAL CONDUCT ASSOCIATES ITD



Business Description Clinical Conduct Associates is a clinical research consultancy organisation. CCA provides international contract clinical services with primary focus in the key therapeutic areas: oncology/hematology, cardiology, antibiotic/antiviral, CNS, surgery, medical devices, respiratory medicine, metabolic/endocrine.

#### **Products & Services**

Clinical Conduct Associates offers:

- Comprehensive clinical research consultancy services, with expertise across European countries
- Wide selection of services including study start up, ethics/regulatory/PCT/R&D submissions, vendor selection, contract negotiation
- Specialised and innovative patient recruitment solutions incorporating Internet Clinical Trial Solutions (www. internetclinicaltrialsolutions.com), advanced recruitment techniques that combine patient care pathway and behavioural strategies
- Audit services
- Vendor alignment
- Monitoring services: site selection, initiation visits, monitoring, close out
- Trial master file quality control

CCA excels in providing expert project support for clinical trials, from protocol design and feasibility assessments through to final study report.

Key Customers Large pharmaceutical manufacturers, biotechnology companies, small start ups, other CRO's.

Standards ISO 9001

Additional Languages French, German, Japanese, Polish.

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# COLORMAN (IRELAND) LTD

**Business Description** Colorman is one of the largest printing companies in Ireland and specialises in the print production of printed material for the pharmaceutical and healthcare industries. Colorman also has the FSC and PEFC chain of custody.

Products & Services Colorman provides leaflets, booklets, manuals and cartons to the pharmaceutical and medical device industries, and due to the critical nature of these sectors has implemented a range of initiatives and procedures to ensure traceability, conformance and risk assessment. A range of these initiatives includes security bar code systems with in-line barcode scanners, line clearance, batch traceability, environmental conditions and cross contamination and segregation procedures. These procedures are fully documented. Colorman provides certificates of conformance and first article report forms for all deliveries and products manufactured.

Key Customers Abbott Ireland, Boston Scientific, Trinity Biotech.

**Standards & Certifications** ISO 9001:2008, PEFC (programme for the endorsement of forest certification) and FSC (forest stewardship council) certifications.

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### COMPLETE LABORATORY SOLUTIONS



Business Description CLS is the leader in providing contract laboratory sampling and testing to industry. The company's extensive experience allows it to provide a 'turnkey' style solution to their clients from collection, tracking, testing, online results and full certificates of analysis and discussion, to ensure that clients remain as market leaders in the supply chain.

Products & Services CLS MedPharma is CLS's dedicated division for testing medical devices and pharmaceutical products. At CLS MedPharma a full range of analytical, microbiological and validation testing on medical devices, combined devices, pharmaceutical products, cleanrooms, and hospitals is provided. The company was established in 1994 and it has continued to grow with its client base to become the leader in this niche market. CLS MedPharma is 100% Irish owned and has invested highly in employees with in-depth industrial knowledge to ensure the company understand clients business and requirements, both in Ireland and internationally.

Examples of work: cleanroom validation, product validation, process validation, routine quality control testing, method development, method transfers, stability storage and testing, product release testing, API testing, supply of analysts on contract to client sites.

**Key Customers** Medical device manufacturers, combined devices (drug eluting), pharmaceutical, hospitals & clinics.

Standards: ISO 17025, GMP, ISO 9001:2008.

Additional Languages Irish, German and French.

Note CLS MedPharma operates a partnership style in helping clients to deliver new product to market with confidence and ensure their current and next generation products has the highest level of testing possible. Supplying analysts on contract: Colin O' Toole cotoole@cls.ie, mob. 087 8600935 Quality compliance CLS MedPharma: Miriam Murphy mmurphy@cls.ie, mob. 087 6173151

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## COMPLIANCE & RISKS ITD

Business Description Compliance & Risks is an enterprise software and professional data services company providing web-based compliance software and data services. Compliance & Risks focusses on all local and global regulatory developments impacting on clients' products. Clients use the company's services to understand the considerable volume of rules and regulations.

## **Products & Services** Products on offer include:

- C2P (Compliance to Product ) Enterprise, a complete compliance software management and data services system that resolves the information avalanche of global environmental regulations
- C2P Navigator is a trimmed down version of C2P Enterprise which is designed exclusively for tracking global environmental regulations that impact a company's products and business activities

C2P replaces e-mails, spreadsheets, and paper trails with an on-line suite of communication and collaboration tools that are designed for managing compliance. C2P helps organise and accelerate each step of tracking global regulations, defining issues, assessing risks, assigning tasks, monitoring compliance, and producing reports — all the way to full compliance.

Key Customers Top SandP (Standard and Poor's) 500 companies.

Additional Languages French, Italian, German, Spanish.

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### CREST SOLUTIONS LTD

Business Description Crest Solutions is a leader in the provision of solutions to highly regulated industries, including pharmaceutical, healthcare and medical devices manufacturing. Crest Solutions enables companies to fundamentally improve their packaging, automation, compliance & traceability activities.

**Products & Services** Visual inspection, packaging management & traceability solutions for pharmaceutical & medical devices manufacturers.

- Inspection Systems: reliable, high performance inspection guarantees product quality & process accuracy, quality control, fail-safe reliability and improved productivity
- LineDirector™: software to manage the production line & peripherals providing fast changeovers, supporting verification, inspection, and traceability
- Protrack™ product lifecycle traceability software provides compliant track & trace functionality to fully managed batch & unit product manufacture
- PharmaMarker™ & LineMarker™: provide complete packaged solutions to meet new track and trace regulatory requirements
- PrintInspector™: in-line high accuracy print verification system for inspecting medical device labels

Key Customers Over the past 12 years Crest Solutions has assisted more than 70 companies worldwide to transform the way they do business. Customers include Allergan, Abbot Vascular, Baxter Healthcare, GE Healthcare, Boston Scientific, GlaxoSmithKline, Stiefel, Medtronic, Millipore, Teva, Pfizer and Servier.

**Standards & Certifications** Crest Solutions delivers software systems to comply with regulated standards using GAMP; e.g. IMB, USFDA, supplying fully validated 21 CFR part 11 solutions. Crest Solutions is an ISO 9001:2000 certified organisation.

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## DAKOTA PACKAGING ITD

Business Description Dakota Packaging has been a leading supplier of high quality folding and litho-laminate cartons to the pharmaceutical and healthcare industries for the past thirty years. Products include anti-counterfeit technology, pill packs with silver scratch day indicator, multi-integral fitments packs, and printed Braille.

**Products & Services** Dakota obtains optimum running values established on client packaging lines. Any product thus produced at Dakota is then measured and validated against these values ensuring optimum running speeds at all times. Combined with fast turnaround and assisted by a highly flexible planning and production system, this ensures customers get a product on time.

- 3x6 colour printing presses with WB/UV varnish capabilities
- 1x4 colour with w/b varnish capability
- 4x die cutters of which two have full blanking facilities
- · 4 high-speed glueing lines capable of straight line
- crash lock and multi-point glueing
- Full in-house repro facility complete with CTP Dakota also provides packaging design, prototyping, and machine commissioning trials

Key Customers Allergan Pharmaceuticals, Servier Laboratories, Stiefel Laboratories, Gilead, Organon, Abbott, Forest Tosara, Elan, Norbrook Laboratories, Rottapharm Ltd.

Standards & Certifications ISO 9001:2000, PS 9000:2001.

