SCENDEA

COLLABORATE | INNOVATE | SUCCEED

Scendea is a leading product development and regulatory consulting practice serving the pharmaceutical and biotechnology industry. We are committed problem solvers, redefining the meaning of customer service, with a focus on reducing time-to-market and minimising development costs.

A combination of scientific excellence, industry experience and a collaborative approach enable us to deliver high-quality innovative solutions, which allow our clients to succeed.

Our international team offers strategic and operational support in the fields of quality/CMC, non-clinical/toxicology, clinical/medical and regulatory, which guide products efficiently from early development to marketing approval.

CONTENTS

Page - 05 ABOUT.

Page - 06 PRODUCT & THERAPEUTIC EXPERTISE.

Page - 07 TEAM.

Page - 13 SERVICES.

Page - 19 TEAM EXPERTISE (CVs).

ABOUT

Scendea is a leading product development and regulatory consulting group serving the pharmaceutical and biotechnology industry.

COLLABORATE. INNOVATE. SUCCEED.

Scendea was founded as a result of a management buyout of the product development and regulatory consulting function of a clinical research organisation. Our origin dates back over 20 years, with involvement in over 1,000 development programmes.

Scendea's expert team delivers strategic and operational support in the fields of quality/CMC, non-clinical/toxicology, clinical/medical and regulatory to successfully guide products from early development to marketing approval.

A combination of scientific excellence, industry experience, commercial awareness and a collaborative approach allow our expert team to solve complex issues associated with medicinal product development. Scendea has team members based in the UK, Ireland, the Netherlands and the US, who deliver innovative and high-quality solutions aligned to jurisdiction-specific regulatory requirements.

At Scendea we collaborate, innovate, and together with our clients, we succeed.

PRODUCT & THERAPEUTIC EXPERTISE.

Scendea's origin dates back over 20 years, which includes involvement in over 1,000 development programmes in over 100 indications, in 25 therapeutic areas. Scendea's areas of expertise include oncology, infectious disease, respiratory and rare/orphan indications.

More than half of the development programmes supported to date include biologics. As such, our expert team hold exemplary knowledge in cell and tissue engineered products, gene therapies, vaccines, immunotherapies, antibody-based products (mAb, polyclonal, bi/tri-specific and antibody-drug conjugate), peptides and other recombinant products.

Scendea's team includes experts who have a particular focus in small molecule compounds, with over 30% of projects including new chemical entities. Generic [ANDA] and hybrid [505(b)(2)] compounds make up a further 10% of our projects.

In addition, our team have a high level of expertise in other project classes such as combination products, surgical and nutraceutical/functional food products.

TEAM

Scientifically Qualified.
Technically Minded.

Dr Gavin Edwards

Director & Principal Consultant.

Dr Gavin Edwards is a Director and Principal Consultant at Scendea; Gavin leads Global Operations and is accountable for revenue generation, client satisfaction and service delivery. Gavin is a business leader with over 15 years' experience, including an exemplary record leading large multinational consultancies.

Gavin has worked with companies including Lonza and ERA Consulting and served as Senior Director and Global Regulatory Service Line Leader at PAREXEL. Gavin's expertise includes pre-licensing activities for biotechnology products. Gavin served as CMC-lead author for the first biosimilar antibody approved globally. Gavin holds a BSc in Biochemistry and a PhD in Molecular Biology.

Dr Natalie Thomas

Director & Principal Consultant.

Dr Natalie Thomas is a Director and Principal Consultant and a member of the leadership team at Scendea. Natalie provides strategic regulatory, non-clinical and clinical development advice to clients in support of global development programmes. She currently sits on the Editorial Board of the regulatory professional journal, Regulatory Rapporteur.

Natalie began her career as a Research Scientist in the Australian Pharmaceutical industry. She moved into Medicinal Product Development and Regulatory Affairs consulting over ten years ago, working in roles at ERA Consulting and Voisin Consulting, prior to joining Clinical Network Services in 2014.

Dr Richard Turner

Director & Principal Consultant.

Dr Richard Turner is a Director and Principal Consultant at Scendea; Richard provides scientific and technical leadership and delivers expert CMC/Quality development advice to our clients. Richard has over 30 years' experience in the biopharmaceutical industry, beginning his career as a Research Scientist before joining the UK's MHRA as a Pharmaceutical Assessor. Whilst at the MHRA, Richard also acted as an expert to the EDQM and EMA.

Richard has held senior positions at Antisoma, Elan Pharma, ERA Consulting, Lonza Biologics and Daiichi-Sankyo Development. Richard holds a BSc in Applied Biology and a PhD in Biochemistry.

Dr Robert Dow

Chief Medical Officer.

Dr Robert Dow is the Chief Medical Officer at Scendea, responsible for providing technical/ regulatory advice and product development strategies. Robert was formerly the CMO at PPD and has over 37 years' experience in pharmaceutical and biotech industry. Robert has held a variety of executive positions including at PPD, Syntex, Hoffman La Roche, and Cell Genesys.

Robert has substantial experience in managing the transition of medicinal products from pre-clinical to clinical development and has experience in the fields of toxicology, pharmacokinetics, clinical science, clinical operations, regulatory affairs and drug safety. Robert holds a BSc (Med.Sci), a MB ChB, a MRCP (UK) and is a Fellow of the Royal College of Physicians of Edinburgh.

Dr Krassimira Ourumova

Principal Medical Consultant & Deputy Chief Medical Officer

Dr Krassimira Ourumova is a Principal Medical Consultant and Deputy Chief Medical Officer at Scendea. Krassimira provides both scientific, regulatory and clinical development advice and product development strategies to our clients.

Krassimira has 10 years of experience in clinical practice and over 25 years in pharmaceutical and biotech industry covering all aspects of pharmaceutical product development with a focus in clinical science and operations. Krassimira has extensive experience interacting with the FDA, EMA and a number of national regulatory authorities. Krassimira has held a variety of leadership positions including at MSD, GSK Bio and Daiichi Sankyo. Krassimira is a Medical Doctor certified in Anaesthesiology and Intensive Care.

Erik Doevendans

Principal Consultant.

Erik Doevendans is a Principal Consultant at Scendea. Erik has expertise in the full range of EU/US product development and regulatory projects undertaken at Scendea. Erik's strength is in CMC and regulatory strategy associated with biologics. Erik also has expertise in the field of Quality Assurance.

Erik has over 20 years' industry experience in the pharmaceutical industry holding positions at Pharming, Xendo and Dopharma. Erik was previously a Pharmaceutical Assessor at the Dutch MEB, and an expert to the EMA. Erik holds a degree in Pharmacy.

Amy B. Fix

Principal Consultant.

Amy Fix is a Principal Consultant at Scendea with over 20 years' experience in defining and executing strategy for global regulatory affairs for medicinal products. Amy has extensive experience interacting with the FDA and the EMA. Amy has previously held senior positions at Novavax, Emergent BioSolutions, Baxter, MedImmune and Shire.

Amy has successfully conducted numerous global regulatory meetings, and has been responsible for multiple INDs, BLAs, NDAs, and post-marketing programs and has worked with the WHO on global health initiatives. Amy holds a BSc in Biology, MSc in Molecular Biology and an MBA in Management.

Dr Christian Clauss

Principal Consultant.

Dr Christian Clauss is a Principal Consultant at Scendea with over 30 years' experience in Global Regulatory Affairs and Quality Assurance. Christian has expertise in the full range of EU/US product development and regulatory projects undertaken at Scendea. Christian is also a registered Qualified Person (QP).

Christian has extensive experience interacting with the FDA and EMA and has previously held senior positions at Novartis, Baxter, Sotio and Valident. Christian has successfully implemented multiple global product development and regulatory strategies. Christian holds a Master in Pharmacy, MSc in Bio-Pharmacy, a MBA (IAE) and PhD in Pharmacy.

Dr Angeles Escarti-Nebot

Principal Consultant.

Dr Angeles Escarti-Nebot is a Principal Consultant at Scendea with experience in the initiation, management and execution of regulatory projects from early development to marketing authorisation. Angeles has previously held positions in Paraxel and PhamaLex and her areas of expertise include regulatory strategy, non-clinical and quality development programs for the EU and US markets.

Angeles has a strong scientific background with more than seven years' experience on biotechnology research and more than 10 years' experience in a regulatory environment. Angeles holds a PhD in molecular biology (gene and cell-based therapies), BA in Pharmacy, MS in Clinical Genetics and MS in Neuropharmacology.

Dr Igor Gonda

Principal Consultant.

Igor Gonda is a Principal Consultant at Scendea responsible for providing technical/regulatory advice and product development strategies. Igor has over 40 years' experience in all aspects of pharmaceutical product development including extensive experience interacting with the FDA and EMA as well as patient advocacy groups. Igor has held a variety of executive positions including at Genentech, Acrux and Aradigm.

Igor has an in-depth understanding of inhalation product development. Igor has significant experience in the respiratory and infectious disease fields. Igor holds a BSc in Chemistry, a PhD in Physical Chemistry and has conducted inhalation product research and lectured at several universities in the USA, Europe and Australia.

Kenneth Kleinhenz

Principal Consultant.

Kenneth Kleinhenz is a Principal Consultant at Scendea with over 25 years' experience in product development and regulatory affairs. Kenneth has extensive experience interacting with the FDA and the EU Authorities. Kenneth has held numerous executive-level quality assurance and regulatory affairs positions including at Cytori Therapeutics, Avelas Biosciences, MacroPore Biosurgery, Becton Dickinson and Pacific Pharmaceuticals.

Kenneth is a veteran of the United States Navy where he served as a Clinical Microbiologist for 6 years at the Naval Hospital, San Diego. Kenneth holds a BSc in Microbiology and an MBA in Technology Management.

Dr Patrizia Nestby

Principal Consultant.

Dr Patrizia Nestby is a Principal Consultant at Scendea with over 20 years' experience in defining and executing strategy for global regulatory affairs for medicinal products. Patrizia has worked within industry and consultancy environments.

Patrizia is a biomedical scientist with a PhD in Neuropharmacology from the Free University of Amsterdam, The Netherlands. She has an MSc in Regulatory Affairs (completed with distinction) from the University of Cardiff. Patrizia is an Honorary Fellow of The Organisation of Professionals in Regulatory Affairs (TOPRA).

Dr Clare Ryder

Head of Project Management & Principal Consultant.

Dr Clare Ryder is Head of Project Management and a Principal Consultant at Scendea. Clare provides operational leadership to the project delivery team ensuring timely, high quality on budget delivery of contracted services. In addition, Clare provides strategic regulatory and scientific advice to clients for global development programmes and has experience across the full product lifecycle.

Clare has 25 years' experience in the pharmaceutical and CRO industries with extensive experience gained in regulatory affairs over 19 years. Clare holds a BSc in Chemistry and PhD in Synthetic Organic Chemistry.

Cynthia Lee

Principal Consultant.

Cynthia Lee is a principal consultant at Scendea. She specialises in auditing, providing training/coaching for API, finished product pharmaceutical and contract laboratories in cGMP manufacturing, laboratory, and Quality Assurance operations.

Cynthia has 30 years of experience in the pharmaceutical industry, 20 years of service with the FDA as a pharmaceutical chemist and investigative analyst and the past 10 years as an independent consultant active in assisting firms with corrective actions from FDA inspections, performing mock inspections and gap assessments, coaching prior to and during FDA inspections, and providing due diligence assessments.

Dr Martin Moxham

Principal Consultant.

Dr Martin Moxham is a Principal Consultant at Scendea, specialising in non-clinical and clinical aspects of pharmaceutical product development and regulatory affairs. Martin's role at Scendea is to act as the technical lead for projects requiring non-clinical and clinical expert knowledge.

Martin has over 28 years' industry experience, with over 20 years' in managerial roles in positions with Akos International Consultancy, Mitsubishi Pharma Europe, iRegulatory and Alkermes. Martin holds a PhD in Biochemical Pharmacology from the Royal Postgraduate Medical School and is a fellow of TOPRA.

Yoshi Shinoki

Principal Consultant.

Yoshi Shinoki is a Principal Consultant at Scendea with over 35 years' experience in product development and regulatory affairs. Yoshi was formerly the head of Parexel Consulting in Japan and has extensive experience with interacting with the PMDA. Yoshi has held numerous executive-level clinical development and regulatory affairs positions including at Eli Lilly, Covance and Parexel.

Yoshi has led various development projects focused on initiating clinical development or obtaining marketing approval in Japan. Yoshi is a registered Pharmacist and holds a BSc from Kyoto Pharmaceutical University.

Dr Jens van Wijngaarden

Principal Consultant.

Dr Jens van Wijngaarden is a Principal Consultant at Scendea with over 14 years' experience working within the Dutch MEB, for the last 8 years holding the highest regulatory affairs position as principal advisor to the Board. He was also the NL Boards' representative at the ATMP's Committee and Appeal and Hearings Committee.

From 2012 - 2021, Jens initiated and led the scientific advice department within the Dutch MEB, where he provided advice to over 500 companies. Jens has a real strength in defining and implementing creative regulatory strategies and holds an MSc and PhD in Biomedical Sciences.

Zeb Younes

Principal Consultant.

Zeb Younes is a principal consultant at Scendea with over 20 years' experience in biopharmaceutical development, Zeb has experience with tissue, cell and gene therapies, vaccines, recombinant proteins including enzymes, hormones, monoclonal antibodies and their derivatives and has authored and supported preparation and review of scientific advice briefing packages.

Zeb has extensive experience interacting with the FDA, EMA and other regulatory agencies such as EU nationals, ANVISA and Health Canada for scientific advice discussions. Zeb holds a 1st in Class BSc (Hons) in Medical Biochemistry.

Dr Hannah Lewis

Consultant.

Dr Hannah Lewis is a Consultant at Scendea, working within the regulatory team. As part of her role, Hannah is responsible for the authoring and compilation of regulatory submissions to European and US agencies. Hannah also provides consulting and procedural support to clients within her role as project manager.

Hannah holds a PhD and MRes in Cardiovascular Research from King's College London and has 5 years' experience working in an academic research environment. Hannah has a background in physiology and is a member of The Organisation for Professionals in Regulatory Affairs (TOPRA).

Bethany Aykroyd

Associate Consultant.

Bethany Aykroyd is an Associate Consultant at Scendea. Bethany is responsible for the authoring and compilation of regulatory submissions to European and US agencies, in addition to providing consulting and procedural support to clients within her role as project manager.

