Kinesys provides a broad base of services to pharma and biotech clients, small and large alike. Our support covers technical, regulatory and management consultancy. We are proud of our people and our achievements. Come and talk with us!

Directors & Senior Consultants

Gerry McGettigan

Gerry, a molecular biologist, has 25 years’ experience in the biotechnology and pharmaceutical industries, in regulatory affairs, clinical development and business development, and in various Non-Executive Director roles. He has worked with large and medium pharma companies (Almirall, Spain and Glaxo, UK) and was Regulatory & Scientific Affairs Director of The Liposome Company, a US biotechnology firm. He founded the European regulatory affairs and product development consultancy company, GMG BioBusiness Ltd, which was sold to a top 5 CRO in 2005. He also set up and was CEO of the Catalan biotechnology development agency, Biocat, based in Barcelona. Gerry is currently Chairman of Clear Surgical Ltd, and Non-Executive Director of Syntropharma and Biopta.

Martin Jordan

After starting his biopharmaceutical career in Regulatory Affairs at Almirall in 1987, and thereafter in Palex (both Spain), Martin was head of EU Regulatory Affairs for Convatec (UK), a device subsidiary of BMS. He subsequently joined the board of MTC Europe, the largest specialist MedTech regulatory firm in the EU. He then set up and managed the European operations of Biomatrix Inc., a successful US biomaterials company subsequently acquired by Genzyme. Martin’s activities are in the area of Market Access and HTAs. He has significant commercial and regulatory experience with borderline & combination products as well as devices incorporating human and animal tissues, and a unique understanding of how the regulatory positioning of such products can affect their commercial success.

Emma Holmes

Emma Holmes has 20 years experience in Regulatory Affairs both in UK and on mainland Europe. Emma started out with Rentokil, subsequently moving to Bristol Myers Squibb. At BMS she was responsible for regulatory submissions to Central and Eastern Europe. Emma then moved to the BMS European HQ where she handled a number of key European projects. She returned to UK in 2003 to join GMG BioBusiness Ltd as Director, Regulatory Affairs. In this role she managed a team of regulatory professionals and ran the company's project management system. Emma's experience covers all stages of drug development. She has lead CMC, Nonclinical and Clinical projects across a range of therapeutic areas: oncology, CNS, anti-infectives, metabolism / endocrinology. She regularly advises on MAA, Scientific Advice, Paediatric Investigation Plans and Orphan projects, amongst others.

Mark Turner

Mark has over 21 years experience working in the industry primarily in Regulatory Affairs, In-Licensing and Business Development. Mark has comprehensive knowledge of EU and International Regulatory Affairs and Process Development in conjunction with new active substance, biotechnology, advanced therapies and generic product development. Mark is an expert in due diligence, life cycle management and global licence portfolio development. Specialties: Over 20 years global EU regulatory experience including Centralized, Decentralized and Mutual Recognition/national licensing of MAA’s, project management, due diligence, manufacturing compliance and technical transfer processes in EU. Therapeutic area experience in HRT, oral
contraceptives, CNS, generics, cardiovascular, metabolic disorders and endocrinology, oncology, anti-infectives / fungals, liposomal technologies, and GI.

Elaine Murphy

Elaine is a chemist with 22 years experience in bio-pharmaceuticals. She has worked in Regulatory Affairs with Cortecs, an emerging biotechnology company, Chugai, a medium size Japanese pharma firm, and was Regulatory Director of BMS in UK. She was a principal partner with Gerry McGettigan in their consultancy firm, GMG BioBusiness Ltd, where she oversaw the successful running of a range of projects and general management of the organization, including regulatory strategy, clinical trial applications, orphan drug designations, legal status changes, and major MAAs. Elaine has contributed to the successful development of small molecules and biotechnology agents in the fields of respiratory, oncology, haematology and GI diseases, and has particular expertise in biotechnology CMC issues. Latterly she has also taken a significant interest in Emerging Markets with Amgen.