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# DPS ENGINEERING & CONSTRUCTION LTD



**Business Description** DPS is a leading process engineering and project management company. The company reputation is based on forming successful partnerships with clients, providing innovative designs and cost effective solutions, sound judgment, strong management and technical excellence. DPS offers high calibre and highly motivated teams and resources.

**Products & Services** DPS Engineering offers a comprehensive range of services to clients, across different sectors, and has the experience and track record to deliver these services outlined below to meet each client's project and resourcing needs.

DPS has executed projects and supplied engineering resources to a wide range of industrial sectors including:

- Pharmaceutical & biotechnology
- Medical technologies
- Oil & gas/energy
- Micro electronics
- Science & education
- Consumer healthcare

Key Services are as follows

- Management services, including project and programme management, cost/schedule and client teams
- · Planning and front end, including master plans, site selection, concepts and front end studies
- Engineering design, including process, mechanical, electrical, automation, CSA, HVAC
- · Construction and field, including construction management and supervision, commissioning/qualification, H&S
- Professional outsourcing, includes temporary and permanent positions

Key Customers APfizer, GlaxoSmithKline, Merck Sharp & Dohme, Johnson & Johnson, Bristol Myers Squibb, Ipsen, Eli Lilly, Genzyme, Takeda.

Standards ISO 9001:2008

**Additional Languages French, Dutch** 

# **Contact Name / Title**

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### FIRGEN PHARMA

**Business Description** EirGen Pharma focusses on the development, registration and commercial manufacture of high potency, high barrier to entry solid dose (tablet and capsule) products for the global pharmaceutical market.

**Products & Services** EirGen Pharma is fully licensed to manufacture oncology, cytotoxic, steroidal, immunosuppressant and hormonal molecules in a purpose-built high containment facility utilising innovative isolation technology. The company offers the following services:

- Formulation development
- Analytical development
- Clinical trials manufacture
- Commercial manufacture and packaging of oral solid dosage forms
- Stability studies

Standards & Certifications Clinical trials licence, manufacturing licence. Approved for cytotoxic products.

**Additional Languages French** 

#### **Contact Name / Title**

Tom Brennan, Technical Director Patsy Carney, Managing Director

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### FPT-LIGHT LTD

Business Description Design, development and manufacture of advanced illumination systems, integrating advanced LED light sources with optical, mechanical and electronic components. A range of standard and custom products offer solutions for many demanding applications in life sciences, vision systems, irradiation etc.

Products & Services UV/visible/infrared emitters, line-light, ppot-light, back-light, Co-axial-light, obliquelight, exci-light, fibre-light, projector-light, narrowband, broadband/multi-wavelength light sources, LED arrays, power supplies, control electronics, optical components, product design, development and testing.

Key Customers Fraunhofer Gesellschaft, Astellas, GlaxoSmithKline, Johnson & Johnson, Bio-Rad, Intas, Philips, Zeiss, Uhlmann, Alcon, Teleflex Medical.

# **Contact Name / Title**

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## FAULKNER PACKAGING

**Business Description** Faulkner Packaging is a manufacturer of specialised anti-static and barrier flexible packaging for bulk intermediate pharmaceuticals, biodiagnostic kits, medical electronics and biohazard applications.

Products & Services Faulkner manufactures the following products for the healthcare industry -

- Moisture barrier aluminum drum liners for storage and transportation of bulk intermediate pharmaceuticals
- · Moisture barrier bags with zipper closure and easy open notch to package biodiagnostic kits
- 95 kPa specimen bags for transporting biological specimens by road (UN NO 3373). As per packaging
  instruction P650, there are two test rigs in-house which test this product to beyond the required specification
- Anti-static and non anti-static polyethylene drum liners for the transportation of bulk pharmaceuticals

Key Customers Pfizer, GSK, Elan, Wyeth Yamanouchi, Honeywell, Takeda, LG Chemicals, Randox, Biotrin, Bayer Diagnostics, HP, Intel and Siemens, amongst others.

Standards & Certifications ISO 9001

Additional Languages French, German.

#### **Contact Name / Title**

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### FIRECREST CLINICAL

Business Description Firecrest Clinical Ltd. is a clinical technology organisation that brings together experts in clinical trials, pharmacy, medicine, communications and technology, to create web-hosted solutions to the many challenges faced in optimising clinical trial efficiency.

**Products & Services** Firecrest Clinical is a global leader in the design, development, and delivery of integrated training, communications, and performance support solutions across all phases of drug development from Phase I through to post-marketing studies. Firecrest's solutions:

- Ensure that adequate resources and training is provided to all sites
- Deliver unparalleled performance support and study management tools
- · Deliver consistency, quality, and compliance across all sites
- Facilitate sponsor-investigative site collaboration
- Overcome the challenges and logistics of communicating with a global audience

Products and solutions have been designed to optimise clinical trial efficiency and minimise protocol execution burden.

Additional Languages Spanish, Polish, Cantonese, Mandarin.

# **Contact Name / Title**

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E-Mail

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## FLOW TECHNOLOGY LTD

Business Description Flow Technology is a process engineering company specialising in the design and supply of process installations and the supply of equipment to the pharmaceutical industry. The company has an experienced team of process engineers, design engineers and craftsmen to provide complete competitive solutions for secondary pharmaceutical and biotechnology projects.

### **Products & Services**

- Turn-key process projects including chromatography, cleaning-in-place, point-of-use, biowaste deactivation, temperature control skids and process modules
- Supplies process equipment with applications, engineering and after sales service support, sanitary agitiators, double tubesheet shell and tube heat exchangers, filter housings, cleanroom furniture, mix-proof valves, plate heat exchangers both gasketed and welded, custom designed high polish fixed spray-balls, aseptic diaphragm valves, sanitary centrifugal pumps and rotary jet cleaning heads

Key Customers Abbott, Baxter, BMS, Centocor Biologics, Eli Lilly, Genzyme, GSK, Janssen, J&J, Merck, MSD, Novartis, Pfizer, Teva.

**Standards & Certifications** Quality standards are specific to each project.

**Additional Languages** Swedish, Danish.

### **Contact Name / Title**

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> Co. Cork Ireland

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Website www.flowtechnology.ie

## GXP SYSTEMS ITD



**Business Description** GxP Systems, a leader in regulatory compliance consultancy and project management services, enables medical device, biotechnical and pharmaceutical clients to systematically and continuously lower the cost of compliance within their organisations, without compromising on quality or regulatory requirements.

**Products & Services** A highly skilled team of validation and quality specialists, automation and industrial engineers, IT and business analysts, provides a range of compliance consulting, engineering and contract services, including:

- Regulatory compliance
- Pre- and post-audit assessment
- Quality system review
- Lean validation
- Process improvement and system remediation
- Project and program management

GxP Systems offers two types of contract services: complete managed services or supplemental resources. In addition, GxP Systems delivers customised training to both individuals and groups. With 13 years experience in the regulated industry, its trained instructors are knowledgeable and experienced in the subject material, the complex compliance regulations and the issues they present.

Key customers A unique approach has made GXP Systens a trusted supplier to industry leaders such as Boston Scientific, Wyeth, Genzyme and many other Multinationals, as well as a global partner of ABB.

Standards Currently gaining accreditation for ISO 9000.

## **Contact Name / Title**

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### HIBERNIA COLLEGE LTD

Business Description Hibernia College is an international, third level, on-line college offering accredited, niche-focussed educational programmes designed to address the growing demand for flexible, cost-effective lifelong learning, which is not restricted by location or time.