Bethany holds a BSc (Hons) in Biomedical Science from the University of Essex and an MPhil in Clinical Science (Rare Diseases) from the University of Cambridge. She is also in the final stages of completing a PhD in Physiology, Development and Neuroscience from the University of Cambridge.

Dr Evyenia Shaili

Senior Consultant.

Dr Evyenia Shaili is a Senior Consultant at Scendea, with experience in the initiation, management and execution of regulatory projects from early development to marketing authorisation. Evyenia started her professional career after academia by working as a scientific officer at the Europeans Medicines Agency (EMA), followed by industry experience gained at PAREXEL and Amgen.

Evyenia's experience has focused on pre-authorisation development and regulatory activities. Evyenia has experience in a wide range of therapeutics areas but has a peak of knowledge in the oncology space. Evyenia has a PhD in the field of anticancer drug discovery, an MSc in Mathematical Biology and Biophysical Chemistry and a BSc In Biomedical Chemistry.

Amy Cooke

Consultant.

Amy Cooke is a Consultant at Scendea with experience in Regulatory Affairs/Product Development consulting. In her role as Consultant, Amy works on the full scope of US and EU regulatory and technical/scientific activities, in addition to acting as the Project Manager for a number of Scendea's clients and managing a range of submissions to the Regulatory Authorities in Europe.

Amy holds a BSc in Biomedical Science and MSc in Cancer Biology from the University of Kent and is a member of The Organisation for Professionals in Regulatory Affairs (TOPRA).

Iheoma Anosike

Associate Consultant.

heoma Anosike is an Associate Consultant at Scendea and is involved in the provision of regulatory procedural and submission support to clients, across EU, US and Australia. Alongside authoring documentation for clients, Iheoma is responsible for creating weekly regulatory intelligence briefing reports which summarise the latest guidelines and news from various parts of the world, including Australia, New Zealand, Europe, Canada and the US.

Iheoma holds a BSc in Biochemistry from the University of Birmingham and an MSc in Advanced Chemical Engineering from Imperial College London.

Dr Leticia Monjas Gómez

Associate Consultant.

Dr Leticia Monjas Gómez is an Associate Consultant at Scendea. Leticia is responsible for the authoring and compilation of regulatory submissions to European and US agencies, in addition to providing consulting and procedural support to clients within her role as project manager.

Leticia has experience in drug discovery from several academic research laboratories. She worked in various therapeutic areas including metabolic and infectious diseases. Leticia holds a MSc in Organic Chemistry from the Complutense University of Madrid (Spain), and a PhD in Medicinal Chemistry from the University of Groningen (The Netherlands).

Dr Rehma Chandaria

Consultant.

Dr Rehma Chandaria is a Consultant at Scendea. Rehma works on the full scope of US and EU regulatory, scientific and technical activities, with a particular focus on cell and gene therapies and is project manager and primary point of contact for a range of clients.

Prior to joining Scendea, Rehma worked as a research scientist in the pharmaceutical and biotechnology industry, including roles at GSK and Autolus. Rehma has a background in pharmacy and started her career as a Pharmacist. Rehma has a PhD in Tissue Engineering, and Master's degrees in Drug Discovery Skills, and Pharmacy.

Harriet Thomasson

Consultant.

Harriet Thomasson is a Consultant at Scendea. In her role as Consultant, Harriet acts as project manager for our global clients, preparing a range of documents and interacting with key regulatory authorities on their behalf. Harriet has a wealth of experience in European procedures and enjoys supporting our overseas clients in navigating this complex regulatory landscape.

Prior to joining Scendea, Harriet gained experience as a Medicinal Chemist specialising in small molecule drug discovery. Harriet holds an Integrated Master's Degree in Chemistry.

Dr Sarah Kendall

Associate Consultant.

Sarah Kendall is an Associate Consultant at Scendea. Sarah is responsible for the authoring and compilation of regulatory submissions to European and US agencies, in addition to providing consulting and procedural support to clients within her role as project manager. Sarah is also involved in creating weekly regulatory intelligence briefing reports which summarise the latest guidelines and news from various parts of the world, including Australia, New Zealand, Europe, Canada and the US.

Sarah holds a first-class BSc in Biochemistry from The University of Surrey and PhD in Cardiovascular Science, specialising in stem cell and regenerative medicine, from Kings College London.

SERVICES

Scendea's expert team delivers strategic and operational support in the fields of quality / CMC, non-clinical / toxicology, clinical / medical and regulatory affairs.

HOW WE WORK WITH OUR CLIENTS.

Ad Hoc.

Ad Hoc consulting is a pay-as-you-go solution ideal for smaller activities required on a rapid timescale.

Project Based.

Our Project Based solution is ideal for larger activities with a clear scope. We work closely with clients to build a bespoke solution and define a budget accordingly.

Partial FTE.

Partial FTE is a solution that offers a higher degree of integration with client's activities, through the allocation of a dedicated expert, for a flexible period.

PARTIAL FTE SOLUTION.

Scendea's Partial FTE allows clients to retain a member or members of our market-leading Product Development & Regulatory Consulting team for a flexible period. Through consultation, we work with clients to identify the resource / expertise needs of their organisation and provide a bespoke solution to bridge the resource/expertise gap.

Our Partial FTE solution is ideal for clients who would like a dedicated expert or team of experts but are unable to identify and predict the scope of work upfront. At Scendea, we allow the flexibility to adjust the utilisation at any given time, without penalty, making this the ideal solution for clients with an immediate need for extra resource and/or expertise.

BENEFITS OF OUR PARTIAL FTE SOLUTION.

- Provides access to the right expertise required to achieve your company's objectives.
- Allows clients the ability to rapidly implement and terminate a solution, in line with business needs.
- Considerably more cost effective than other solutions.
- Allows a higher degree of integration and alignment with your internal team.
- A flexible solution allowing you to adjust resource allocation and project length at any given time.

WHEN IS A PARTIAL FTE SOLUTION REQUIRED?

- You may need additional resource when faced with a leave of absence, such as, maternity/paternity leave or sickness.
- During unusual peaks of workflow or high-pressure periods.
- During active recruitment periods. Our Partial FTE solution relieves pressure if your organisation is struggling to find the right candidate.
- If your organisation is experiencing a gap in expertise but cannot justify a full-time hire, such as a part-time head of CMC, non-clinical or clinical or regulatory. Scendea's Partial FTE bridges this gap without long-term commitment.

DISCOVER.

The Scendea team is comprised of highly skilled ex-regulators, CMC, toxicology, medical writing, regulatory affairs specialists and consultant clinicians based in the UK, US and Europe.

Our hand-picked team work closely with clients to design and implement manufacturing, non-clinical and clinical plans, remaining mindful of commercial timelines and budgets whilst adhering to global regulatory standards.

Discover examples of our services.

CMC / QUALITY
DEVELOPMENT ASPECTS.

NON-CLINICAL / TOXICOLOGY
DEVELOPMENT ASPECTS.

CLINICAL DEVELOPMENT
ASPECTS.

RESOLVING PRODUCT
DEVELOPMENT ISSUES.

DRUG DEVELOPMENT
PLANNING.

REGULATORY STRATEGY
DEVELOPMENT.

AGENCY
INTERACTIONS.

PAEDIATRIC
DEVELOPMENT.

ORPHAN DRUG
DESIGNATION.

TECHNICAL / MEDICAL /
REGULATORY WRITING.

CLINICAL TRIAL ASSOCIATED
REGULATORY ACTIVITIES.

MARKETING APPROVAL /
PREPARATION AND REVISIONS.

OTHER US SPECIFIC
REGULATORY ACTIVITIES.

OTHER EU SPECIFIC
REGULATORY ACTIVITIES.

PROGRAMME / PROJECT
MANAGEMENT.

VENDOR SELECTION
& MANAGEMENT.

EXPERTISE

Dr Gavin Edwards BSc (Hons), PhD

Director and Principal Consultant
Date Appointed to Position: January 2019

ACADEMIC QUALIFICATIONS.

PhD Molecular and Cellular Biology - 2007
Department of Pharmacy and Pharmacology, University of Bath, UK.

BSc (Hons) Biochemistry - 2003
Department of Biological Sciences, Lancaster University, UK.

EMPLOYMENT RECORD.

Senior Director, Global Regulatory Service Line Leader
Parexel Consulting – 2017 – 2018

Senior Director, Integrated Product Development, Head of European Head of Practice
Parexel Consulting – 2016 – 2017

Director, Integrated Product Development
Parexel Consulting – 2014 – 2016

Manager, Integrated Product Development
Parexel Consulting – 2012 – 2014

Senior Consultant, Integrated Product Development
Parexel Consulting – 2011 – 2012

Senior consultant
ERA Consulting (UK) – 2010 – 2011

Regulatory Affairs Project Manager
ERA Consulting (UK) – 2008 – 2010

Research and Development Scientist, New Product Development Group
Lonza Biologics – Sep 2007 – Nov 2008

PROFESSIONAL SOCIETIES.

The Organisation for Professionals in Regulatory Affairs (TOPRA)
Member.

The Organisation for Professionals in Regulatory Affairs (TOPRA)
Lecturer, Chair and Member of Organising Committee, TOPRA M.Sc. Regulatory Affairs 2012 - 2015, University of Wales.

The Organisation for Professionals in Regulatory Affairs (TOPRA)
TOPRA Awards 2013, Communication (Finalist).

Previous Experience

Senior Director, Global Regulatory Service Line Leader - PAREXEL Consulting
Responsibilities:

- Responsible for USD 35 million profit and loss.
- Accountable for all group operations and financial outcomes, including revenue generation, client satisfaction and service delivery.
- Responsible for high growth and profitable business through strategic planning, business development and implementation of high-level service delivery within regulatory group.

Senior Director, European Head of Practice - PAREXEL Consulting
Responsibilities:

- European Head of Practice; led team of >100.
- Responsible for high growth and profitable business through strategic planning, business development and implementation of high-level service delivery within service line.
- Accountable for all activity and financial outcomes within Europe, including revenue generation, client satisfaction and service delivery.

Director - PAREXEL Consulting
Responsibilities:

- Portfolio Director for multiple top 25 accounts.
- Line Management responsibility for UK- and Ireland-based line managers.
- Responsible for all aspects of set-up and success of Ireland-based consulting function.
- Supported business growth and profitability through strategic planning, business development and implementation of high-quality service delivery.
- Provide operational and strategic leadership for European business development activities.

Manager - PAREXEL Consulting
Responsibilities:

- Ensured business continuity, high quality service delivery and profitability for UK-based consulting services.
- Line Management responsibility for team of UK and Germany-based Associates, Senior Associates, Consultants and Senior Consultants.
- Support European business development and recruitment activities.

Senior Consultant - PAREXEL Consulting
Responsibilities:

- Served as CMC-lead author for several biosimilar monoclonal antibody-containing products, including the first biosimilar monoclonal antibody approved globally.
- Worked with companies developing biosimilar trastuzumab, infliximab, rituximab, bevacizumab and etanercept.
- Consulted with medicinal products at all stages of development, ranging from proof-of-concept to post marketing authorisation, consulting activities included: attendance of agency meetings, preparation CTD sections for MAA, BLA, and CTA applications, the review of client data packages in order to assess the feasibility of marketing approval, and the preparation of strategy reports.

Regulatory Affairs Project Manager/Senior Consultant - ERA Consulting (UK)
Responsibilities:

- Served as the primary point of contact and project manager for over ten multinational clients, including ERA's second and third 'largest' clients. Ensured the delivery of accurate and well-written client reports in accordance with mutually agreed timelines.
- Consulted with medicinal products at all stages of development, in the area of CMC.

Research and Development Scientist - Lonza Biologics Plc.
Responsibilities:

- Delivery of Lonza's novel manufacturing cell line, Potelligent. This flagship project involved the commercialisation of FUT8 knock-out CHOK1SV which provides a means for the manufacture of afucosyl antibodies.
- Ensured delivery of all aspects of this multi-disciplinary project according to timelines.

Dr Natalie Thomas BSc (Hons), PhD

Director and Principal Consultant
Date Appointed to Position: November 2019

ACADEMIC QUALIFICATIONS.

PhD Biochemistry and Molecular Biology - 2010
Monash University, Australia

Graduate Certificate of Commercialising Research - 2010
Monash University, Australia

Research Honours (Biochemistry & Molecular Biology) - 2004
Monash University, Australia

BSc (Hons) Biomedical Science (Medicinal Chemistry) - 2003
Monash University, Australia

EMPLOYMENT RECORD.

Senior Consultant
Clinical Network Services – 2014 – 2019

Consultant Editor & Regulatory Rapporteur
TOPRA – 2014 – 2014

Senior Regulatory Scientist
Voisin Consulting Life Sciences – 2013 – 2014

Senior Project Manager
ERA Consulting – 2012 – 2013

Project Manager
ERA Consulting – 2010 – 2012

Research Scientist (Part-time)
Alchemia Ltd – 2006 – 2010

Research Assistant
Monash University – 2004 – 2006

Laboratory Tester (Part-time)
Silliker Microtech – 2000 – 2004

PROFESSIONAL SOCIETIES.

Regulatory Affairs Professionals Society (RAPS) - Regulatory Affairs Certification (EU)

The Organisation for Professionals in Regulatory Affairs (TOPRA) - Member

Previous Experience

Senior Regulatory Scientist - Voisin Consulting Life Sciences
Responsibilities:

- Product development plan and strategic regulatory advice, focusing on Advanced Therapy Medicinal Products (ATMPs).
- Preparation of briefing documents for European national scientific advice, EMA central scientific advice/protocol assistance and regulatory applications for Orphan Drug Designations and Paediatric Investigation Plans.
- Regulatory authority interactions including with the EMA (attendance at scientific advice pre- submission meetings and discussion meetings, COMP oral hearings, PIP pre-submission meetings).
- Non-clinical/clinical due diligence, gap analyses and regulatory strategy development activities.

Senior Regulatory Affairs Project Manager - ERA Consulting (UK) Ltd.
Responsibilities:

- Authoring and review of regulatory documentation: Clinical Trial Applications, IMPD (nonclinical/clinical), IB and study protocol (review); and Paediatric Investigation Plans (PIPs).
- Preparation of briefing documents for European national scientific advice, EMA central scientific advice/protocol assistance, FDA meeting packages (pre-IND meetings); preparation/strategic design of list of questions, review of company position statements.
- Regulatory authority interactions with the EMA (including attendance at scientific advice pre-submission meetings and discussion meetings, COMP oral hearings, PIP pre-submission meetings) and national regulatory agencies (including attendance at MHRA, MPA meetings) and the NIBSC (meeting attendance).
- Dossier preparation for 2 MAAs in CTD format; co-authored/ reviewed Modules 2.5 and 2.7, authored Modules 2.4 and 2.6); prepared Orphan Drug Designation (ODD) applications.
- Non-clinical/clinical due diligence, gap analyses and regulatory strategy development activities.
- Conference presentations (off-site conference presentations and training workshops).