Dr. Graeme Deuchar

Graeme has over 15 years experience working as a biomedical research professional. Graeme’s regulatory affairs experience is in a number of areas including biosimilars, scientific advice applications, CTAs and orphan product designations. He has also helped to design and now maintains the Kinesys Oncology & Orphan Products Database. As a researcher, Graeme has an impressive track record of developing and utilising preclinical disease models combined with imaging, in projects designed to improve understanding of disease mechanism and investigate novel diagnostic and therapeutic advances in areas of cardiovascular, pulmonary and neurological medicine. Graeme is a co-founder and acting research director for a recently formed biopharmaceutical company, Aurum Biosciences Ltd where he has a crucial role in planning the current and future research and development programme required to support continued progression of the company’s key technology through to a successfully translated product for acute stroke management. He is an integral member of the project management team responsible for development, regulatory and commercial planning.

Advisory Board

Gillian Watson

Gillian has an impressive pedigree in corporate finance, strategy and BD. Her career began with Morgan Stanley in London and later in Hong Kong. She then worked for Standard Chartered Asia Limited before leaving to attend business school. Thereafter, she joined the power and energy sector in the UK and continental Europe where she held senior management positions relating to company strategy and business development. She was Director of Corporate Strategy for Endesa SA, one of Spain’s leading utility businesses, before returning to Scotland from Madrid in 2006. In 2007, she was appointed CEO of Giltech Ltd, a privately-owned life sciences company, where she steered a board reorganisation and raised both equity and grant. She is currently leading projects in the renewables sector for ES Noble. Gillian also serves on the Boards of Scottish Enterprise, and Martin Currie Global Portfolio Trust. She was previously Vice Chair of the Board of Ayrshire & Arran NHS. Gillian has a degree in Mathematics from Edinburgh University and an MBA from INSEAD in France.

Dr. Xavier Luria

Dr. Xavier Luria is a consultant on drug development and drug regulation. He was Head of Safety and Efficacy at the European Medicines Agency (EMA) during 2005-2012, and was previously with Almirall (Spain), ultimately as Medical Director. At EMA, Xavier worked closely with CHMP, the highest regulatory committee in EU, and other regulatory bodies and committees. In addition to Dr. Luria's specialties in internal medicine, pharmaceutical medicine and biostatistics, he has developed
expertise in specific therapeutic areas. Xavier also has a postgraduate qualification in clinical pharmacology, drug development and regulation (Tufts University, Boston). He is a recognized expert on regulatory systems and benefit-risk assessment (modelling, development and methodologies).

**Dr. Leon Hooftman**

Leon is currently Chief Medical Officer at Synthon Holdings, an innovative Dutch biotechnology company, and was previously CMO at Chroma Therapeutics in the UK. Before joining Chroma he was Head of Clinical Development at Celltech Group, a FTSE 250 biopharmaceutical company. Prior to this he was Director of Clinical Science for Oncology/Immunology at F. Hoffmann La Roche, where he built up extensive experience of biotechnology development programmes, including Rituxan (lymphoma), and CellCept (transplantation). Dr Hooftman qualified in medicine in 1984. He trained in surgery and transplant medicine in Holland, the UK and USA and holds a MD and BSc in medical sciences of Utrecht University. He joined the industry in 1991.

**Gerry MacKay**

Gerry has had a long and distinguished career in the Biopharmaceutical industry and is currently CEO of BioOutsource, a specialist CRO based in Glasgow, UK. Focusing on Biotechnology and Biosimilars, the company has witnessed rapid growth during the last 4 years under Gerry’s leadership, and has worked with around 150 clients across all geographies. Previously Gerry ran several businesses for Millipore in Europe, Asia and North America. Gerry has led several merger and acquisition projects during his career. He graduated in Biochemistry from the University of Glasgow in 1983.

**Esteban Guardia Santisteban**

Esteban is the Founder/CEO of PLASMIA, a Biotech company based in Barcelona (Spain). PLASMIA develops novel and generic pharmaceutical products through bio-catalytic procedures. A practicing physician, Esteban gained his medical degree at the University of Navarra, and also holds a MBA. Esteban has significant experience in Licensing and Business Development with various companies, including Almirall. He was the founder and CEO of the start-up company FARMATEC, and is currently assessor and Board Member for Pharmaceutical and Medical companies.