Products & Services Hibernia's Master of Science in Pharmaceutical Medicine is delivered in collaboration with faculty from Harvard University in the US and the Royal College of Surgeons in Ireland. Hibernia College has also designed, developed and implemented a system which is at the leading edge of international educational delivery. This technology infrastructure allows for increased student-tutor contact and encourages and supports self-directed learning in a way that is not possible using conventional modes of delivery. Other offerings include various short term continuing professional development (CPD) programmes.

Key Customers International pharmaceutical organisations - physicians and non-medical specialists employed in the pharmaceutical industry in areas such as medical affairs, regulatory affairs, clinical monitoring, data management, drug safety and clinical project management.

**Standards & Certifications** Higher Education and Training Awards Council (www.hetac.ie), International Federation of Associations of Pharmaceutical Physicians (IFAPP).

#### **Contact Name / Title**

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### HOSPICODE LTD

**Business Description** Hospicode develops and supplies colour coded medical labelling systems. Hospicode was established in Ireland in 1988 to produce a safe convenient syringe labelling system (SLS) for anaesthetic drugs. It is a market leader with its syringe labelling system being endorsed by the Association of Anaesthetists of Great Britain and Ireland.

**Products & Services** Syringe labels, drug additive labels (DAL), line labels. The company also has a large range of strips of labels which can be both sterile and unsterile. Hospicode Ltd. produces miscellaneous labels on request for specific needs, and can meet any label requirement for any hospital.

Key Customers Henleys Medical Supplies Ltd England, Keaney Medical Ltd, Medeco B.V., N.V. Meditron.

Standards & Certifications IS.EN.ISO 9001:2000

# **Contact Name / Title**

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## TCON RESEARCH

Business Description ICON Plc. is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies

Products & Services ICON offers a broad range of specialised services to assist pharmaceutical, biotechnology and medical device companies to bring new treatments to market faster. Services include:

- Phase I-IV clinical trial design, management and review
- Medical imaging
- Global central laboratory services

- Bioanalytical laboratory services
- Contract staffing
- Strategic product lifecycle consultancy

**Key Customers** Top 20 pharmaceutical companies.

Standards & Certifications ICON's global Quality Management System is ISO 9001 registered. ICON Laboratories are CAP (College of American Pathology) and ISO 17025 accredited.

Additional Languages Many languages spoken

# **Contact People for Overseas Markets:**

The Americas: Paul Colombo, Vice President of Sales for the Americas

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Europe and Asia Pacific: Ulrike Brenner, Vice President of Sales for Europe and Asia Pacific

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# **Contact Name / Title**

Peter Connolly.

Associate Director of Financial Planning & Analysis

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### ID TECHNOLOGY ITD

**Business Description** ID Technology is a privately owned specialist label manufacturing company, with a variety of print and cutting processes which supports cost effective production, whether low/high volume or complex/simple in nature.

## **Products & Services**

- Self-adhesive paper packaging labels (blanks and pre-printed)
- Durable name plates
- Warning labels
- Security labels
- High temperature pcb labels
- Polycarbonate overlays
- Display panel overlays
- Thermal transfer ribbons and printers

ID Technology also provides a bureau service on thermal transfer printing for incorporation of unique label identification such as serialisation (including barcoding) or batch coding. Supply initiatives such as kanban, contract and consignment stocks are also supported.

Key Customers Stryker, Guidant, Cardinal Healthcare, Mitsubishi, Bosch, Electrolux, National Instruments.

Standards & Certifications ISO 9001:2000, currently working on ISO 14001 implementation.

# **Contact Name / Title**

John Clark, Managing Director

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## INTERACTIVE SERVICES LTD

**Business Description** Interactive Services provides award-winning innovative and timely custom learning programs. Most of its customers are Fortune 500 companies which are helped to meet business requirements in the areas of compliance, information security, product launches, proprietary IT systems training and regulatory accreditation.

#### **Products & Services**

- Curriculum planning
- eLearning
- Best practice handbooks
- Classroom training development

## Areas of expertise include:

- Operational risk and regulatory compliance training
- Global new hire orientation programs
- Enterprise IT systems deployments
- Marketing/sales curriculum

# **Key Benefits**

- End-to-end learning solutions
- Industry leading content for the specific needs of an organisation
- 30+ language capabilities
- Scalable and updateable
- Regulator-approved learner tracking infrastructure

Key Customers Boston Scientific, Astra Zeneca, Wyeth, Glaxo Smith Kline, Intel, Citigroup, Firecrest Clinical, Autodesk, Comcast, AXA, Alstom, for example.

#### Standards & Certifications ISO 9000 certification

Additional Languages English is the company's core business language but most of the training developed is translated, and in some cases it can increase to 25+ languages.

#### **Contact Name / Title**

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### INTUITION



Business Description Intuition provides knowledge and learning services to the life sciences, financial and government sectors. Combining an intimate knowledge of these sectors with in-depth educational expertise, Intuition provides a full spectrum of products, services and technologies to support clients' learning requirements.

#### **Products & Services**

- Custom e-learning
- Sales training and marketing learning solutions
- Learning management systems and hosting services
- Consultancy, blended learning design, instructor-led training
- Compliance and regulatory training

# **Key Benefits**

- End-to-end learning solutions: consultancy and programme design, development, web hosting and implementation services
- Deep knowledge of the pharma and med device industries
- Long-term track record in life sciences learning
- · Communicating policy effectively, standardising best practice and implementing regulatory standards
- · Sales training and marketing effectiveness

Key Customers AstraZeneca, Merck, Novartis, Sanofi-Aventis, NHS, UK Department of Health, Microsoft Certified Partner, Research In Motion.

Standards & Certifications Quality Management System ISO 9001:2000 certified.

Additional Languages French (including Canadian), Italian, German, Spanish (including Latin American), Dutch, Portuguese, Russian, Mandarin and Cantonese, Japanese, Korean.

## **Contact Name / Title**

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## TRCONA

Business Description Ircona provides innovation and product design services and supply chain management from concept to volume shipment for electronic medical products, including POC (proof-of-concept) and IVD (in vitro diagnostics) handheld and desktop instrumentation. Ircona delivers innovative, competitive, on-time and right-first-time designs for clients, from start-ups to large multinationals.

Products & Services Ircona helps clients achieve their revenue and profit goals through innovative, competitive product realisation. Services include complex problem solving and product design implementation, from concept through to volume production, as well as optics, mechanics, industrial design, FPGA (field-programmable gate array), board design, embedded software, RF, communications and supply chain management, compliant with all relevant medical and safety standards.

Key Customers Confidential, can be shared under client agreement and non-disclosure agreements.

Standards & Certifications ISO 9001, ISO 13485.

**Contact Name / Title** 

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# IRISH EQUINE CENTRE

**Business Description** The Irish Equine Centre and its subsidiary company, Irish Diagnostic Laboratory Services, is a diagnostic laboratory and contract research organisation providing laboratory services for the diagnosis, management and prevention of diseases of horses and other species.