Research Scientist– Alchemia Ltd.
Responsibilities:

- Screening of candidate molecules for colon cancer treatment.
- Evaluation of drug candidate efficacy/safety in vivo.
- Drafting of documentation to support applications to regulatory authorities.
- Design and project management of non-clinical oncology therapy studies.
- Research, data collection, entry and statistical analysis.
- Preparation of extensive reporting documentation (study protocols, study reports, standard operating procedures etc.)
- Scientific techniques: Cell based cytotoxicity assays, immunohistochemistry, histology, small animal model generation and use (predominantly xenograft models).

Research Assistant - Monash University, Melbourne, Australia.
Responsibilities:

- Contribution to the design and execution of studies to support the non-clinical evaluation of novel chemotherapeutic formulations.
- Scientific techniques: Cell based cytotoxicity assays, immunohistochemistry, histology, in situ hybridisation, small animal model generation and use (predominantly xenograft models), and high-performance liquid chromatography (HPLC).
- Preparation of reporting documentation and compliance with GLP.

Dr Richard Turner BSc (Hons), PhD, CBiol

Director and Principal Consultant
Date Appointed to Position: July 2014

ACADEMIC QUALIFICATIONS.

PhD Microbial Biochemistry – 1990
University of East Anglia, UK

BSc (Hons) Applied Biology – 1986
Thames Polytechnic, London, UK

PROFESSIONAL SOCIETIES.

The Organisation for Professionals in Regulatory Affairs (TOPRA) – Member

Institute of Biology – Chartered Biologist

EMPLOYMENT RECORD.

Director Regulatory Affairs - Daiichi Sankyo Development
2011 – 2014

Head of International Regulatory Affairs – Lonza Biologics
2008 – 2011

Director of Regulatory Affairs – ERA Consulting
2005 – 2008

Associate Director, European Regulatory Affairs – Elan Pharma Inc.
2005 – 2005

Regulatory Affairs Manager – Antisoma plc
2001 – 2004

Senior Registration Executive – YRCR-ICON
2000 – 2001

Pharmaceutical Assessor – Medicines Control Agency
1997 – 2000

Research Scientist – Delta Biotechnology Ltd
1991 – 1997

Research Associate - Metallobiology Unit, University of East Anglia
1990 – 1991

Research Assistant - Metallobiology Unit, University of East Anglia
1986 – 1990

EMPLOYMENT RECORD.

Research Assistant - Vaccine Research and Production Laboratory, Centre for Microbiology and Research
1984 – 1985

Research Technician - Biotechnology Dept., Ciba-Geigy Pharma
1984 – 1984

Technician – Amersham International Plc
1982 – 1983

Previous Experience

Director Regulatory Affairs - Daiichi Sankyo Development (DSD)
Responsibilities:

- Provide EU and global regulatory strategies to global International Project Teams (IPT) for EU development of the company's portfolio of biotechnological medicinal products and biosimilar medicinal products for oncology and metabolic indications.
- Manage the compilation and submission of CTAs, IMPDs, MAAs, PIPs, Scientific Advice applications and Orphan Drug Designation applications for oncology products in EU and non-EU European territories.
- Provide advice and direction to global product development teams for CMC, non-clinical and clinical development from pre-phase I to MAA for new biological, biosimilar and chemical oncology development candidates.
- Ensure regulatory compliance of all in phase EU clinical trials for oncology and metabolic indication products.
- Manage interactions with EU and non-EU regulatory authorities within DSD's responsible regions, including Scientific Advice, PIPs, and responses to agency queries.
- Provide high level advice for the development of biosimilar monoclonal antibody products in the EU, US and Japan and global commercialisation.
- Represent Regulatory Affairs as the global lead on biosimilar development teams.
- Provide regulatory lead during in-license procedures for expansion of Daiichi Sankyo's European and global oncology portfolio.
- Manage and mentor junior members of the DSD regulatory team with particular reference to development of biotechnological and biosimilar medicinal products.
- Provide education to senior regulatory colleagues in Japan, US and Asia on ongoing and forthcoming EU regulatory requirements for biotechnological medicinal products, biosimilars and procedural requirement for clinical trials, MAAs, Orphan Drug Designations etc.

Head of International Regulatory Affairs – Lonza Biologics plc.
Responsibilities:

- Develop, implement and direct global policies for Regulatory Affairs services covering Lonza Biologics mammalian and microbial manufacturing facilities worldwide.
- Ensure regulatory compliance of global Lonza Biologics manufacturing sites.
- Provide high level strategic and scientific regulatory advice to Lonza Biologics' customers to ensure successful completion of global regulatory filings (MAAs BLAs, NDAs, Scientific Advice requests, Orphan Drug Designations etc.).
- Provide regulatory lead in Lonza Biologics strategic partnership for development of portfolio of biosimilar monoclonal antibodies.
- Support Lonza Biologics business development, R&D, manufacturing and quality assurance to obtain new business and maintain company business objectives.
- Provide a structured regulatory database of global regulatory requirements for manufacture and development of biopharmaceuticals.
- Represent Lonza Biologics and customers during interactions with global regulatory authorities.
- Ensure Lonza Biologics global manufacturing facilities maintain the required GMP licensure to support manufacture of recombinant proteins for all phases of clinical development and commercialisation.
- Liaise with Lonza Biologics customers' regulatory departments to provide tailored services for the global development of their products.
- Review regulatory documentation provided to customers to ensure compliance to current regulatory standards and expectations.
- Manage and develop UK and US based Regulatory Affairs professionals.

Director of Regulatory Affairs – ERA Consulting (UK) Ltd.
Responsibilities:

- Provide scientific and development advice for client projects at CMC, non-clinical and clinical levels.
- Provide strategic regulatory advice for client projects for all phases of development, with particular emphasis on the European arena, including organizing and leading meetings with regulatory authorities.
- Manage and mentor all members of staff at ERA's London and other global sites with regard to client projects.
- Project manage client projects to ensure timely delivery of project within the specified budget.
- Write and review regulatory documentation pertinent to client needs, including gap analyses of data packages, Scientific Advice documentation, labelling, CTA/IND/IB documentation and full MAA sections, including expert reports.
- Partake in business development activities for the UK office and the Group as a whole, including conference presentations, exhibition attendance and individual client business development meetings.
- Manage the day to day business of the UK office, including budget development, staff development and recruitment activities.

Associate Director European Regulatory Affairs – Elan Pharma Inc.
Responsibilities:

- Review of CMC data required for regulatory submissions, including MAA, responses to consolidated questions, Scientific Advice and CTA applications for Elan's biotechnological products.
- Initiate, write and compile regulatory submissions with respect to CMC data for global regulatory submissions.
- Advise cross functional teams on CMC and related regulatory issues.
- Provide guidance on regulatory requirements to manage change control.
- Liaise with Elan business partner (Biogen Idec) on development of Tysabri (natalizumab).
- Lead interactions with EU regulatory agencies relating to CMC and clinical development of biotechnological products.
- Management of Regulatory Affairs managers working on all aspects of CTAs.
- Provide regulatory intelligence principally on CMC and clinical trial issues.
- Develop and train regulatory and clinical development personnel on operational and QA SOPs.

Regulatory Affairs Manager – Antisoma plc.
Responsibilities:

- Global regulatory development and strategy from proof of principle through pre-clinical and clinical to marketing authorisation.
- Initiate, write, compile and submit complete CTAs (CMC, Preclinical and Clinical sections) and Orphan Drug Designation applications for FDA (IND), European (CTX/CTA) and other global regulatory authorities.
- Organise and lead meetings with regulatory authorities.
- Provide expertise for all CMC aspects of drug development, ensuring compliance with ICH, FDA and EU guidelines for both biotechnological and small molecules.
- Advise on manufacturing strategies, testing, specifications, controls and resolution of CMC issues. Ensure compliance of international and local GMP regulations including appropriate change and deviation controls. Set up and maintain technical agreements with external contract manufacturers and testing houses.
- Develop and maintain acceptable batch release, labelling and distribution procedures to ensure consistent clinical drug supply.
- Provide regulatory guidance for preclinical toxicology and pharmacology testing to comply with relevant guidelines.
- Evaluate and advise clinical strategies and protocols for clinical trial submissions.
- Write and review SOP for in house quality systems.
- Liaise with external contractors providing manufacturing and testing services relating directly to regulatory requirements for clinical trial and marketing authorisations.
- Represent regulatory department on specialist and cross functional project teams, and to senior management including executive board. Represent Antisoma regulatory department at technical, clinical and regulatory project teams with strategic commercial partner (Roche).
- Maintain international regulatory intelligence within Antisoma for biotechnology, CMC, preclinical and clinical aspects of clinical trials and marketing authorisations.

Senior Registration Executive – YRCR-ICON
Responsibilities:

- Preparation of Drug Master Files, marketing authorisations and CTAs in Europe and US.
- Writing CMC expert reports and associated tabulated summaries.
- Provide general regulatory, strategic and drug development advice to clients particularly in the field of biotechnology CMC, TSE legislation and comparability.
- Project management and quality control of client regulatory submissions.
- Lead multifunctional project teams for biotechnology and biological submissions.

Pharmaceutical Assessor – Biological & Biotechnology Unit, Medicines Control Agency
Responsibilities:

- Scientific and regulatory assessment of CMC/quality data for biotechnology and biological national drug marketing authorisations for new active substances, abridged applications, post-marketing variations and biotechnology or biological CTX applications.
- Scientific and regulatory assessment of European centralised procedures, mutual recognition procedure and post marketing variation submissions for biotechnology and biological drugs.
- Regulatory assessment of all labelling of industry submissions.
- Represent the Biological and Biotechnology Unit at meetings with applicant company.
- Development of draft CHMP guidelines where UK is Rapporteur and provide comment for draft guidelines where other member states are Rapporteur.
- Represent UK on development of ICH draft guidelines relating to quality of biotechnological medicinal products.
- Presentation of marketing authorisation applications to UK Committee on Safety of Medicines, the CSM Biological Sub Committee, the CHMP and Biotechnology Working Party.
- Assessment of data for European Directorate on Quality of Medicines (EDQM) Certification Procedure.
- Development of the EDQM Certification procedure regarding Transmissible Spongiform Encephalopathy.
- Providing Scientific Advice and Regulatory Advice to applicant companies.
- Recognised EMEA and EDQM expert.

Research Scientist – Delta Biotechnology Ltd.
Responsibilities:

- Management of a team of scientists developing downstream processing and analytical strategies for recombinant proteins, principally recombinant human serum albumin (rHA), manufactured from Saccharomyces cerevisiae.
- Awareness of the current requirements of FDA and EU regulatory processes with regard to biological drug development.
- Scientific assessment of potential new technology for use within the Company to achieve cost-effective large-scale protein production.
- Support of GMP manufacturing campaigns, investigation of manufacturing deviations/changes and assessment of upstream development on product quality and manufacturing consistency.

Dr Robert Dow BSc, MB ChB, FRCP, FFPM

Chief Medical Officer
Date Appointed to Position: July 2020

ACADEMIC QUALIFICATIONS.

BSc Med.Sci
St Andrews University

MB ChB
University of Dundee

MRCP (UK)
Royal College of Physicians

PROFESSIONAL CERTIFICATION.

FRCPE- Fellow of the Royal College of Physicians in Edinburgh

FFPM - Fellow of the Faculty of Pharmaceutical Medicine of the Royal College of Physicians in the United Kingdom

EMPLOYMENT RECORD.

Chief Medical Officer & Board Member
PPD – 2016 – 2019

Interim Chief Medical Officer
PPD – 2016 – 2017

Senior Vice President & Global Head of Medical Affairs
PPD – 2014 – 2016

Vice President & Global Head of Medical Affairs
PPD – 2012 – 2014

Vice President, Strategic Product Development
PPD - 2009 - 2012

Chief Medical Officer
Cell Genesys Inc. - 2007 - 2008

Senior Vice President, Medical Affairs
Cell Genesys Inc. - 2005 - 2006

Chief Executive Officer
Biolitec Pharma Ltd – 2002 - 2005

Chief Executive Officer
Quantanova Ltd – 2001 - 2002

Chief Executive Officer
Scotia Holdings PLC - 1998 - 2001

Medical & Development Director
Scotia Holdings PLC - 1997 - 1998

Non-Executive Board Member
Oxford Asymmetry International - 2000

Head of Global Drug Development
F Hoffmann-La Roche – 1995 - 1997

Vice President
Roche – 1994 - 1995

Program Director
CellCept -1993 - 1994

Vice President & Director - **Institute of Immunology & Infectious Diseases - 1992 - 1993**

Vice President
Syntex - 1991 - 1992

Director, Drug Safety & Efficacy
Syntex - 1989 - 1992

Director of Clinical Pharmacology
Syntex - 1985 - 1992

Head of Clinical Pharmacology
Syntex - 1982 - 1985

Previous Experience

Chief Medical Officer - Pharmaceutical Product Development (PPD)
Responsibilities:

As Chief Medical Officer reporting to the CEO I was senior physician responsible for all medical safety in PPD, which employs 18,000 people and conducts clinical research in 42 countries around the world. In addition, I have direct line management responsibilities described below for SVP and Global Head of Medical Affairs.