**Prof. Peter O’Shaughnessy**

Prof O’Shaughnessy graduated with a BSc in Pharmacology from the University of Glasgow in 1976 and a PhD from the University of Bristol in 1979. After a post-doctoral period at the University of Michigan he became a Lecturer in Anatomy at the University of London before moving to the University of Glasgow in 1993 to take up a Lectureship in Physiology and Pharmacology at the Veterinary School. He was awarded a Personal Chair in 1998 and until recently was the Head of Dept of Preclinical Sciences at the Veterinary School. His particular areas of research expertise are in Reproductive and Developmental Biology. He sits on the Editorial Board of 3 journals. During the past ten years Peter has been Head of a commercial GLP-status laboratory at the University of Glasgow and has prepared expert reports in both human and veterinary medicine. He has assisted pharmaceutical and biotechnology companies with strategic and technical preclinical advice for regulatory submissions.

**Andrew Fox**

Andrew Fox is Senior Director, Regulatory Affairs at Exilixix and previously held a similar role at Onyx Pharmaceuticals. He leads their regional regulatory team based in the United Kingdom, covering Europe and other regions. He has previously held regulatory positions with Amgen, Warner Lambert and Sanofi Pasteur vaccines in Europe, the United States and in several Emerging Market countries. Andrew has worked in Regulatory Affairs for nineteen years, working almost exclusively with biologics and biotechnology products. He has broad experience in technical and regulatory aspects of the manufacture and control of biologicals and in clinical development for a variety of therapeutic areas including vaccines, rheumatology and oncology. Andrew has worked extensively on scientific and technical aspects of regulatory policies and guidelines for biologics and biosimilars. He has been an industry member of the World Health Organization working party on standards for approval for
biosimilar medicines, and has been a lead technical contributor to multiple policy discussions with regulators and legislators in the United States, Canada, Europe, Japan and Australia.

Our Services

Strategic Product Development

The combined experience of our Principals and Advisory Board of well over 100 years with pharma and biotech companies, as well as our business and academic expertise, puts us in an excellent position to advise companies on the general approach to designing their development programmes within the overall business strategy, and to directing the business and commercial strategy itself. The Principals and Advisory Board can draw on the experience we have of running companies, being responsible for business operations, heading up regulatory and clinical development functions, and holding non-executive directorship roles.

The specific experience we have includes:

- Set up the European function of a US biotech company with novel parenteral products
- Managing a European device company that was successfully sold to a major biotech player
- Project management of all development and regulatory projects for a consultancy firm successfully sold to a major US CRO
- Overseeing the registration all oncology products for a major US pharma in Eastern Europe
- Responsibility for the Regulatory, CMC and Clinical functions for various products that were ultimately registered and successfully marketed (details can be provided on request)
- Advising in Non-Executive Director roles for various companies including a firm developing transdermal products, a start up developing a stroke diagnostic, and a tissue testing company
- Setting up and running the Biotechnology Development Agency in Barcelona, Spain

Regulatory Affairs

We can help you find answers to the big questions, and the frustrating but often important small questions, that arise in your regulatory and development strategies. Our experience of larger pharma and SME companies helps us to understand the broader challenges facing large organisations as well as the needs of the smaller, developing companies:

- What is the best regulatory strategy to realise your business aims?
- How do development studies dovetail with value inflexion points?
- What will regulatory agency expectations be for your products and where are the likely pitfalls and major challenges?
- Is your development strategy consistent with your business imperatives?
- Design of development programmes and specific nonclinical and clinical studies.
- Selection of CROs to conduct studies from Phase 1 to Phase 3.
- “Hands-on” operational Regulatory Affairs and Clinical / Medical support.

Biotechnology & Biosimilars

Biotechnology-derived products now account for an increasing proportion of the biggest selling drugs on the market. This trend is set to continue with both novel recombinant agents and the follow-on Biosimilars. There has been a major increase in the development of monoclonal antibodies, growth factors, recombinant blood factors and other biotech products since the mid 1990's. Now we are also seeing important developments in stem cell, gene therapy and other advanced therapies.

Management Consultancy

The Team provides strategic, tactical analyses and consultancy to assist management and company development. We have set up, run and sold businesses, and represent several others at Board level. We have all held, and some of the Team continue to hold, senior executive roles in a number of companies prior to going into the consultancy field. The Management Team and Advisory Board are able to effectively combine business knowledge with product development, technical and regulatory skills to help drive your business forward. This has been demonstrated effectively at a number of emerging and developing companies in UK and elsewhere, as well as with major Pharma companies. We can provide Non-Executive Directors with a range of experiences in pharma and biotech companies. We can also assist with funding of start up and spin out companies.