#### **Products & Services**

- Provides commercial laboratory and consultancy services (including CRO) to the pharmaceutical, vaccine, agriculture and food industries, clinical trials, pharmokinetics studies and product registration
- Analyses include PCR, ELISA, HPLC and other appropriate techniques
- Handles large batches and commercially sensitive samples
- Monitoring role in the Irish National Residue Plan under EU food safety legislation
- Carries out a range of tests for the food industry including prohibitive substance testing, BSE, Aujeskys disease and tuberculosis in the badger population
- Performs routine analyses of samples as part of an EU Disease Eradication Programme
- Participates in GLP studies and analyses resulting from clinical trials which are a requirement for the registration and re-registration of the pharmaceutical and vaccine products

Key Customers Government departments, food business, agri business, pharmaceutical and vaccine companies.

Standards & Certifications INAB accreditation (ISO 17025), GLP compliance, OIE reference laboratory.

Additional Languages French, German, Italian.

## **Contact Name / Title**

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### JAVA CLINICAL RESEARCH LTD

**Business Description** Java Clinical Research is a full service contract research organisation providing a complete clinical trial service to the pharmaceutical, biotechnology and medical device industries. Java Clinical is unreservedly committed to the success of each client programme, with on-time delivery and to the highest quality standards.

#### **Products & Services**

- Study management and monitoring clinical development & planning study protocol & CRF design investigator selection patient recruitment project management
  - monitoring to GCP-ICH standards, European and FDA regulatory requirements and company procedures
- Regulatory Support regulatory submissions ethics committee applications
- Provision of ICH-GCP training to CRAs and site personnel
- SOP writing
- Investigational site audits for adherence to ICH GCP, international and local regulatory requirements
- Provision of expert consultancy advice & support across all phases of the clinical trial programme
- Specialist platelet pharmacology service

Key Customers Markets include the pharmaceutical, biotechnology and medical device industries in Ireland, Europe and the USA.

Standards & Certifications All trials are conducted in accordance with national and European legislation.

#### **Contact Name / Title**

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### JOHN SISK & SON ITD



Business Description Sisk Pharma is a dedicated bio-pharma construction division within Sisk and has delivered projects exceeding €1.4 billion in value since 2000. With extensive operations across Ireland, UK, Europe and Middle East, Sisk operates in all sectors of the industry and has built a business with turnover exceeding €1 billion per annum through strong client relationships, adding value and maintaining a financially strong business.

Products & Services Safety is the primary concern on all projects, with a target of zero incidents/zero injuries on all sites. Sisk provides full construction management services and takes on full cost risk of projects and can offer guaranteed maximum pricing if required. All Sisk personnel are long-term staff with multidisciplinary skills. Capabilities include full commissioning execution and qualification support through leveraged documentation. Sisk has delivered biologics, finishing, API, solid oral dosage, laboratory, R&D, medtech facilities for a wide range of international companies, and employs all forms of delivery models including CM (management contract), design & build, main contractor, and package contractor.

Key Customers Johnson & Johnson (5 major manufacturing facilities), Pfizer (multiple projects/sites), Abbott, Genzyme, Gilead, GSK, Eli Lilly, NIBRT, Merck, Baxter, BMS, Allergan, Takeda, Fujisawa, Schering Plough, Astellas, Novartis, Elan.

Standards ISO 9001:2008 – quality management system, IS EN ISO 14001:2004 – environmental management system, OHSAS 18001:2007 – occupational health & safety management syste, Engineers Ireland accredited employer, Considerate Contractor – UK, Investors in People, RoSPA Gold Medal Award 2010.

Additional Languages German, French, Arabic.

Note John Sisk and Son is part of the SISK Group, one of Ireland's largest privately owned family businesses, and celebrated 150 years in business in 2009. The SISK Group has businesses in manufacturing, distribution and healthcare with an overall group turnover in 2009 of 1.2 billion.

# **Contact Name / Title**

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#### KELLS STATNLESS LTD

Business Description With over 40 years engineering experience, Kells Stainless are specialists in the design and manufacture of stainless steel process equipment; Kells has the ability to meet specific customer requirements over a wide range of industries and take pride in its capacity to understand client needs and to work as a team to fulfil those requirements.

**Products & Services** Storage tanks, mixing, blending, heating and cooling vessels, reactor vessels, modular skid units designed to international standards. At the company's modern 3000m<sup>2</sup> manufacturing facility, pride is taken in the skills and experience in the fabrication of equipment in stainless steels, nickel alloys, and exotic materials.

Key Customers Kells Stainless services the pharmaceutical, biotech, chemical, food and beverage industries and work for key customers such as Pfizer, Genzyme, GSK, Roche, Eli-Lilly, Centocore, Coca-Cola, to mention but a few.

Standards An ISO 9001:2000 accredited company working to international standards such as EN 13445, ASME, API etc.

**UK Office** 

**Singapore Office** 

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#### **Contact Name / Title**

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## KENTLWORTH PRODUCTS LTD

**Business Description** Kenilworth Products Limited is a leading manufacturer of self-adhesive labels, extended text/multilayered labels, pharmaceutical booklets and Fix-a-Form labels for the pharmaceutical and healthcare industries in Europe.

Products & Services Kenilworth can print up to 12 colours and can produce both Duel and Tri-web products. The company's in-house origination and product development team assists clients with cost effective, fully tailored solutions

# Product range includes:

- Self-adhesive labels
- Fix-a-Form leaflet and booklet labels
- Braille solutions to meet EU directive 2004/27/EC
- Infusion hanging labels
- Tamper evident and brand protection labels
- Data replication labels
- Spinformation® rotating labels
- Integration of Bollino vignette labels on existing product labels
- Ampoule and syringe labels
- Duel and Tri-layer label solutions

Standards & Certifications ISO 9001:2000, PS 9000:2001.

Additional Languages Spanish, French.

#### **Contact Name / Title**

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## KENT STATNLESS

Business Description Kent Stainless has developed an automatic opening pneumatic gully to clear the build up of water from sprinkler systems, or at washdown time in an otherwise sealed environment. The sealed gully covers can be opened from a local switch, or automatically when activated by a sensor detecting liquid build-up.

#### **Products & Services**

- Pneumatic opening drainage gullies
- Double contained drainage channels and gullies
- Sealed cleanroom drainage gullies
- Surface protection inc. bump rail, bollards, cladding, kerbing
- Cleanroom fitout inc. recessed utility stations, cabinets, lockers
- Sanitary ware inc. sinks, WCs, sluice units
- Cleanroom furniture inc. stepover benches, trolleys

Key Customers Abbott – Cootehill, Longford, Sligo, Clonmel, Allergan – Limerick, Baxter – Limerick, Biogen – Hillerød, Boston Scientific – Cork, Galway, Centocor – Cork, DePuy – Suzhou, Cork, Eli Lilly – Kinsale, Genzyme – Waterford, Geel, Haverhill, GSK – Dungarvan, Cork, Dartford, Singapore, Nairobi, IVAX – Waterford, Janssen – Cork, Geel, Johnson & Johnson – Cork, Bridgend, K.A.U.S.T. – Saudi Arabia, M.I.S.T – Abu Dhabi, Merck Sharp & Dohme – Enfield, Hoddeson, Clonmel, Carlow, Singapore, Millipore – Cork, Novartis – Grimsby, Cork, P&G – Nenagh, Limerick, Pfizer – Ringaskiddy, Cork, Sandwich, Lindhagensgaten, Morpeth, Singapore, Connecticut, Roche – Clare, Schering Plough – Limerick, Rathdrum, Cork, Servier – Arklow, Dublin, Takeda – Dublin, Vistakon – Limerick.