Board Member - PPD
Responsibilities:

Non-executive Board Membership of X-Rx, a privately-owned biotechnology company based in New York, USA

Interim Chief Medical Officer - PPD
Responsibilities:

In addition to the responsibilities below for SVP Medical Affairs, the Global Pharmacovigilance Group and Medical Communications group report to me. I am senior physician responsible for all medical safety in PPD, which employs 18,000 people and conducts clinical research in 42 countries around the world

Senior Vice President and Global Head of Medical Affairs - PPD
Responsibilities:

Reporting to the Chief Medical officer, leading three functions. The Global Product Development organisation provides medical, scientific and product development expertise to PPD clients and internal operational and business development teams, and comprises 24 physicians and 8 clinical scientists servicing seven therapeutic areas – Oncology/ Hematology, Infectious Diseases, Cardiovascular/Metabolism, Immunology, General Medicine, Respiratory Medicine, Neurosciences and Real World Outcomes/Evidence Based Medicine. The Global Consulting group, a team of 24 regulatory experts and product development team leaders who provide drug development, asset management and regulatory strategic consulting to PPD's clients. The Strategic Client Solutions Group, a team of 6 industry professionals with business development and financial backgrounds who provide strategic capability focused on the development of new or existing service offerings and generation of evidence which substantiates our differentiated position in the market

Vice President and Global Head of Medical Affairs - PPD
Responsibilities:

Global Head, Medical Affairs reporting to the Chief Medical Officer. Responsible for providing strategic leadership across the therapeutic areas within the Global Product Development organization. This group provided the medical, scientific and product development expertise to PPD clients and internal operational and business development teams

Vice President, Strategic Product Development - PPD
Responsibilities:

Vice President, Strategic Product development, reporting to the Chief Medical Officer. Strategic review and input into clinical protocols and drug development plans, servicing large pharma and biotechnology companies and venture funds.

Chief Medical Officer
Senior Vice President, Medical Affairs - Cell Genesys Inc.
Responsibilities:

Member of Executive Committee and Operations Management Committee. Managed Regulatory Affairs, Medical Affairs, Clinical Research, Safety, Data Management and consultants. Responsible for all global clinical, regulatory, reimbursement and strategic marketing activities for a phase 3 program of a cell based therapy, genetically modified to secrete GmCSF, for the treatment of hormone refractory prostate cancer and phase 2 studies in bladder and pancreatic cancer and leukemia

Chief Executive Officer - Quantanova Ltd
Responsibilities:

Responsible for research, development and commercialization of a broad photodynamic therapy (PDT) portfolio, including EMEA approval for Foscan® in the treatment of head and neck cancer. Established operating infrastructure of new company. Finalized in-house manufacture and contracted distribution and invoicing for marketed product. Conducted pricing and reimbursement negotiations with all major EU countries. Completed commercial licensing deals in approximately 10 countries.

Chief Executive Officer, Medical & Development Director - Scotia Holdings PLC
Responsibilities:

Conducted rigorous review of the company's projects. Sold loss making nutraceutical business and focused the company on rebuilding 4 major platform technologies:
Photodynamic Therapy-Reorganized the development program for lead product Foscan®. Initiated development programs in pancreatic cancer, prostate cancer, metastatic bone cancer and non-melanoma skin cancers.
Satiety - licensed lead product, a food ingredient, to General Mills.
Reformulation Technologies – obtained development deals on more than 15 products.
Lipid Biology - conducted genomic research in relation to several targets, filed patents, and sold rights to Xenon.
Raised funds of £50 million in 1997 and £11.2 million in 2000.

Non-Executive Board Director - Oxford Asymmetry International
Responsibilities:

Participated in Board initiative to successfully merge company with Evotec.

Head of Global Drug Development - F Hoffmann-La Roche
Responsibilities:

Responsible for global development programs for Roche products, and ex-US development of Genentech products.
Direct line responsibility for worldwide clinical, biometric, regulatory, drug safety and project management activities with a budget of $1bn and a staff of 2,000 people. Initiated and completed a major organizational review, resulting in a downsizing involving the sale of one major site and closure of nine minor sites. Defined a new organizational structure and commissioned 28 task forces to ensure drug development processes were optimally aligned to be productive, high quality, and cost-effective to meet strategic target. Filed NDAs simultaneously in the US and Europe for six new chemical entities: INVIRASE (a protease inhibitor for HIV); POSICOR (a novel calcium channel blocker for angina and hypertension); TASMAR (a COMT-inhibitor for the treatment of Parkinsonism); XENICAL (a lipase inhibitor for obesity); the IDEC C2b8 antibody (for the treatment of non-Hodgkin's lymphoma) and ZENAPAX (a humanized anti-TAC antibody for the prevention of acute renal rejection). Created a semi-independent virtual drug development company to develop three Roche products. Senior Roche representative on the Joint Roche/Genentech Development Committee.

Vice President - Syntex Development Research Centers (Acquired by Roche 1994)
Responsibilities:

Provided general management and restructuring of the Development Research Centers. Developed a virtual organization in Edinburgh to enable the company's future NCEs to have proof of concept evaluation rapidly performed in Europe. Member of the Syntex Operating Board and the Roche Portfolio Management Board

Program Director - Mycophenolate Mofetil (CellCept)
Responsibilities:

Led a worldwide program-orientated team of 210 people with an annual budget of $50 million responsible for planning, budgeting and executing all aspects of the CellCept® program including pre-clinical and Phase 1 to 3 clinical studies, worldwide regulatory approval for prevention of renal, liver and heart transplant rejection, pharmaco-economic strategy, pricing strategy, co-ordination of business planning, and chemical and formulation production.

Vice President & Director - Institute of Immunology & Infectious Diseases
Responsibilities:

Responsible through Medical Department Heads and the Product Development Organization Directors for all pre-clinical and clinical development activities to support successful worldwide regulatory approval of CellCept® (mycophenolate mofetil) and oral Cytovene® (ganciclovir).

Vice President
Director, Drug Safety & Efficacy
Director of Clinical Pharmacology & Research Service
Head of Clinical Pharmacology - Syntex Research Scotland (SRS)
Responsibilities:

Responsible for phase 1 and 2 clinical studies, computing, biostatistics, project management, library and information services, the toxicology/pathology group and regulatory affairs

Dr Krassimira Ourumova, M.D.

Principal Medical Consultant and Deputy Chief Medical Officer
Date Appointed to Position: May 2021

ACADEMIC QUALIFICATIONS.

Doctor of Medicine
Medical University of Sofia

Post Graduate Specialisation in Anesthesiology and Intensive Care
Medical University of Sofia

SOCIETY MEMBERSHIP.

Bulgarian Physician's Union - 1989 to present

Drug Information Society (DIA) - 1998 to present

European Society of Regulatory Affairs (ESRA) - 1998 to 2007

TOPRA - 2009 to present

EMPLOYMENT RECORD.

Director/Owner
Arden Regulatory Clinical & Medical Consulting - 2017 - Present

Senior Director Regulatory Affairs -
Head of Oncology, Business Partner
Daiichi-Sankyo Development Ltd. - 2009 - 2016

Director, Head of Clinical Regulatory Team
GSK Biologicals - 2007 - 2009

Associate Director Regulatory Affairs
MSD Europe (Inc.) - 2004 - 2007

Regulatory Affairs Manager
MSD Europe (Inc.) - 1998 - 2004

Medical Manager
MSD IDEA/BULGARIA - 1995 - 1998

Tutor in Anesthesiology & Intensive Care
Medical College for Nurses, Sofia - 1991 - 1995

Department of Anesthesiology & Intensive Care
University Hospital, Sofia - 1988 - 1995

Mandatory Country Practice
Regional Hospital, Bulgaria - 1984 - 1988

Previous Experience

Director/Owner - Arden Regulatory Clinical & Medical Consulting
Responsibilities:

- Consultant to Pharmaceutical Industry, specialising in: Strategic Regulatory Affairs & Clinical Development.
- Regulatory Intelligence & due-diligence.
- Training in Regulatory Affairs, e.g. European registration procedures, European and ICH guidelines etc.

Senior Director Regulatory Affairs - Head of Oncology, Business Partner - Daiichi-Sankyo Development Ltd
Responsibilities:

Strategic - Planning for the future

- Member of the West Development Committee, the executive body responsible for the approval of Development strategies/programs.
- Member of the Global Regulatory Affairs Management team.
- Core member of the one–voice team responsible for the building, strengthening and re-shaping of the RA function to ensure business needs are met.
- Establish the Regulatory Affairs function as an integral part of the compound development process.
- Develop and Provide Global/Regional Regulatory Strategy.
- Support the development of the Global Clinical Strategy for the compounds in development from pre-clinical up to Marketing authorisation.

Operational - Running the business from day to day

- Set-up the Glob Regulatory Function and lead the European regulatory team responsible for the oncology therapeutic area.
- Effectively liaise and negotiate with European Regulatory Agencies, FDA and partners.
- Provide regulatory support across global development projects including clinical programs, clinical trials, country selection, recommendation of end points, biomarkers, comparators, inclusion/exclusion criteria etc. with the view of gaining regulatory approval.
- Direct/approve aspects of activities relating to: preparation of protocols, clinical trials, data analyses and written study reports.
- Effectively liaise and negotiate with stakeholders involved in the development of the product development plans i.e. pre-clinical, clinical, commercial/marketing, HEOR, project management, Medical Affairs.
- Participate and support advisory boards.
- Direct, coordinate and implement the preparation of regulatory submissions.
- Meet aggressive deadlines in oncology development to ensure that regulatory agencies receive timely and quality submissions (Scientific Advice, Clinical Trial Applications, Marketing Authorisation Applications, Paediatric Investigational Plans, Companion Diagnostics, Orphan Designation Applications) leading to successful approval.
- Management of CRO oversight and partners' relations.

Professional – Lead/manage the regulatory team and support other functions

- Leadership and management accountability: 6 - 10 reports, including consultants and CRO.
- Lead and guide the professional development of the European regulatory team responsible for the oncology therapeutic area to meet the business requirements in relation to the evolving regulatory science and the therapeutic area disease knowledge.
- Guide the professional development of the Global regulatory team.
- Support the clinicians to better understand and interpret regulatory science and requirements.

Director, Head of Clinical Regulatory team - GSK Biologicals
Responsibilities:

- Member of CLIRA - the executive body responsible for the approval of the Global Development strategies/programs.
- Leading role in development of high quality global regulatory strategy and respective documents including the definition of the key messages, alignment with GSK Bio objectives, strategy and global regulatory requirements.
- Major input into the creation of the Global Clinical Program, Global Data Sheet (GDS) and the European Summary of Product Characteristics (SPC), and ensures that the GDS / SPC are consistent with the data presented in the clinical dossier.
- Interface with other GSK Bio departments (Clinical, Safety, R&D, …) to ensure harmonised file contents and on-time submission to Regulatory Authorities.
- Efficient interactions with Regulatory Authorities to achieve company objectives (EMEA, WHO, EU National Agencies, Chinese and Japanese Agencies) including representation of GSK Biologicals during meetings with these Authorities.
- Establishment of the Clinical RA team -Management accountability: 5 direct reports.
- Development and motivation of collaborators to achieve quality output, accountability and recognition across the organisation and towards the regulatory authorities.
- Ensuring dissemination of knowledge of regulatory guidelines, advice and expertise to relevant departments / teams.
- Ensuring that all relevant policies and standard operating procedures (SOP) are respected.
- Interaction level: Upper Management of GSK Bio, Regulatory Authorities.

Oncology

Establish and lead the European & Global clinical regulatory team responsible for ASCI - Antigen-Specific Cancer Immunotherapeutic(s) - combination therapeutic vaccine/diagnostic products.

Responsibilities:

- Key member of the Global Regulatory Teams.
- Strategic input to the global development programs for ASCI(s) and the respective diagnostics.
- Guidance, coordination and review in the preparation of documents and interactions with agencies, advisory boards like scientific advice packages, Paediatric Investigational Plans, briefing documents etc.
- Internal trainings for the team members to ensure knowledge and understanding of the oncology regulatory guidelines, oncology regulatory environment and the oncology diseases.

Associate Director Regulatory Affairs - MSD Europe (Inc.)
Responsibilities:

- Regulatory Affairs Experience with Marketing Authorisation Applications (MAA) using Regulatory Procedures (CP and MRP/DCP), Scientific advice (EMEA and national), Orphan designation, Regulatory Strategy experience in various therapeutic areas - oncology, CNS, anti-infective etc., including biotech products.
- Experience in regulatory training and all regulatory aspects from early stage of development to maintenance of marketed products.
- Strategic and regulatory intelligence support to global cancer development projects from an EU perspective.
- Company representation at the EFPIA Efficacy Working Group.

Oncology

European responsibilities for all oncology products (small molecules and biologics) in development.

Activities:

- Strategic input to the Global RA strategy form European perspective.
- Knowledge dissemination, interpretation and clarification of the EU requirements.
- EMEA interactions (e.g. MAA, variations, SA, Orphan designation etc.).
- Preparation of the EU dossier and filing.
- Leading the MSD RA oncology team - a team of regulatory Directors/managers from the subsidiaries to ensure knowledge of the evolving oncology environment, building expertise, compilation of database etc.
- Strategic input into the global regulatory strategy to ensure compliance with the European requirements.

Regulatory Affairs Manager - MSD Europe (Inc.)
Responsibilities:

- Pan European responsibilities for a migraine (MRP) and HIV (CP) products including MAA submissions and maintenance.
- Responsibilities for the regulatory affairs in the CEE countries.
- Strategic guidance to regulatory managers in the countries in relation to the new product submission using purely national procedures and/or recognition of the EU CP & MRP.
- Regulatory activities related to the preparation of the EU enlargement.
- Representation of the company at the EFPIA EU Enlargement Group.

Medical Manager - MSD IDEA/BULGARIA
Responsibilities:

Responsibilities covering clinical, medical and regulatory functions in the newly established MSD office in Bulgaria.

Dr Christian Clauss, PhD, I.A.E, RAC

Principal Consultant
Date Appointed to Position: February 2021

ACADEMIC QUALIFICATIONS.

PhD Pharmacy
University of Paris

DEA (M.S.) Biopharmacy
University of Paris

EMPLOYMENT RECORD.

Senior Consultant
Hisut Consultant Ltd - 2017 - Current

Senior Consultant
Validant Inc (USA) - 2015 - 2017

Senior Consultant
Kythera - 2015 - 2015

Global Corporate Vice-President
Sotio Ltd - 2004 - 2014

Senior Consultant
Novartis - 2013 - 2014

Senior Consultant
Atheln Biomed - 2010 - 2012

Chairman of Regulatory & Clinical Strategy Comittee
L.F.B - 2008 - 2010

Director Global Regulatory Affairs
Baxter Healthcare Corporation - 2004 - 2008

Senior Director Regulatory Affairs
Baxter Healthcare Corporation - 2001 - 2004

Corporate Director
Becton-Dickinson - 1998 - 2000

OTHER QUALIFICATIONS.