Standards ISO 9001:2008 - quality, ISO 14001 - environment, FACTA – access covers, BS 6443 - dye testing, BS 2910 – radiography testing, WP1008 – weld procedure, ASME IX (Ref QW200) – testing standard, EN 288 – testing standard, working towards ISO18001 - safety.

**Additional Languages French** 

#### **Contact Name / Title**

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# KIRBY GROUP ENGINEERING LIMITED



Business Description International specialist engineering services contractor providing mechanical, electrical, instrumentation, calibration and commissioning services to the lifescience sector. Focus on bulk bio, fill/finish, primary API, diagnostics, medical device and support facility M&E solutions. Design development and turnkey clean-room build project delivery expertise.

**Products & Services** Kirby Group provide multi-disciplinary engineering services to the lifescience sector. Core capabilities include:

- a) Mechanical HVAC building services and support piping systems
- b) Electrical systems and ancillary services such as fire alarm, CCTV, access etc.
- c) Instrumentation services through to IQ/OQ status
- d) Calibration services including short/long term placement of technicians
- e) Facilities maintenance of 'hard' services

Specialist expertise in the turnkey delivery of clean-room build solutions to end users with overall responsibility for management of key vendors, engineering, construction and commissioning services.

Full participation in commissioning and validation process in cooperation with client representatives.

On-going site support services and facilities maintenance are key elements of the Kirby Group offering as is full participation in design development, constructability reviews and cost optimisation exercises.

Key Customers Biologics: Eli Lilly, Merck Sharp & Dohme, Pfizer, Sanofi Aventis.

API/secondary: Abbott, Bristol Myers Squibb, Covidien, Eli Lilly, Gilead Science, J&J, Pfizer, Roche. Diagnostics/medical device: AVE Medtronic, Abbott, Boston Scientific, Cook, Creganna Medical, Merit Medical.

Standards OHSAS 18001 health and safety accreditation, EN14001 environmental accreditation, ISO9001:2008 quality accreditation.

**Additional Languages French** 

# **Contact Name / Title**

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#### KNEAT SOLUTIONS LTD

Business Description Kneat's software enables regulated customers to create and maintain equipment and automation lifecycle documents with less effort and higher quality than existing systems or methods, providing unprecedented value by reducing schedules, increasing productivity and driving compliance in real time in a paperless secure web based environment.

**Products & Services** The software's key capabilities are:

- Library template management
- System modelling
- Class approach, drop a class into any project and all its life cycle docs are auto generated and all aliases are resolved automatically for each unit
- Auto generation of test docs FAT, SAT, IQ, OQ etc.
- Review and approval docs, deviations and change controls
- On-line testing
- Deviation and change control management, with cross document impact assessment auto generation of retest protocols and auto updating of design documentation (and downstream test docs if applicable) post approval and close out
- Real time reporting deviations, change controls etc.
- Clone any part or all of a process train and drop it seamlessly into another project within or across sites –
   all life cycle documents are auto generated
- Multiple users can participate on any project from anywhere also allows multiple users in same docs in controlled secure manner
- Robust user administration and audit trail 21CFRPart 11 compliant

Key Customers Pharmaceutical and medical device manufacturing companies and their turnkey automation and equipment suppliers.

**Standards & Certifications** Operates to cGXP (current good practice), GAMP5 (good automation manufacturing practice) and ISO (pending).

#### **Contact Name / Title**

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## LIFE SCIENTIFIC LTD

Business Description Life Scientific is a unique contract research organisation specialising exclusively in off-patent plant protection product development and registration. Established by Nicola Mitchell in 1995, the company is headquartered in GLP/GMP-certified facilities in Dublin and employs highly skilled and experienced development and regulatory scientists.

Products & Services Life Scientific is a plant protection product development company. The company is unique in being the only full service CRO focused exclusively on off-patent agrochemical product development. With a core team of development and regulatory scientists, Life Scientific specialises in all aspects of plant protection product development, encompassing formulation development, analytical development, efficacy, safety/toxicology and dossier preparation/ product registration. Life Scientific's unique integration of chemistry and regulatory expertise allows for a seamless interface between the company the regulatory authorities, thereby ensuring an accelerated registration process. By getting products to market first, fast and without fail, the company is the contract facility of choice for clients who value speed to market and product innovation.

**Key Customers** Clients range from global leaders in the plant protection product industry to early stage product development and virtual/marketing companies.

Standards & Certifications The company operates from good manufacturing practice (GMP) and good laboratory practice (GLP) certified laboratories.

#### **Additional Contact details:**

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# **Contact Name / Title**

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# M&Q PACKAGING

Business Description M&Q Packaging specialises in manufacturing and extrusion of high heat resistant nylon for a large number of food, non-food and medical applications. M&Q products are made from the highest standard FDA and EU approved material. M&Q Packaging is at the forefront of developments of nylon film technology.

#### **Products & Services**

- Arson evidence bags
- Sterilisation pouches, autoclave bags
- Swab containments
- Cooking, roasting, boiling, microwavable, oven and rotisserie bags
- Airline bags, poultry process
- Industrial meat processing and sausage casing
- Fruit and vegetable fresh bags, multipurpose bags, freezer bags
- Gastronorm pan liners
- Biohazard waste bags
- Solvent recovery bags, bitumen bags

Key Customers British Pepper & Spice, Forensic Science Service UK, Forensic Science Laboratory Ireland, Sirane Innovate, Aer Lingus, Tesco, BACO.

Standards & Certifications BRC (British retail consortium), ISO 9001.

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## MARVAO MEDICAL DEVICES LTD

Business Description Marvao Medical Devices Ltd. is an 'open innovation' company focussed on the design, development, and marketing of novel disposable medical devices that addresses significant unmet clinical needs.

Products & Services Marvao collaborates with technology companies, academia, and clinicians to connect emerging technologies with customer problems in the form of patented design concepts. The company then partners with OEM and distribution companies to translate these design concepts into finished products capable of reaching the proof-of-concept pre-clinical and first-in-man clinical milestones. Marvao's first technology platform employs a patent pending tissue in-growth scaffold geometry suitable for use on a range of percutaneous long-term in-dwelling catheters. This technology will enable clinicians who adopt the product to significantly reduce the risk of catheter-related blood stream infections, a common, costly, and potentially lethal complication associated with conventional catheter designs.

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## MERCURY ENGINEERING

**Business Description** Mercury Engineering is a world-class provider of solutions within the construction industry, from management contracting to building services requirements. A reputation for delivery within schedule and budget has made the company the contractor of choice for nearly 40 years.

Products & Services A comprehensive set of services spans management contracting, mechanical, electrical, data technologies, fire protection, interior fit-outs, and maintenance and facilities management. Mercury Engineering is a world-class provider of solutions within the construction industry, an extensive range of engineering services across a multitude of sectors are renowned for their superb quality standards. Mercury Engineering is committed to exceeding clients' engineering expectations time after time.

Mercury Engineering employs the best people, invests heavily in their training and education and ensures that the highest standards of health, safety and governance is applied throughout the organisation.

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#### MERGON HEAITHCARE

Business Description Mergon Healthcare specialises in precision blow moulding, injection moulding, injection blow moulding and assembly of technical components for the medical device and pharmaceutical industry.

#### **Products & Services**

- Industry leader in moulding of diagnostic reagent and nutraceutical containers
- Design and manufacture of innovative lab components including 3D bioreactors and lab-on-a-chip products
- Design and manufacture of bacteria, MRSA and E. coli resistant hospital beds and furniture
- Manufacture of surgical consumables including wound drainage products and sharps containers
- World-class automation and robotics capabilities
- Project management for major OEMs

Standards & Certifications ISO 9001:2008, cGMP, ISO 13485.

Additional Languages German, French, Spanish.

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# MILLMOUNT HEALTHCARE LTD

**Business Description** As experts in outsourced packaging operations, Millmount Healthcare provides an effective outsourcing strategy from its 3 cGMP compliant, I.M.B. approved manufacturing facilities. Major pharmaceutical manufacturers use Millmount Healthcare for blister packaging, bottling and warehousing requirements to achieve high-quality results with lower overheads.

Products & Services The ability to adapt to partners requirements is key to Millmount Healthcare remaining successful. A wide range of outsourced services are offered to meet industry's needs, including:

- Blister packaging
- Container/tub filling
- Pharmaceutical warehousing and storage
- · cGMP Packaging for vitamins and dietary supplements
- Secondary packaging
- Cartoning
- Labelling/over-labelling
- Repacking
- De-blistering
- Hand packing
- European site of importation for drugs coming off patent

**Key Customers** Millmount Healthcare has become the outsource service provider of choice for pharmaceutical, nutraceutical and healthcare manufacturers in Ireland and across the Eurozone. Each of its clients becomes a partner with whom close engagement is practiced, ensuring that the desired service exceeds expectations.

**Standards & Certifications** Irish Medicines Board approved, state-of-the-art GMP facilities with class 100,000 cleanrooms contained in our three manufacturing sites. Environmentally certified to BS 8555 standard by STEM (sustainable together through environmental management).

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# MOLL INDUSTRIES IRELAND LTD



**Business Description** Moll Industries Ireland Ltd. is an expert moulding partner and viable outsourcing solution for the medical device and pharmaceutical sectors, and conducts its business on the values of service, partnership and value.

Products & Services Moll Ireland is located in Donegal Town, servicing a range of medical device and pharmaceutical companies with Class 10K and 100K cleanroom moulding and assembly capabilities including:

- 2500 sq m moulding facility
- Injection moulding 50-300 tons
- Cleanroom moulding operation (10k & 100K)
- Cleanroom assembly cell (10K)
- General moulding white wall GMP

- Validations per GHTF guidelines
- Process and quality controls
- Automation & secondary operations
- Fully assembled devices
- Warehouse 280 pallet spaces on-site

A prime objective of the company is its commitment to providing cost effective products to the highest levels of customer service while meeting customers specifications and ensuring compliance to all industry regulatory standards.

**Key Customers** Moll Industries Ireland Ltd. supplies an international customer base including Abbott Nutritional, Abbott Medical Optics, Alcon, Allergan, Hospira and Stiefel.

**Standards ISO 9001:2008** 

Note Moll Industries Ireland Ltd. is a 100% Irish owned company following an MBO and had previously formed part of Moll Industries Inc. Dallas, US.

# **Contact Name / Title**

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# MULTIPRINT LARFLS

Business Description Multiprint provides and supplies printing and pressure-sensitive labels. Multiprint's business philosophy is to develop long-term relationships with customers, thus exceeding expectations using modern management thinking, innovative techniques and the latest technology to deliver results in measurable terms.

Products & Services Multiprint's business focus is on UV self-adhesive labelling which gives unrivalled depth in understanding customers' requirements. UV printing also ensures high quality results and consistency in colour from batch-to-batch/reel-to-reel. The main markets supplied into are personal healthcare, drink and fast moving consumer goods (FMCG) sectors. Multiprint Labels is an approved supplier to all the major multiples in the Republic of Ireland and the UK.

Key Customers Procter and Gamble, Interspray, Abbot, Intel, Kingsland Wines and Spirits, Constellation Group, Whyte and Mackay, Cooley Distillery.

Standards & Certifications ISO 9002, PS 9000, British Retail Consortium.

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#### NEW FRA PACKAGING ITD

**Business Description** New Era Packaging Ltd. is a printer of self-adhesive label products to the pharma and medical device industries for over thirty years. The facility boasts the most up-to-date printing equipment together with state-of-the-art, pre-press origination facilities.

Products & Services Extensive product range; high technical ability and infrastructure. Processes include UV flexo, Letterpress, rotary screen, cold foil and Braille. Products include:

- Plain and printed labels/tags up to nine colours (including Braille and Tactile print)
- Sub-surface UV Flexo printed on clear filmics
- Security labels and tapes
- Peel-N-Reseal/Dry Peel labels
- Pharmapak multipage booklet labels (with and without Braille)
- Chempak multipage booklet labels
- Wrap labels
- Hanging labels
- Cold Foil and Silkscreen
- Plain and printed packaging tapes

New Era has the expertise to take customer artwork from the design stage and manage it through to the finished product, and also provides a full after-sales service.

Key Customers Auden McKenzie, Custom Pharma, Norbrook Labs, Baxter Healthcare, DePuy, Rosemont Pharm, B-Braun, Hospicare, Harmac Medical, Sandoz, Becton Dickinson, Johnson & Johnson, Wyeth Pharmaceuticals.

Standards & Certifications ISO 9002, BRC/IoP Global Standard.

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#### NOVACHEM CORPORATION LTD

Business Description Novachem is a market leader in the manufacturing and distribution of an extensive and comprehensive range of engineering, manufacturing and industrial adhesives and sealants.

#### **Products & Services**

- Novachem offers an extensive range of UV adhesives, UV medical device adhesives ISO 10993 certified, UV
  low RI adhesives, anaerobic adhesives, cyanoacrylate adhesives, two-component polyurethanes, methacrylate
  adhesives (structural acrylics) and epoxy resins
- Expertise: extends to epoxies, urethanes and multi-functional light curing systems
- Innovative leader in the global adhesive and sealant market and strives to make significant contributions to manufacturing industry
- Technical group works closely with clients to identify criteria for resin systems to meet production needs and final product specifications
- Excellence in R&D allows Novachem to be the leading provider of adhesives at a global level

#### **Contact Name / Title**

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# OVE ARUP & PARTNERS IRELAND, T/A ARUP



**Business Description** Arup, founded by Ove Arup in 1946, is one of Ireland's largest consulting engineering practices with over 350 personnel. Arup provides a full range of multidisciplinary engineering consultancy services from offices in Dublin, Cork, Limerick, Galway and Belfast. As part of a worldwide group Arup is in a position to offer an integrated global services to our clients.

Products & Services Arup provides a wide range of consulting services to clients in the manufacturing sector. The approach is to deliver cost savings and improved efficiencies to clients through strategic advice and the application of optimised design and advanced technologies. Arup works in collaboration with client's in-house teams providing specialist and support services and skills tailored to suit specific projects. Through the application of strategic thinking, local knowledge and comprehensive range of consulting skills clients are enabled to pursue new opportunities for investment in R&D and manufacturing and to secure internal investment. Specialist services currently available to manufacturing clients across a diverse range of projects include:

- Energy management and conservation
- Mechanical/electrical/civil/structural engineering
- Environmental management, facilities management, project management
- · Masterplanning, BEM, safety health & welfare
- Risk & fire consultancy

Key customers Novartis, Eli Lilly, DePuy, Pfizer, Creganna, Stryker, Vistakon, University College Cork, Trinity College Dublin, University College Dublin, Health Service Executive.

Standards ISO 9001:2008, ISO 14001:2004, BREEAM accredited assessors, designs to EN Standards.