CSA (Master in Applied statistics) 1981

I.N.S.E.A.D. (European Marketing Program) 1989

I.A.E. Marketing (Business Administration) 1989-90

CEIPI Patent and Technology Licensing 1992

GCP training re-certification US&UK, UK Royal Colleges of **Physician, 2019**

Vice-President Europe
Boston Scientific - 1996 - 1998

Global Corporate Vice-President
Baxter-Clintec - 1993 - 1996

Marketing and Sales Vice-President Europe
Dow Corning - 1987 - 1993

Regulatory Affairs & Quality Assurance Manager
Dow Corning - 1981 - 1987

Asoociate Director
DREBS - 1977 - 1981

Associate Biologist
Various Paris Hospitals - 1973 - 1977

Previous Experience

Senior Consultant - Global Regulatory Affairs & Quality Assurance - Hisut Consultant Ltd
Responsibilities:

- Global Regulatory Affairs.
- Head of QA&RA for Magnetrap SA since 1st September, 2020.
- Successful Preparation and Submission of critical IDEs INDs and IMPD to CDRH, FDA.
- Management and Preparation of scientific advices briefing with FDA and EMEA.
- Medical Device Class III implant projects (Mid 2017- 2020) PhysIOL from idea to implantation.
- Implement ISO 13485-2016 compliance (e.g Magnetrap SA, Natec, Stentys, Cyrpa...).
- Conduct GCP Audit and renew GCP certification.
- Manage successful IND, Q-Sub, BLA submission (Endotool Technology, Physiol etc...).

Senior Consultant - Global Regulatory Affairs & Quality Assurance (Pharma, Biotech, Medical Development) - Validant Inc (USA)
Responsibilities:

- Global product development strategy and due diligence management.
- Global Regulatory Affairs and Quality Assurance.
- Prepare and implement QA system certified with FDA, ICH Q10 and EU requirements.
- Establishment of RA strategy, DCP, MRP, centralised, NDA, National.
- Conduct QA/QP Audit for Biotech Companies in compliance with FDA cGMP and Eu requirements.
- Prepare and conduct successful scientific advices briefing documents and organisation of meeting with EMA, Scientific Advice and FDA Type B meeting.
- Implement compliance to EU and FDA (GMP) for CIPLA (India Goa) for Biosimilars and Dr Reddy's (Hyderabad) for Biosimilars.
- Implement GMP remediation for Dr Reddy's, Visakhapatnam sites & review of ANDA and DMF for FDA.
- Provided Training in Data Integrity, Risk Management (ICH Q9 and FMCEA), EU GMP vs FDA cGMP requirements, ICH Q8 Process Validation, IND process, FDA meeting Type A, B, C and EMA scientific advice.
- European & French registered Qualified Person.

Senior Consultant- Global Regulatory Affairs & Quality Assurance (Pharma, Biotech, Medical Development) - Kythera (California, USA and Brussels, Belgium)
Responsibilities:

- Implement global product development strategy and due diligence management.
- Establishment of RA strategy, DCP, MRP, centralised, NDA, National.
- Prepare and conduct successful scientific advices, briefing documents and organisation of meetings with National Authorities, Scientific Advice.
- Direct management of ain project with Kythera (USA), in Europe.

- Re-design the Registration file for Belkyra which was submitted end of 2015 in a decentralised RA procedure with Sweden as the referenced Member state. The approval was successfully granted in October 2016.
- European registered QP.

Global Corporate Vice-President Regulatory Affairs & Quality Assurance - Sotio Ltd (Prague) Advance Cells Immuno-therapy
Responsibilities:

- Implemented global product development strategy and due diligence management.
- Held full accountability for Global Regulatory Affairs and Quality Assurance.
- Prepared and implemented QA system certified with FDA, ICH Q10 and EU requirements, etc.
- Managed Clinical Trials Authorisation (IND&CTA) submission and received approval for Phase III in US and Europe with more than 20 countries in total for Advanced Cellular Therapy products.
- Built RA strategy
- Prepared and submitted INDs and IMPD to CBER, Canada and European National Authorities.
- Developed and conducted successful scientific advices briefing documents and organisation of meeting with EMA, Scientific Advice and FDA Type B meeting.
- Served as board member and member of global management team.

Senior Consultant - Global Regulatory Affairs- Novartis Vaccine (Siena, Italy)
Responsibilities:

- Prepared and successfully submitted INDs and IMPD to CBER, Canada and European National Authorities for different new quadrivalent influenza vaccines (cell culture based and egg based).
- Prepared scientific advices briefing documents and organisation of meeting Novartis Vaccine.
- Prepared CMC dossier submitted with success in US, EMEA and Canada for 2 new cell culture vaccines.

Senior Consultant- Global Regulatory Affairs - Atheln Biomed, Inc.
Responsibilities:

- Conducted global product development strategy and due diligence management for global Biosimilars.
- Supervised Global Regulatory Affairs and Quality Assurance.
- Achieved CE & ISO certification for > 5 companies (Ascendx, Bluberi, Cyrpa, etc...).
- Prepared and implemented QA system certified with FDA and ISO 13485 (Ascendx, Cyrpa, etc...).
- Managed Clinical Trials (Pfizer, Hays Pharma).
- Prepared RA strategy (Arkos, Cinfa, CMC, Perouse, 3P).

Chairman of the Regulatory and Clinical Strategic Committee - L.F.B
Responsibilities:

- Coordinate Global Biotech projects including:
- Designed and implemented Clinical and Regulatory Strategy:
  - Monoclonal Antibodies e.g CD20, Adnc,
  - Coagulation Factor
  - High Tech Therapies
  - Transgenic Factor VII projects
  - Plasma extracted products Factor VII, Von Wilbrand Factor, Fibrin,
- Prepared and successfully submitted Orphan drugs designation for two products in Eu and USA (EMEA and FDA).
- Prepared Clinical trials synopsis including Adaptative Design in Oncology.

Director Global Regulatory Affairs, New Product Development - Baxter Healthcare Corporation (Paris, Westlake CA, Vienna)
Responsibilities:

- Global Biotech projects included:
- Conducted due diligence for in and out licensing of Biotech projects, conducted technical assessment for more than 500 projects.
- Conducted global RA assessments for: Recombinant coagulation factor development for acute stroke and other diseases; FOPP and Biosimilars; Rare diseases and Orphan drugs.
- Organised scientific advice EU/USA.
- Managed successful BLA submissions to FDA in USA: CEPROTIN®.
- Conducted Recombinant Factor VII and recombinant Von Wilbrand Factor regulatory development.
- Prepared and received Orphan product designation in EU and USA.

Senior Director Regulatory Affairs - Baxter Healthcare Corporation (Europe, Middle East, Africa)
Responsibilities:

- Led the function and key projects, ie Epoetin Omega managed a team of 16 team members / budget $4.5M.
- Managed regulatory affairs for Medical Devices, Pharmaceuticals Biotechnology and BioSimilars
- Established SOPs, centralised translation procedure and publishing tools for the EDMS.
- Achieved extensive track record of successful registration that beat milestones (Clearfield).

Corporate Director - Regulatory & Public Affairs - Becton-Dickinson (Europe)
Responsibilities:

- Co-ordinated European RA and public affairs operations to enhance business development B.D.
- Fostered business development relationship with the different European authorities with focus on collaborating with EUCOMED, EDMA, HIMA in area covering Regulatory Affairs, Reimbursement, conformity assessment, Global harmonization, Vigilance, In Vitro diagnostic.
- Oversaw CE marking of all the IVD products.

Vice-President Europe - Quality Syste,, Regulatory, Clinical and Governmental Affairs - Boston Scientific
Responsibilities:

- Created, managed and recruited staff for the Regulatory Affairs and clinical functions.
- Supervised and trained 45+ Full Time Employees.
- Established post-market vigilance system in Europe, including clinical tracking and central procedures in compliance with EN540.
- Managed vigilance cases and reimbursement issues throughout Europe.
- Responsible for 94 clinical trials conducted with success in 1997.

Global Corporate Vice-President - Quality Assurance, Regulatory and Governmental Affairs - Baxter-Clintec
Responsibilities:

- Created, managed, organised and staffed the global international RA and QA functions.
- Managed more than +85 Full-Time employees and the budget in 1996 was +€5 Millions.
- Responsibilities included Parenteral Pharmaceuticals, Medical Devices and enteral products.
- Managed the submission of 95 new product licenses that were granted during 1995 in Asia, Europe and America.
- Designed and implemented Quality Systems and Received ISO 9001 and EN 46001 (ISO 13485) certification for the entire organisation, achieved in less than 6 months (3 manufacturing sites and all the contract manufacturing activities).
- Managed Non-PVC dual bag submission and received approval for CLINIMIX® CLINOLEIC®, OLICLINOMEL® and for more than 100 products worldwide.
- Supervised successful certification and CE marking for more than 500 products.

Marketing and Sales Vice-President Europe - Dow Corning (Sofia Antipolis, FR)
Responsibilities:

- Managed 15 products/markets, including pharma and Medical Devices.
- Managed +20 Full-Time staff.
- Developed the European strategy and five and ten-year plans.
- Implemented market research (Price, Distribution, Product & Promotion) and set up of the sales organisation in Europe.
- Managed and implemented joint development agreement with Novartis (Ciba-Geigy), Pharmacia, Leiras, Avantis, Sanofi.
- Achieved +20% Compounded Growth Rate (CGR) and + 25%. Profit Before Tax CRG.
- Received corporate Marketing award 1991.

Regulatory Affairs and Quality Assurance Manager - Dow Corning (Sofia Antipolis, FR)
Responsibilities:

- Developed and established the European Organisation and Plant. Recruited and trained the European team.
- Implemented GMPs and obtained DHSS, USA and Pharmaceutical French Agreement.
- Managed +15 Full-Time Staff.
- Design and Managed QC laboratories.
- Initiated manufacturing operations.
- Managed Pharmaceutical Registration of SILASTIC® Foam Dressing.
- Served as Member of Health Care Business Board Europe.
- Initiated and conducted Clinical trials.

Associate Director - Contract R&D Department - DREBS
Responsibilities:

- Leveraged specialisation in toxicology, pharmacology, mutagenesis, immunopharmacology and bioavailability, clinical trial management, and pharmacokinetics with CEA (National French Nuclear Institute).

ADDITIONAL INFORMATION.

- Former Chairman of the Eucomed Funding and Reimbursement Focus Group.
- Former President of APIMMCA (French Association of Qualified Person).
- Former General Secretary RAPS Europe, RACS (1996 – 2001).
- Member of: British Institute of Quality (IQA) and British Institute of Regulatory Affairs.
- Member of French and International Professional Societies; (French Association of Galenician, APGI), SFEA, European Society for Biomaterials, ISO TC Biocompatibility testing Member of EUCOMED.
- Former Chairman of the EUCOMED Funding and Reimbursement Focus Group.

Erik Doevendans MSc

Principal Consultant
Date Appointed to Position: February 2019

ACADEMIC QUALIFICATIONS.

Post-MSc Pharmacy – 1997
Utrecht University, The Netherlands

TRAINING COURSES.

Molecular Biology – 2001
Utrect University

Biostatistical Methods – 2000
NIBSC

GMP – 1998
Pharmaceutical Consultancy Services

Practical Aspects of Pharmaceutical Validation
David Begg Associates

EMPLOYMENT RECORD.

Owner and Consultant – BD Consultancy B.V.
2009 – Current

Senior Director Regulatory Affairs & Manufacturing Operations – Pharming N.V.
2005 – 2007

Senior Consultant/Project Leader – Univalid B.V.
September 2003 – 2005

Senior Assessor of Biological and Biotechnological Medicinal Products - Center of Biologicals and Medical Technology (BMT), National Institute for Public Health and the Environment (RIVM)
1999 – 2003

QC Officer – Institute for Animal Science and Health
1998 – 1999

QA Officer/Research Associate – Dopharma
1997 – 1998

Owner and Consultant – BD-Consultancy B.V.
Responsibilities:

- Biologics Development Consultancy B.V. (BD-Consultancy) provides assistance and project management capacity in the development of biopharmaceuticals and in the preparation and review of EMA and FDA regulatory applications.
- Current assignments include; CMC expert for Belgium Biotechnology company, CMC expert for Dutch biotechnology company and Regulatory & CMC expert for Dutch Biologics Company (plasma derived products).
- Previous assignments include; assessment of business plans and drug development plans for venture capitalists, writing of expert reports (QOS, Modules 2.4 and 2.6) for biotechnology products, preparation and attendance of meetings with regulatory authorities (National and EMA) for clients, strategic advice on pharmaceutical, pre-clinical and clinical development of several biotechnological and gene therapy products and interim director regulatory affairs.

Senior Director Regulatory Affairs & Manufacturing Operations – Pharming N.V.
Responsibilities:

- Heading of the departments of Regulatory Affairs and Manufacturing Operations
- Responsible for regulatory processes in US and Europe
- Responsible for CMC and pre-clinical modules / strategy
- Regulatory and methodological input into clinical programs / strategy
- Participation in project-teams (new indications C1INH and new products: Prodarsan and recombinant human Lactoferrin)
- Responsible for downstream processing and fill and finish (both performed at CMOs)
- Project-manager for Pharming for downstream processing and fill and finish

Achievements Include:

- Regulatory validation of transgenic rabbit platform.
- Solved all quality (CMC) and pre-clinical issues that arose during Centralised Procedure of Rhucin.
- Clinical program Rhucin successfully executed.
- Management of technology transfer and validation of downstream processing and fill and finish.
- Phase I study for Prodarsan (for treatment of Cockayne Syndrome; a hereditary early ageing disease).
- Obtained manufacturing license for transgenic platform.
- Validated transgenic cattle and rabbit platform.

Senior Consultant / Project-leader – Univalid B.V. (now Xendo B.V.)
Responsibilities:

- Reviewer of Chemical Pharmaceutical part of Marketing Authorization Applications/Variations of recombinant DNA medicinal products, plasma derived medicinal products, and vaccines.
- Participation in development projects
- Providing Regulatory input for biotech companies
- Review of dossiers prior to filing / Gap analyses / writing of expert reports
- General pharmaceutical counselling (Formulation / QA / Production / Regulatory affairs

Senior assessor of biological and biotechnological medicinal products – BMT, RIVM.
Responsibilities:

- Senior assessor of Chemical Pharmaceutical part of Marketing Authorization Applications/Variations of recombinant DNA medicinal products (including the first bio- similar; Omnitrope), plasma derived medicinal products, and vaccines.
- Expert for BWP of the Committee for Human Medicinal Products.
- Assessor of dossiers filed under the Immunological Medicinal Product Decree (release of Immunological pharmaceuticals under the authority of the Dutch Pharmaceutical Inspection).
- Expert for the Dutch Medicines Evaluation Board.

Achievements Include:

- Development of assessment policy for release of investigational medicinal products under the Immunological Medicinal Product Decree.
- Promotion to Senior assessor within 3 years'.

QC Office – Institute for Animal Science and Health (ID-Lelystad)
Responsibilities:

- Study director development, optimisation and validation of (QC) test methods.
- Optimisation of the fermentation/purification process of Foot- and Mouth disease vaccine.
- Trouble shooting concerning Quality Control and Production of Foot and Mouth disease vaccine.
- Member of VMP group for new production site for FMD vaccine.

QA Officer/Research Associate – Dopharma B.V.
Responsibilities:

- Implementing and monitoring of GMP (EU) / executing and reporting external GMP-audits.
- Inspection of facilities and monitoring of studies under GLP.
- Co-ordination of validation (VMP) – validation of processes, equipment.

Dr Angeles Escarti-Nebot BSc (Hons), MSc, MBA, PhD

Principal Consultant
Date Appointed to Position: October 2020

ACADEMIC QUALIFICATIONS.

PhD in Molecular Biology (gene/cell-based therapies) - 2006
Universidad Autónoma, Madrid, Spain.

MBA in Health & Pharmaceutical Industry - 2008
IE Business School, Madrid, Spain.

Master of Science in Clinical Genetics - 2002
Universidad Alcalá de Henares, Madrid, Spain.

Master of Science in Neuropharmacology - 2002
Universidad Complutense, Madrid, Spain.

Bachelor of Science in Pharmacy - 2000
Universidad Complutense, Madrid, Spain.

EMPLOYMENT RECORD.

Director, Principal Consultant, International Service Coordinator
PharmaLex UK – 2018 - 2020

Associate Director/Manager
Paraxel Consulting - 2015 - 2018

Scientific Regulatory Affairs Manager
Asphalion, Scientific & Regulatory Services - 2012 - 2015

Head of Non-clinical Development Department
Proretina Therapeutics - 2011 - 2012

Director of Laboratory/Scientific Director
Vivotecnia Research - 2009 - 2011

Business Development Manager
Vivotecnia Research - 2008 - 2009

PhD Researcher
National Centre for Cardiovascular Diseases Research - 2007 - 2008

PhD Researcher/PhD Student
National Centre for Biotechnology - 2001 - 2007

Previous Experience

Director, Principal Consultant, International Services Coordinator - Pharmalex UK
Responsibilities:

Global regulatory strategy programs.
Experience on expediting product development: conditional marketing approval submissions, PRIME program. Subject matter expert for early development programs for biological and biotechnological products, cell and gene-based products as well as tissue engineered products. Main areas of expertise include Regualtory Strategy, Non-clinical and Quality development programs. Early Development (Quality and Nonclinical) International Service Coordinator.

- Account growth from 15K to 450K GBP in a year acting as the program director for a US based company. Main activities include: leading the preparation of type B and type C meetings with the FDA, Breakthrough designation request in the FDA, EU regulatory strategy and Orphan Drug Designation in the EU, Regulatory and Scientific due diligence of potential new assets for the company… etc.
- Account growth for an orphan product: initial request of Global Regulatory Strategy for the EU and US markets evolved to BLA and MAA preparation in line with the proposed strategy.
- EU program director for a US based company for an ATMP orphan drug product within the PRIME program. Main responsibilities include: leading the EU Regulatory Strategy for a Conditional Marketing Authorisation via the centralized procedure, PIP procedure and PDCO meetings, Protocol Assistance and follow up procedures, PRIME meetings, Promotional Materials review and Global Regulatory Intelligence.
- Account transformation from a services provider relationship with the client to a regulatory partnership.

Associate Director/Manager - Parexel Consulting
Responsibilities:

Scientific regulatory support to biotechnology, pharmaceutical and medical technology companies in the design and implementation of innovative and global regulatory strategies to expedite product development. Support business development and contribute to the operational and financial management of PAREXEL Consulting. Management of projects/clients allocating resources, controlling budget and ensuring on time first time quality deliverables. Key contributor to the new Project Management Unit within the department. Client relationship management and project oversight activities.
Line management activities leading a team of 7 Project Leaders. Previously, leading a team of up to 13 individual contributors – snr. consultants and consultants.

- Scientific regulatory support to biotechnology, pharmaceutical and medical technology companies in the design and implementation of innovative and global regulatory strategies to expedite product development.
- Support business development and contribute to the operational and financial management of PAREXEL Consulting. Management of projects/clients allocating resources, controlling budget and ensuring on time first time quality deliverables.
- Key contributor to the new Project Management Unit within the department.
- Client relationship management and project oversight activities.
- Line management activities leading a team of 7 Project Leaders. Previously, leading a team of up to 13 individual contributors – snr. consultants and consultants.

Scientific Regulatory Affairs Manager - Asphalion
Responsibilities:

Design of biological, biotechnological, ATMP products CMC and non-clinical regulatory strategies to meet EMA and FDA requirements for clinical stages and marketing authorization application. Preparation of regulatory documentation (ODD, scientific/protocol assistance, IMPD, IB, CDT, PIP). Active participation in meetings with regulatory bodies (CAT, CHMP, PDCO). Regulatory support to several biotech companies in an on-demand basis. Scientific and regulatory due diligences for venture capital companies and biotechnology/pharma companies. Management of multicultural and multidisciplinary teams (ad hoc teams). Project management. Interaction with clients (scientific and finantial departments) and regulatory bodies to achieve project objectives.

- Responsible for CMC and non-clinical sections (scientific and regulatory issues) for the CTD preparation for a biosimilar (antibody) for EMA authorization.
- Global CTD consolidation project for cell-based medicinal products. Scientific and strategic regulatory support for M3 module.
- Lead the renewal procedure and CTD compilation for cell-based medicinal product. Scientific and strategic regulatory support for M3.
- Designed and supervised the non-clinical and CMC Regulatory program for an mRNA therapeutic vaccine for HIV. Preparation and supervision of the regulatory documentation and regulatory procedures.
- Designed the non-clinical and CMC regulatory strategy for a nanobody medicinal product.
- IMPD preparation for oncolytic virus-based therapy including regulatory support for a phase II clinical trial authorization submission.

Head of Non-clinical Development Department - Proretina Therapeutics
Responsibilities:

Lead the non-clinical development department and the biology/pharmacology laboratory, designing and planning the CMC and non-clinical regulatory development plan to support clinical trials. Designed and supervised the regulatory CMC and non-clinical strategy. Contact with the EMA for ODD, Protocol Assistance and follow up meetings as well as for additional regulatory paperwork (IMPD, CTD). Partipated in the screening of new products to be added to the company's pipeline conducting scientific regulatory due diligences. Manage CRO relationships, selection of appropriated CRO, budget negotiation, study design and study monitoring. Manage academia research group relationships acting as project team coordinator. Management of a multicultural multidisciplinary team of 5 people.

- Designed and prepared the EMA Protocol Assistance documentation for an Orphan Drug development program for a sustained release of a protein product to be administered by the intravitreal route and achieved ODD.
- Designed the quality (CMC) and non-clinical regulatory program for a recombinant protein product and achieved CHMP/EMA agreement.

Director of Laboratory/Scientific Director - Vivotecnia Research
Responsibilities:

Lead contract research for non-clinical development division, designing and overseeing research projects related to toxicology, pharmacology and biomedical sciences. Coordinated and supervised pharmacology/toxicology/PKPD GLP and non-GLP studies mainly focused on advanced therapies. Designed and supervised in vivo and in vitro assays for Quality programs for ATMPs and biologics. Schedule projects, allocate resources and manage budgets. Oversee training and education programs. Review and approve regulatory and scientific documentation. Supervise multidisciplinary product development projects. Conducted mission-critical development projects to meet FDA and EMA requirements. Management of a multicultural and multidisciplinary team of 30 people.

- Started up the Efficacy and Multidisciplinary Non-Clinical Development Department that also included in vitro and in vivo assays for quality programs. The department was focused on gene, cell and protein-based therapies performing efficacy, PK and toxicology studies and the set-up and validation of bioanalytical methods (even for clinical trials) according to regulatory guidelines.
- Started up the unit for anticancer drugs assessment.
- Actively involved in follow-on contracts with 100% of client companies recruited in prior position.
- Recruited new clients and generated additional contracts via client networking.

Business Development Manager - Vivotecnia Research
Responsibilities:

Developed new business opportunities, conducting research on potential clients and networking to make new contacts. Managed client relationships, working in conjunction with science and operations colleagues to deliver top quality service. Developed new business proposals to provide efficacy and toxicology assessments for pharmaceutical and biotech clients' dossiers to fulfill FDA and EMA requirements.

- Developed efficacy and multidisciplinary business unit that generated €350k in 1st year and has consistently grown since.
- Effectively handled clients working in tandem with science and operations colleagues and delivered best output.
- Identified new business opportunities, performed research on potential clients and networking to augment the business operations.
- Prepared new business proposals for pharmaceutical and biotech clients'.

Research Experience

PhD Researcher - National Cenre for Cardiovascular Diseases Research
Responsibilities:

Designed studies and conducted research within the Cardiovascular-Regenerative Department, including mesenchymal stem cell research for heart disease treatment and regenerative therapies focused on differentiation pathways including transcriptional routes and miRNA biology. Executed bench work on DNA and RNA techniques, protein techniques, cell culture (including stem cell isolation and culturing) and cytometry. Stayed abreast of development in the field by reviewing scientific literature. Supervised a student.

- Diligently designed and administered PhD project for student.
- Outlined the objectives and experimental activities to accommodate resources.

PhD Researcher/PhD Student - National Centre for Biotechnology
Responsibilities:

Performed epidermal stem cell genetically modified with viral vectors therapies for the treatment of genetic disorders (Thesis title: Epidermal stem cells genetically modified with viral vectors for the treatment of Hemophilia B). Executed bench work, including molecular biology and protein techniques, histo techniques, animal models, tissue engineering, cell and tissue culture, epidermal and mesenchymal stem cell culture. Stayed abreast of developments via scientific literature. Obtained funding for projects and laboratory. Discovered and resolved scientific strategy problem.

- PhD in molecular biology.
- Designed improved skin-expression viral-based vectors.
- Obtained a genetically modified factor IX cDNA to avoid collagen IV binding to improve systemic levels.
- Designed a method to increase the number of epidermal stem cells from human skin samples by cell sorting that improved stem cell culturing for subsequent epidermal transplant in an animal model.

Amy B. Fix MBA, MSc, BSc

Principal Consultant
Date Appointed to Position: May 2020

ACADEMIC QUALIFICATIONS.

MBA Management - 2004
John Hopkins University, USA

MSc Molecular Biology - 1997
Biotechnology Program, University of Virginia, USA

BSc Biology - 1994
University of Illinois, USA

PROFESSIONAL CERTIFICATION.

Regulatory Affairs Certificate, RAC, 2002

EMPLOYMENT RECORD.

Senior Vise President, Regulatory Affairs/Quality Assurance
Arcellx, Inc - 2019 - Present

Senior Vise President, Regulatory Affairs
Novavax, Inc – 2016 - 2019

Vise President, Regulatory Affairs
Novavax, Inc – 2013 - 2016

Senior Director, Regulatory Affairs
Emergent Biosolutions, Inc - 2012 - 2013

Contractor Regulatory Affairs Subject Matter Expert
Conceptual Mindworks/BARDA - 2012 - 2012

Head, Global Regulatory Affairs, Vaccines
Baxter - 2009 - 2011

Vaccines Franchise Regulatory Lead
Baxter - 2011 - 2011

Associate Director, Regulatory Affairs
Baxter - 2007 - 2011

Director, Regulatory Affairs
Vanda Pharmaceuticals, Inc - 2006 - 2007

Senior Manager, Regulatory Affairs
MedImmune, Inc - 2005 - 2005

Manager, Regulatory Affairs
MedImmune, Inc - 2004 - 2005

Manager, Regulatory Affairs
Shire Pharmaceuticals - 2002 - 2004

Senior Regulatory Affairs Specialist
Human Genome Sciences - 2002 - 2002

Regulatory Affairs Specialist
Human Genome Sciences - 2000 - 2002

Regulatory Affairs Medical Writer
Human Genome Sciences - 1999 - 2000

Technical Writer
IIT Research Institute - 1997 - 1999

Previous Experience

Senior Vise President, Regulatory Affairs/Quality Assurance - **Arcellx, Inc.**
Responsibilities:

- Established Regulatory and Quality functions
- Strategic development of CAR-T cell therapy programs
- Successful first IND for treatment of relapsed and refractory multiple myeloma
- Successful pre-IND meeting for second program in relapsed and refractory multiple myeloma

Senior Vice President., Regulatory Affairs
Vice President, Regulatory Affars - Novavax, Inc.
Responsibilities:

• Member of Novavax Senior Management Committee
• Responsible for Regulatory Affairs and Regulatory Operations

- Established Regulatory Department, including CMC, Clinical/Nonclinical and Operations
- Established Clinical Quality Assurance Department
- Established Electronic Submissions and Electronic Document Management System
- Established departmental SOPs
- Oversight of CROs
- Responsible for Regulatory Affairs due diligence activities

• Strategic oversight of Novavax vaccine portfolio

- RSV Vaccine Maternal Immunization Development Program
- Strategic input into clinical development program
- Successful meetings with global regulatory agencies allowing for initiation of Phase 2 and Phase 3 maternal immunization clinical trials
- Obtained approval to conduct Phase 3 clinical trial in 11 countries (~4600 subjects)
- Obtained Fast Track Designation
- Obtained $90 million funding from BMGF
- Active involvement in WHO and EMA RSV Guidance documents
- RSV Vaccine Older Adult Development Program
- Successful End of Phase 2 meeting and initiation of Phase 3 clinical trial (~12,000 subjects)
- Obtained Fast Track Designation
- RSV Vaccine Pediatric Development Program
- Influenza Vaccine Development Programs
- Quadrivalent Seasonal and Pandemic Vaccines (VLP and nanoparticle)
- Fast Track Designation H7N9 Vaccine and NanoFlu (quadrivalent nanoparticle seasonal influenza vaccine)
- Agreement with FDA on use of accelerated approval to support licensure of NanoFlu
- Ebola Vaccine Development Program
- Successful Phase 1 clinical trial during 2014 Ebola outbreak
- Key participant in WHO and FDA meetings regarding vaccine development
- Agreement with FDA regarding pathway to licensure, including use of animal rule