Additional Languages French, German, Polish, Spanish, Portuguese, English, Croatian & Italian.

Note A client focussed company, aiming to support green field development and upgrade extensions and enhancements to existing sites.

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#### PRODIECO PHARMACEUTICAL COMPONENTS

**Business Description** Prodieco supplies tooling for blister packaging machines, with all design work and manufacturing done on site in Dublin. Prodieco has many dedicated designers on the team, all using 3-D Solidworks.

Products & Services Prodieco offers toolsets for all blister packaging lines, machines include Uhlmann, Bosch, ima, cam and Noack. This includes forming tools, sealing tools, dedicated feeders, perforation tools, cutting tools and cartooning parts. The company also offers 3-D design services for blister drawings. Six on-site blister machines allows us to test and validate all tooling prior to dispatch. In addition, two feeder test rigs enable Prodieco to test Simtap feeders and also vertical feeders.

Key Customers Teva Group, Actavis Group, Boehringer, Pfizer, Mylan.

Standards & Certifications ISO 9001

Additional Languages German, Spanish, Italian, Polish.

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## PROTECTAS HEALTH LTD

**Business Description** Protectas Health Ltd. is the world's first dedicated cord blood bank for high performance horses and other animals. Protectas collects blood from the umbilical cord of new born foals, and using a patent protected process, extracts valuable stem cells from this blood.

#### **Products & Services**

- Collection and storage of Mesenchymal Stem Cells (MSC) from the umbilical cord blood of horses, which is then stored in three cryogenic freezers to maximise security of samples
- MSC's a valuable resource for the horse owner and can be used for research or therapeutic purposes
- When treating injuries, MSC's provide regenerative properties rather than the traditional repair properties of alternatives

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# QUMAS LTD

Business Description QUMAS has over 15 years experience in highly regulated industries, providing worldclass compliance solutions to over 250 customer deployments, including seven of the top ten pharmaceutical companies, four of the top ten biotechnology companies, and five of the top ten medical device companies.

**Products & Services** The QUMAS Compliance Solution™ consolidates and standardises regulatory compliance into a comprehensive framework that eliminates the cost of managing disparate and isolated applications. The three main elements of all QUMAS Solutions are:

- QUMAS DocCompliance<sup>™</sup> regulatory content management for electronic control of all documentation throughout the product lifecycle from R&D, to manufacturing and sales & marketing
- QUMAS ProcessCompliance<sup>™</sup> workflow and process management for deviations, CAPA, change control, audit
- MyQUMAS™ web-based single point of access for monitoring and responding to all compliance activities

QUMAS also offers pre-defined packaged solutions designed to address a specific business function and includes all required software, implementation services, training, and documentation to support that business function. Key Benefits

- Deep life science industry knowledge
- Compliance expertise
- Proven successful deployment/implementation experience

Key customers Boehringer Ingelheim, GlaxoSmithKline, Janssen (J&J), Takeda Ireland, Millennium Pharmaceuticals, Vertex Pharmaceuticals, Napp, Biogen Idec, Vistakon (J&J), Lantheus Medical Imaging, Sigma Aldrich, Eirgen, for example.

Standards ISO 9001:2000 certified for over 10 years and has been successfully audited by over 90 clients.

Additional Languages French, German, Italian, Spanish.

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## REAL REGULATORY ITD

**Business Description** Real Regulatory is a team of proven and committed experts in regulatory affairs, providing consultancy and hands-on assistance to the pharmaceutical, medical device and related industries. The company's team of professionals has many years experience and a wide range of expertise across the spectrum of regulatory affairs activities.

**Products & Services** Real Regulatory has the necessary expertise and capabilities that allow us to deliver on the extensive regulatory requirements. These include:

- Procedures that relate to the development and life cycle of new chemical entities (NCEs)
- Devices and diagnostics
- Known compounds
- Quality assurance matters

Key Customers Real Regulatory works with pharmaceutical and medical device companies of all sizes, and at all stages of development through to lifecycle management. Clients also include venture capitalists, CROs, natural health product and food companies.

Additional Languages French, German.

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## RECONCILE ENGINEERING

**Business Description** Reconcile Engineering is an innovative engineering and automation solutions provider, and is a leader in the development of label inspection systems. The company's systems can be found in many of the major pharmaceutical, healthcare, optical disc, automotive and printing industries throughout the world.

**Products & Services** Having developed unique production/packaging solutions, Reconcile offers complete bespoke & fully integrated turn-key solutions.

- Solutions to current gaps in the market in terms of "zero tolerance packaging"
- Conveying and labelling systems for a wide range of products
- Continuous ink jet, thermal ink jet & laser marking solutions complete with safety guarding provided
- Systems to assist customers in the reconciliation of their production lines
- Bespoke design and manufacture of complete validated automation solutions
- Solutions to increase capacity on existing equipment, complete integration offered

Key Customers Bausch & Lomb, GSK, Baxter, Eli Lilly, Catalent Pharma, Seven Seas, MSD Ireland, Arvato Digital Services.

**Additional Languages Czech** 

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# SCHIVO GROUP LTD



**Business Description** Schivo is a precision engineering business serving the medical device and aerospace industries, including critical assembly, cleanroom systems, machining, fabrication, full product build, and a vertically integrated SAP supply chain system. Schivo specialises in CNC multi axis machining.

**Products & Services** There are two principle areas to the business:

- High Precision Engineering, assembly and test Schivo Precision Limited
- Sheet Metal Fabrication, assembly and test Schivo Fabrication Limited

Locations in the UK and Ireland offer full supply chain support with the latest and most up-to-date technology including critical assembly, cleanroom systems, machining, fabrication, full product build, and a vertically integrated SAP supply chain system. The company specialises in CNC multi-axis machining and utilising highly skilled engineers and is capable of handling complex components using the latest CAD CAM programming. Materials machined include, Titanium, Inconel 718, Inconel 625 and other nickel based alloys as well as aluminium and exotic steels.

Key Customers Multi-national medical device organisations (predominantly operating in the orthopaedic, oncology and mass spectrometry fields) and 1st tier aerospace suppliers.

**Standards & Certifications** ISO 9001:2000, ISO 13485, AS9100, Schivo Group also has many company specific accreditations such as Rolls Royce (UK and Germany).

**Additional Languages French** 

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#### SEAL PACK ITD

**Business Description** Sealpack Ltd. is a leading supplier of quality labels and labelling systems to laboratories, hospitals and the medical device sector, and has built and established long-term partnerships with customers based on professionalism, reliability and trust.

**Products & Services** Sealpack works closely with every client to ensure rapid service and high quality products. Product range includes:

- Bar code labels (pre-printed)
- Variable information labels
- Die cutting and punching specialists
- Tamper evident and security labels
- Hazard warning labels
- Colour coded labels
- Cryogenic labels
- Blood pack labels and tags
- Special adhesives for laboratory environment

Key Customers Medical device sector, laboratories, hospitals.

Standards & Certifications ISO 9001:2000

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#### SI CONTROLS ITD



Business Description SL Controls provides international consultancy, design, simulation and commissioning services for industrial automation equipment and control systems worldwide. SL Controls has a positive track record with large projects successfully completed for multi-national corporations, with a large emphasis on the biomedical and pharmaceutical industries.

**Products & Services** SL Controls is a highly successful systems integration company based around core strengths in automation, integration & validation. Key areas of expertise and services include:

- Platform wide control systems
- Vision systems
- 21 CFR Part 11
- Batch execution & batch traceability
- GAMP 5 compliance
- Manufacturing control networks
- Overall systems effectiveness benchmarking
- Data analysis
- Overall equipment effectiveness
- Statistical process control (SPC)
- Service desk support
- Secure shell off-site support
- Knowledge capture systems
- Knowledge transfer systems

Key Customers Abbott Ireland, Wyeth Medica, Boston Scientific, Intel Ireland, Pfizer Ireland, Zogenix Incorporated, Nypro Ltd, Hewlett Packard, Henkel, KCI Medical, Baxter Healthcare, Vistakon Ireland, Patheon, Komax, Missouri Tooling & Automation.

Standards & Certifications ISO 9001:2000 certified, Microsoft Certified Partner.

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## SOCRATES HEALTHCARE LTD

Business Description Socrates develops software solutions for the global healthcare informatics sector, and specialises in integrated practice management and electronic health record (EHR) solutions for healthcare providers. Socrates' products enable medical practices to run more efficiently, reducing cost and optimising revenue for physicians, while improving patient safety.

Products & Services The healthcare Practice Management suite includes an advanced EHR solution to create a paperless office environment for doctors. The solutions are 100% Microsoft-based, delivered in the cloud on a software-as-a-service basis or as client-server. In Ireland, a thriving community of GP practices are completely reliant on the company software to assist them in every aspect of their clinical and administrative workflows. For US physicians company solutions are designed for full CCHIT compliance including e-prescribing, drug interactions, insurance eligibility and claims submissions.

Key Customers The Diageo Medical Centre, The Mater Private Hospital, Blackrock Hall Primary Care Centre, The Galway Clinic, Hermitage Medical Clinic, Charter Medical Group, for example. A US client list is available upon request.

Standards Microsoft Gold Certified Partner, Socrates is a member of the EuroRec Institute promoting the use of high quality Electronic Health Record systems in Europe, the Healthcare Informatics Society of Ireland (HISI), and the Healthcare Information and Management Systems Society (HIMSS) dedicated to promoting a better understanding of health care in the US.

Additional Languages German, Italian, French.

US Office: Socrates Healthcare Inc. 345 Park Ave 17th Floor New York, NY 10154-0037

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#### STERTPACK

**Business Description** SteriPack is a leading global supplier of medial packaging, package testing and contract manufacturing services for the medical device industry. SteriPack has a strong global presence with manufacturing facilities located in Ireland, Poland and Malaysia, with sales offices strategically located worldwide.

**Products & Services** SteriPack manufactures all products in a class 100,000 environment, and specialises in providing customised products supplied to customers exacting specifications. The range of products include pouches, header bags, blister lidding, rollstock, and contract services.

Standards & Certifications ISO 9001:2008, ISO 13485:2003, ISO 17025.

Additional Languages French, German, Polish, Malaysian, Mandarin.

Sales Offices Ireland, USA, Germany, France, United Kingdom, Poland, Malaysia, China, India and Japan.

# **Contact People for Overseas Markets:**

Germany: Christian Muller

Benelux / Scandinavia: Jes Greenwood

France: Max Carrein UK: Mike Bigwood India: Sanjay Sharma

Rest of the World: Barry Moore, John Ward

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#### SYNECCO

Business Description Synecco designs and manufactures devices for clients in the medical device and healthcare sectors. The core focus is the delivery of value-add solutions, from design services through to manufacturing. Headquartered in Galway, teams in China, the US and Ireland work with client organisations providing integrated solutions from product design through to manufacturing and fulfilment.

**Products & Services** Focussing on a total cost solution, Synecco delivers a high quality, lowest total cost design and manufacturing solution. Whether working in design or manufacturing phases, the most innovative and up-to-date techniques and processes are employed. Clients benefit from a dedicated and efficient service to support their requirements.

The company supply chain services are broken down into ten main functions -

- 1. Definition
- 2. Design
- 3. Development
- 4. Prototyping
- 5. Verification
- 6. Tool design & manufacture
- 7. Validation & regulatory
- 8. Production
- 9. Packaging & sterilisation
- 10. Logistics

**Key customers** Key customers are European- and American- based, with on-going developments in the Asian Market.

Additional Languages A variety of Chinese languages.

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# TOPCHEM LABORATORIES LTD TOPCHEM PHARMACEUTICALS LTD



Business Description TopChem Laboratories Ltd. (est. 2000) and TopChem Pharmaceuticals Ltd. (est. 2007), both located in Ireland, offer a broad base of integrated outsourcing services including GMP manufacturing capability for Phase 1 and niche, small volume generic API products, to pharmaceutical, biotechnology and generic drug companies worldwide.

#### **Products & Services**

Laboratories - www.topchemlabs.com

- Research chemicals (own product list of 200 products)
- · Reference standards and metabolites
- Active pharmaceutical ingredients R&D quantities of over 600 commercial products
- Synthetic route selection and development
- Process R&D
- · Troubleshooting manufacturing products and processes
- Technical consultancy

Pharmaceuticals - www.topchempharma.com

- Development of API processes and products to order
- Supply of qualification GMP batches
- GMP manufacturing from grammes to 300 kg/year
- · Niche, low-volume generic APIs
- Submission of DMFs to US, EU and other agencies
- Support services (reference standard impurities, metabolite, technical consultancy)

# **Contact Name / Title**

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# VENN LIFE SCIENCES LTD

Business Description Venn Life Sciences is a full-service clinical research organisation (CRO) providing comprehensive clinical trial management services to pharmaceutical, biotechnology and medical device companies. Headquartered in Ireland with offices in Europe, North America, Latin America and Australia, Venn's core team is enhanced by international partnerships.

Products & Services Venn provides a broad range of clinical trial services in Phase I-IV, through its experienced and focussed operations team and a network of skilled investigators and partners.

Venn's clinical trial services include -

Protocol development

Investigator gualification & site selection
 Project management

Medical monitoring

Site management

Data management

Medical writing

Organisation of investigator meetings

 Project rescue Health economics Feasibility

Clinical monitoring of Phases I-IV

Patient recruitment

Biostatistics/data analysis

Pharmacovigilance regulatory services

Quality assurance

Electronic data capture

Venn specialises in the fields of oncology, cardiology and neurology with added strengths in medical devices while retaining wide experience in a variety of other indications.

Standards ICH-GCP Guidelines Compliant along with company own SOPs.

Additional Languages English, French, German, Dutch, Spanish, Italian, Afrikaans, Croatian, Greek, Japanese, Hindi, Marathi, Norwegian, Lebanese, Russian, Slovakian.

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## ZENITH TECHNOLOGIES LIMITED



**Business Description** Zenith provides high 'value-added' automation solutions to customers in the biotech, pharmaceutical, power and oil and gas sectors. Zenith works across all the major DCS and PLC platforms and is based in Cork with offices in the US, the UK, Singapore and India.

#### **Products & Services**

- Consultancy FEED, project justifications, project health checks, system selection
- · Systems integration across all major automation platforms
- Training automation, IT, cGMP etc.
- Commissioning and qualification
- Managed services e.g. automation

Key Customers Novartis, GlaxoSmithKline, Pfizer, Merck, Wyeth.

Standards & Certifications ISO 9001:2000

Additional Languages German, French, Spanish, Italian, Hindi and Mandarin in regional offices.

#### **Contact Name / Title**

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