• Regulatory oversight of joint venture with Cadila Pharmaceuticals (India)

- Licensure of Novavax's VLP seasonal influenza vaccine in India
- Completion of Phase 1/2 and Phase 3 clinical trials of 3-dose rabies vaccine

• Joint Steering Committee of Novavax AB and Matrix-M adjuvant

Senior Director, Regulatory Affairs - Emergent Biosolutions, Inc.
Responsibilities:

• Advanced Development and Manufacturing (ADM) Program

- Represented Regulatory Affairs on BARDA ADM contract
- Evaluated and contributed to selection of pandemic vaccine candidate partner
- Responsible for Regulatory activities related to facility, BARDA task orders, and surge capacity for pandemic vaccines

• International Licensure of BioThrax (Anthrax Vaccine Adsorbed)

- Responsible for European authorization (National licensure and Mutual Recognition Procedure) and Canadian licensure of BioThrax
- Maintenance of licensure in India and Singapore

• Due Diligence

- Responsible for Regulatory assessment of all due diligence projects

• Publication, Press Release and External Communications

- Responsible for Regulatory review and approval of all materials

• Other Responsibilities

- Oversight of Regulatory Operations group
- Responsible for overall Regulatory budget and forecasting

Contractor Regulatory Affairs Subject Matter Expert - CMI/BARDA
Responsibilities:

• Regulatory Oversight of BARDA Influenza Contracts

- Responsible for Regulatory oversight of Seasonal and Pandemic Influenza vaccine and anti-viral contracts, including review of all Sponsor documents, contracts and amendments, and participation in Sponsor meetings
- Responsible for Regulatory review of White Papers and Proposals

Head, Global Regulatory Affairs, Vaccines
Vaccines Franchise Regulatory Lead
Associate Director, Regulatory Affairs - Baxter
Responsibilities:

• Global Development of Vaccines Projects

- Managed global regulatory teams and directed regulatory strategy for global programs
- Managed development programs for early and late stage viral and bacterial vaccine candidates
- Interpandemic and Pandemic Influenza (H5N1, H9N2 and H1N1), Tick-borne encephalitis, West Nile, Ross River, Lyme, and Meningitis C
- Responsible for global dossier submissions and post-marketing activities of licensed vaccines
- Responsible for core company data sheets and product labels
- Interacted with international partners and vendors on vaccine projects
- Responsible for Japanese development of H5N1 Pandemic Vaccine
- Successfully achieved government funding with partner
- Regulatory representative on international project team with partner company
- Successful meetings with the PMDA
- Conducted due diligence activities
- Prepared company position papers on regulatory issues
- Presented at global conferences

• US Vaccine Projects

- Primary US regulatory contact with FDA for all US vaccine projects (5 INDs)
- Regulatory representative on BARDA Influenza contract
- Preparation of BLA for Interpandemic Influenza Vaccine
- Multiple pre-IND, End of Phase 2, other FDA meetings; prepared for pre-BLA meeting
- Contributed to preparation of proposals in response to US government RFPs
- Led assay validation team for clinical program assays
- Participated in audits, data review, and finalization of validation protocols and reports
- Supervised and directed activities of Regulatory staff
- Responsible for US Regulatory budget, forecasting and hiring

Director, Regulatory Affairs - Vanda Pharmaceuticals, Inc.
Responsibilities:

• Regulatory Activities

- Core regulatory representative on cross-functional Product Development Team for Phase III circadian rhythm sleep disorder project
- Team member on eCTD team for schizophrenia drug
- Participated and provided input on eCTD and medical writer vendor selection
- Participated in legacy document inventory
- Drug product label review
- Pre-NDA briefing book and questions
- Responsible for Module 1 (Regional Administrative Information)
- Risk Minimization Action Plan, including selection of consultant and preparing a risk MAP that is both cost effective and practical for Vanda
- Small business application fee waiver activities, including external meeting attendance and contact with SBA office
- Financial disclosure compilation and summary
- Responsible for Module 4 (Nonclinical)
- Reviewed and organized over 160 nonclinical studies into content plan according to CTD structure
- Responsible for review of all Nonclinical Summary and Overview documents
- Responsible for European filing strategy, including vendor selection and management, pre-submission activities, and conversion of US eCTD into EU eCTD, and budget
- Responsible for companion pharmacogenomic/diagnostic strategy, including participation in internal pharmacogenomic task force meetings, Office of In Vitro Diagnostic meeting and briefing book preparation, pharmacogenomic label language
- Responsible for implementation of Compliance function, including QA vendor management, writing and review of SOPs, Vanda preparation for FDA audit, and budget

• Nonclinical Activities

- Interacted with toxicology consultant and CRO and participated in GLP audit of CRO
- Responsible for ongoing carcinogenicity, phototoxicity and embryo-fetal development studies

• Clinical Activities

- Participated in GCP audit of Phase 1 unit
- Responsible for site selection of ~15 sites on Phase III transient insomnia study

Senior Manager / Manager, Regulatory Affairs - MedImmune, Inc.
Responsibilities:

- Regulatory representative on Product Development Teams for Autoimmune and Allergy Diseases
- Responsible for Regulatory strategy for projects
- Responsible for Nonclinical, Clinical, and CMC activities and strategy
- Developed timelines and templates for IND submission
- Responsible for pre-IND meeting
- Prepared and submitted successful IND
- Primary FDA contact for projects
- Managed associates who worked on projects under my lead
- Performed due diligence activities on a cross-functional team for products
- Responsible for global submissions
- Performed operational activities including safety reporting; informed consent, protocol, IB and toxicology report reviews; annual report compilation and submission; CMC Change Control review, and IND withdrawal for various projects, and SOP generation
- Primary internal regulatory representative on cross-functional team for Follow-On Biologics (FOB)

Manager, Regulatory Affairs - Shire Pharmaceutical Development, Inc.
Responsibilities:

- Regulatory submission/maintenance of four investigational and one post-marketing drug products
- Therapeutic areas including gastro-intestinal, central nervous system, and coagulation disorders
- Member of international project teams to ensure global regulatory strategy
- Submitted/maintained 3 INDs; maintained one NDA, including submission of labeling revisions
- Complied and updated Investigator's Brochures
- Compiled FDA briefing documents and conducted FDA meetings
- Participated in Key Opinion Leader (KOL) and Investigator meetings
- Performed operational activities including safety reporting, informed consent and protocol review, annual report compilation and submission, CMC change control review, regulatory timeline and regulatory template generation, CRO regulatory activity management, SOP generation
- Primary contact for FDA on drug products
- Submitted Special Protocol Assessment
- Obtained pediatric exclusivity for orphan drug product

Senior Regulatory Affairs Specialist
Regulatory Affairs Specialist
Regulatory Affairs Medical Writer - Human Genome Sciences, Inc
Responsibilities:

- Therapeutic areas including oncology, immunodeficiency and autoimmune diseases
- Active member on multiple project teams, including nonclinical and clinical sub-teams
- Trained/supervised Regulatory Affairs Associates
- Provided Regulatory guidance and strategy to project teams
- Primary contact for FDA on active INDs
- Responsible for preparation of product-specific documents
- Pre-IND briefing documents and Pre-CTA briefing documents
- Original IND submissions and amendments
- Clinical Trials Application
- Orphan Drug applications and Orphan Annual Drug reports
- USAN applications
- Interacted with departmental leaders to develop product plans with respect to Regulatory objectives
- Created first HGS IND template and nonclinical Final Report format and progress tracking system
- Coordinated nonclinical Final Report generation and reviewed scientific and statistical data.

Technical Writer - IIT Research Institute/Life Sciences CRO
Responsibilities:

- Generated nonclinical acute and chronic toxicology reports and established report templates
- Analysed and interpreted data to generate Regulatory-compliant reports
- Quality control of data, Statistics, and Final Reports

Dr Igor Gonda PhD

Principal Consultant
Date Appointed to Position: May 2020

ACADEMIC QUALIFICATIONS.

BSc Chemistry
University of Leeds, UK.

PhD Physical Chemistry
University of Leeds, UK.

EMPLOYMENT RECORD.

Non-Executive Board Member
Inspiring Pty Ltd (Aus) - 2020 – Present

Founder and CEO
Respidex LLC - 2018 - Present

Board Director
The Alpha-1 Project – 2013 - 2019

CEO and President - Board Member (2001 - 2018)
Aradigm Corporation – 2006 - 2018

CEO and Managing Director
Acrux Limited - 2001 - 2006

CSO
Aradigm Corporation – 2000 - 2001

Vice President, Research and Development
Aradigm Corporation – 1995 - 2000

Senior Scientist & Group Leader
Genentech Inc. – 1992 - 1994

Senior Lecturer/Lecturer - Department of Pharmacy
University of Sydney – 1983 - 1992

Visiting Associate Professor - School of Public Health
John Hopkins University – 1990

PROFESSIONAL ACHIEVEMENTS.

Member of 'Ad Hoc' committee on Standards for Aerosol Inhalations - British Pharmacopoeia Commission - 1982 - 1988.

Member of the Working Party on Metered Dose Aerosols - Australian Drug Evaluation Committee - 1989 - 1991

Member of the Working Party on the Therapeutic Goods Order for Metered Dose Pressurised Inhalations - Therapeutics Goods Administration - Australia - 1990 - 1991

President - The Australian Pharmaceutical Science Association - 1991 - 1992

Member of International Board - International Society for Aerosols in Medicine - 1991 - 1995

Founding Member of the Board of Directors - International Pharmaceutical Aerosols Consortium - Regulatory Science - 2001 - 2002

Astra-Zeneca Industrial Achievement Award - 2001

Member of the External Advisory Panel - California Institute of Regenerative Medicine - 2013

EMPLOYMENT RECORD CONT.

Visiting Scientist - Advanced Drug Delivery Research
Ciba-Geigy, Horsham, UK - 1989

Research Scholar, School of Mathematics
Macquarie University Sydney - 1983 - 1983

Senior Visiting Research Fellow - Department of Chemistry
Clarkson College of Technology, New York – 1987

Lecturer - Department of Pharmacy
University of Aston, UK - 1975 - 1982

Project Chemist
Nicholas Research Laboratories - 1974 - 1975

Previous Experience

Founder and CEO - Respidex LLC
Responsibilities:

Consulting for pharmaceutical and medical device companies.

Board Director - The Alpha-1 Project
Responsibilities:

Pro-bono advice for the venture philanthropy branch of this patient advocacy group.

CEO and President - Aradigm Corporation
Responsibilities:

Fundamentally transformed the mission and the business model that required to restructure and refinance the company, develop new products and new partnerships and provide vision and motivation for the employees. Established a culture of collaboration within and outside the company focused on the patients with severe rare respiratory diseases with unmet needs that included working closely with patient advocacy groups, key opinion leaders, regulatory authorities and contract research and manufacturing organizations. Provided leadership to obtain the means for the development and commercialization of a highly innovative treatment for severe respiratory infections through funding with new strategic investors, industrial partnership, government support (including funding of a substantial international biodefense program), sale of non-strategic assets and R&D tax rebates.

CEO and Managaing Director - Acrux Limited
Responsibilities:

Lead the development and rapid growth of the company from its university base in 2001 to become listed on ASX as one of the leaders in the emerging Australian life science sector. Responsible for building shareholders' value through development and commercialization of multiple transdermal and dermal drug delivery human and veterinary healthcare products. Overall responsibility for directing the development, operations and quality assurance of the company and its wholly owned subsidiaries. Leadership in the key business development activities including partnering with other organizations. Securing company's financing prior to commercial product sales through private and public equity raisings (IPO in 2004), funding by partners and government grants. Public and investor relationship management. Development of the company's workforce by implementation of infrastructure that promoted alignment of personal growth with corporate goals and generation of socioeconomic value.

CSO - Aradigm Corporation
Responsibilities:

Leadership of the New Product Research Department focused on preclinical and clinical exploration of new therapeutic and technological opportunities. Responsible for strategic science and technology development, R&D alliances, public relations with the scientific and clinical communities, intellectual property management in a leading public pulmonary drug delivery company. Key contact for comparative technology assessment of Aradigm's R&D for the investment community. Appointed to the Board of Directors, April 2001. Chairman of International Scientific Advisory Board of Aradigm Corporation until August 2006.

Vice President, Research and Development - Aradigm Corporation
Responsibilities:

Leading the R&D organization containing initially 12 people. In 5 years, R&D and engineering parts of the organization grew to ~100 people engaged in multidisciplinary research and development of products for major pharmaceutical markets such as diabetes and pain management. Provided challenging career development programs for the R&D employees. Key technical person for forming strategic business alliances with major pharmaceutical and biotechnology companies. Essential member of the executive team in successful mezzanine financing, the initial public offering and subsequent public and private financing rounds. Principal Investigator on a National Institute of Health/National Cancer Institute Small Business Industrial Research Grant for gene therapy.

Senior Scientist and Group Leader - Pharmaceutics
Senior Scientist and Group Leader - Aerosol Drug Delivery group R&D - Genentech
Responsibilities:

Responsible for the development of non-parenteral delivery of protein, peptides and gene products. Supervised 15 scientists and technicians.

Prepared and executed the development plan for pulmonary delivery of the first human recombinant protein administered by inhalation (rhDNase, brand name Pulmozyme). The product went in record time (4.5 years) from cloning to FDA approval and is now used globally as a major part of therapy of cystic fibrosis. Founded and led a multidisciplinary group (protein and peptide formulation and analysis, aerosol physics and engineering, pulmonary disease and absorption models, lung delivery of viral gene vectors) that provided key techniques and findings for one of the most rapidly growing branches of the biotech industry. Involved in partnering between Genentech and other companies. Facilitated development of people who now play leading roles in industrial and academic R&D.

Kenneth Kleinhenz

Principal Consultant
Date Appointed to Position: May 2020

ACADEMIC QUALIFICATIONS.

BSc Microbiology
University of California, San Diego, USA.

MBA Technology Management
University of Phoenix, Arizona, USA.

EMPLOYMENT RECORD.

VP Global RA/QA & COO
Cytori Therapeutics – 2005 - 2017 & 2019 – Present

Vice President Regulatory
Avelas Biosciences – 2018 – 2019

Senior Director RA/QA
MacroPore Biosurgery – 1999 – 2005

Technical Director
IFM Manufacturing – 1998 – 1999

Chief Microbiologist
Becton Dickinson - 1997 - 1998

QA/RA Manager
Pacific Pharmaceuticals – 1993 - 1997

Research Associate
Specialty Laboratory – 1991 - 1993

Research Associate
Medical Biology Institute – 1990 - 1991

Research Associate
Molecular Biosystems – 1988 - 1990

Clinical Microbiologist
Naval Hospital – 1982 - 1988

PROFESSIONAL CERTIFICATION.

American Chamber of Commerce Japan (AACJ) - Health Care Committee - 2014 - Present

American Chamber of Commerce Japan (AACJ) - Regenerative Medicine Sub Committee - 2014 - Present

Alliance for Regenerative Medicine: Government Relations and Regulatory and Reimbursement Committee - 2010 - 2015

Medical Device Manufacturing Group (MDMA): FDA Working Group - 2010 - Present

Interested Parties of the Committee for Advanced Therapies (CAT) - European Medicines Authority (EMA) - 2010 - Present

Previous Experience

VP Global RA/QA & COO - Cytori Therapeutics
Responsibilities:

Acquired a liposomal doxorubicin and docetaxol oncology assets and reinitiated manufacturing and quality control to update the open INDs. Created regulatory strategy for FDA and EMA submission withBE clinical data against RS and RLD. Coordinated and implemented US FDA, European CE Mark and Japanese PMDA regulatory strategies for device-based cell therapies. Coordinate and prepare IDE and 510(k) submissions to FDA for Class III cell-processing devices at CBER and Class II tissue devices at CDRH. Prepared CE Design Dossiers and Clinical Evaluations for CE Class IIa electromechanical devices and Class IIb reagent enzymes. ITA and CTA approvals for clinical studies in Canada and Europe. Obtained international regulatory approvals for device-based cell therapies in European Union, Australia, New Zealand, Russia, Ukraine, Israel, Serbia, etc. Built a global regulatory team of external, region-specific, cell-therapy legal experts to manage emerging cell therapy issues in key international countries in Europe and Asia Pacific. Established relationships with cell-therapy and device regulators in major global markets: USA, Canada, Germany, UK, Spain, France, Italy, Australia, Japan, etc. Maintain a 21 CFR 1270 tissue banking facility, ISO 13485 / 9001 and FDA 21 CFR 820 compliant quality systems for a fully-integrated device manufacturing facility that passed several inspections without incident. Active member of various international cell-therapy lobbying efforts. Managed key relationships with Roche, Olympus Japan, and GE Healthcare.

Vice President Regulatory - Avelas Biosciences
Responsibilities:

Maintained IND and implemented key QMS controls for an injectable drug-device combination product that was being studed for its ability to detection in situ tumor margins for patients underging breast cancer surgery.

Senior Director RA/QA - MacroPore Biosurgery
Responsibilities:

Coordinated and implemented US FDA, Health Canada MDB, European Notified Body CE Mark and Japanese PMDA regulatory strategies for bioresorbable implants. Coordinated and prepared 510(k) submissions to FDA for Class II bioresorbable implants at CDRH. Prepared CE Design Dossiers and Clinical Evaluations for MDD Class III bioresorbable implants. Negotiated with FDA and European Notified Body for expanded product claims. Coordinated regulatory activities for international regulatory approvals in China, Asia Pacific Rim, Central America, and the Middle East. Planned, prepared, and executed sterilization, packaging, stability, and manufacturing process validations for medical implants. Built and maintained ISO 13485 / 9001 and FDA 21 CFR 820 compliant quality systems for a fullyintegrated manufacturing facility that passed several inspections without incident. Managed key relationships with Medtronic Sofamor Danek.

Technical Director - IFM Manufacturing
Responsibilities:

Maintained FDA and FTC compliance for all aspects of the pharmaceutical and nutraceutical manufacturing facility. Directed the quality of tablet, capsule, and soft gel manufacturing. Developed new nutritional formulations. Represented the corporation on all technical issues. Reported directly to CEO.

Chief Microbiologist - Becton Dickinson
Responsibilities:

Implemented all aspects of AAMI 11137 irradiation sterilization guidelines for sterile plastic, glass, and liquid products in a Cobalt-60 [60Co] irradiation facility. Established, implemented and monitored sterilisation dose for new and existing products. Directed the laboratory's compliance with USP / AAMI routine microbiology sterilisation testing such as bioburden, dose verification, environmental monitoring, and organism identification activities. Directed steam sterilization activities for SAL 10-6 processing of irradiation-sensitive products. Maintained compliance of class 10,000 clean room according to Federal and ISO standards.

CA/RA Manager - Pacific Pharmaceuticals
Responsibilities:

Formerly Xytronyxs, Inc. Created and maintained an FDA compliant 21 CFR 820 Quality system which included: document control, quality control, retention samples, shipping, receiving, and vendor auditing Quality system was inspected by FDA in a pre-PMA compliance inspection which lead to a PMA Approvable letter. Coordinated contract manufacturing activities. Monitored clinical trials and co-wrote technical section of PMA submission. Negotiated a PMA approval for a dental diagnostic device that detected the severity of periodontal disease at the chair-side.

Research Associate - Specialty Laboratory
Responsibilities:

Developed and modified ELISA assays to evaluate and monitor various immunoglobin (Ig) levels. Created several Ig secreting human PBL populations via in vitro immunizations. Created hybridomas and performed tissue culture. Performed Western Blot protein electrophoresis. Planned and implemented inhouse clinical trials to establish parameters of tumor marker assays.

Research Associate - Medical Biology Institute
Responsibilities:

Transplanted human immune systems into SCID mice to evaluate HIV vaccines and anti-HIV therapies. Worked in biosafety level III (BSL3) facility to perform HIV virus tissue culture and inject live HIV virus into hu-PBL-SCID mice. Performed 32P liquid hybridization and acrylamide gel electrophoresis. Experienced with handling, eye bleeding, and sacrificing animals. Trained new technicians. Company phlebotomist.

Research Associate - Molecular Biosystems
Responsibilities:

Developed DNA-probe clinical assays under GMP guidelines. Supervised and maintained biosafety level III (BSL3) laboratory containing most all species of Mycobacterium. Performed many molecular biology techniques.

Clinical Microbiologist - Naval Hospital
Responsibilities:

Processed, cultured and identified all common microbes as well as many uncommon bacteria. Cultured and identified acid-fast bacilli, molds, and fungi. Routinely screened for and identified all clinically significant parasites. Utilized various clinical assays to detect anomalies in human serum.

Cynthia Lee BSc (Hons), MSc

Principal Consultant
Date Appointed to Position: January 2021

ACADEMIC QUALIFICATIONS.

BSc Chemistry
University of Washington, Seattle, WA.

MSc Food Science and Technology
University of Washington, Seattle, WA.

EMPLOYMENT RECORD.

President and Principal Consultant
Cynmician, Inc. - 2010 - Current

Principal Consultant
FDA Quality & Regulatory Consultants - 2020 - Current

Principal Consultant
PricewaterhouseCoopers - 2017 - 2019

Principal Consultant
Step Change Pharma, Inc. - 2014 - 2017

Principal Consultant
NSF International - 2013 - 2016

Managing Consultant
Tunnell Consulting, Inc. - 2013 - 2014

Associate Consultant
FDA Compliance Group LLC - 2013 - 2016

Associate Analytical Chemist
Jess Yuen Associates - 2010 - 2013

Member of Technical Review Board
NSF International - 2011 - 2013

Analytical Chemist/Investigator
US Food and Drug Administration, Pacific Regional Lab - 1990 - 2010

Previous Experience

President & Principal Consultant - Cynmician, Inc.
Responsibilities:

President and Principal Consultant providing consulting/auditing for finished product pharmaceutical manufacturers in cGMP manufacturing, laboratory, and Quality Assurance operations.

Principal Consultant - Cynmician, Inc.
Responsibilities:

Principal Consultant providing consulting for an OTC manufacturer in cGMP manufacturing, laboratory, and Quality Assurance operations.

Principal Consultant - FDA Quality & Regulatory Consultants
Responsibilities:

Principal Consultant providing consulting/auditing for finished product pharmaceutical manufacturers in cGMP manufacturing, laboratory, and Quality Assurance operations.

- Nov 2019: Provided gap assessment for virtual pharmaceutical company. Assessment objectives included readiness to commercial manufacturing, FDA audit, and data integrity audit. Responsibilities included reviewing analytical data, laboratory procedures and practices. The Quality Management System was reviewed at the same time and in parallel.
- Mar 2019 – May 2019: Provided a comprehensive assessment of a corporation's stability program across six sites to identify potential gaps and improvement opportunities needed to design a future state program and develop implementation plans to achieve future state.
- Jan 2018 – Sept 2018: Part of a team that provided coaching/training to local subject matter experts (LSME) at a manufacturing site to ensure that LSMEs are capable and ready for effectively communicating with regulatory inspectors. This coaching culminated in a successful FDA inspection.
- May 2017 – Dec 2017: Part of a team that provided technical assessments and remediation to four pharmaceutical manufacturing sites to ensure that procedures and processes are followed and that people are operating according to the written/approved procedures and following cGMPs. Assessment objectives included readiness to commercial manufacturing, conformance to the application, and data integrity audit. Responsibilities included reviewing analytical data, laboratory procedures and practices. Provided technical expertise to management to resolve compliance issues.

Principal Consultant - FDA Quality & Regulatory Consultants
Responsibilities:

Principal Consultant providing consulting/auditing for finished product pharmaceutical manufacturers in cGMP manufacturing, laboratory, and Quality Assurance operations.

- Feb 2016 – August 2016: Part of a team that provided 3rd party batch record review and certification for pharmaceuticals at a finished product manufacturing site.
- July 2015 – April 2016: Part of a team that provided GMP oversight to six pharmaceutical manufacturing sites to ensure that procedures and processes are being followed and that people are operating according to the written/approved procedures and following cGMPs.

Principal Consultant - NSF International
Responsibilities:

Principal Consultant providing consulting/auditing for finished product pharmaceutical manufacturers in cGMP laboratory operation and Quality Assurance operation.

- Dec 2014: Part of a team that provided due diligence assessment for the purposes of evaluating the compliance status of existing ANDAs, ANDAs under review and ANDAs under development for compliance with FDA cGMP standards. Assessment objectives included readiness to commercial manufacturing, conformance to the application, and data integrity audit. Responsibilities included reviewing analytical data primarily in the stability area, laboratory procedures and practices, and the Quality Management System.

Managing Consultant - Tunnell Consulting, Inc.
Responsibilities:

Managing Consultant providing consulting/auditing for finished product pharmaceutical manufacturers in cGMP laboratory operation and Quality Assurance operation.

- Part of a team that provided technical assessment of Abbreviated New Drug Applications for Pre-Approval Inspection. Assessment objectives included readiness to commercial manufacturing, conformance to the application, and data integrity audit. Responsibilities included reviewing analytical data, laboratory procedures and practices. The Quality Management System was reviewed at the same time and in parallel. Provided technical expertise to management to resolve compliance issues.
- Managed method validation project for R & D laboratory for method validation/verification certification of finished product, drug substance, and excipient methods. Responsibilities included reviewing gap assessments, method validation/verification protocols, analytical methods, previous validation/verification reports, and current validation/verification reports to provide certification. Provided technical feedback for protocols and reports in order to comply with cGMPs. Tracked the progress of the project and routinely reported to management. Provided technical expertise to management to resolve compliance issues.
- Provided mock FDA audit for Quality Control laboratory for finished product pharmaceutical manufacturer.
- Provided follow up audit for Quality Control laboratory for finished product pharmaceutical manufacturer.

Associate Consultant - FDA Compliance Group LLC
Responsibilities:

Associate Consultant providing consulting/auditing for finished product pharmaceutical and dietary supplement manufacturers and contract laboratories, in cGMP laboratory operation and Quality Assurance operation.

Associate Analytical Chemist - Jeff Yuen and Associates
Responsibilities:

Associate Analytical Chemist providing consulting/auditing/training for API and finished product pharmaceutical and vaccine manufacturers in cGMP laboratory operation and Quality Assurance operation.

- November 2010 – April 2011: Managed method validation remediation project between client and CRO laboratories. Responsibilities included writing and approval of all method validation protocols and reports, providing technical expertise and advice to CRO laboratories to resolve all technical issues, managing data reviewers to ensure that the project had an adequate number of qualified reviewers, and tracked the progress of the project and routinely reported to management.
- July 2011 – December 2011: Managed laboratory remediation project for a sterile finished product manufacturer. Responsibilities included evaluating method validation packages of analytical methods, providing technical expertise and advice to laboratory staff and upper management, re-writing key laboratory standard operating procedures, and tracked the progress of the project and routinely reported to management.

Member of the Technical Review Board - Jeff Yuen and Associates
Responsibilities:

Member of the Technical Review Board for the Reference Standards Program providing technical assistance for the review and evaluation of the qualification of reference standards traceable to USP and EP reference standards.

Analytical Chemist/Investigator - US Food & Drug Administration, Pacific Regional Lab
Responsibilities:

Member of the Technical Review Board for the Reference Standards Program providing technical assistance for the review and evaluation of the qualification of reference standards traceable to USP and EP reference standards.

- GMP and Pre-Approval Drug inspections (100+) at finished drug product manufacturers, API manufacturers, and contract laboratories domestically and internationally.
- Provided national and local training on conducting laboratory inspections to FDA chemists and consumer safety officers at FDA courses. Lectured about laboratory GMPs at industry workshops and regional AOAC meetings. See Att. A.
- Member of the Course Advisory Group planning the agenda, speakers, course description, and criteria for attendance of a FDA training course entitled “Introduction to Pharmaceutical Inspections for Analysts”.
- Performed analysis of complex drug samples, including consumer complaints, imported drugs, fraudulent drugs, surveillance samples, and USP reference standards (collaborative testing program).
- Experience with instrumentation includes HPLC with Fluorescence, UV, RI, MS detectors, GC-MSD, -NPD, Dissolution, FTIR/ATR Spectroscopy, UV-Vis Spectrophotometer, Karl Fisher Titrator, Polarimeter, and Capillary Electrophoresis.
- Conducted an audit of the Quality Management System for the Pacific Regional Laboratory Northwest as part of American Association for Laboratory Accreditation for ISO 17025 requirements.
- Performed method verification and scientific evaluation of New Drug Applications and Abbreviated New Drug Applications.
- Represented FDA as a senior chemist in providing consultation to internal customers such the Center for Drug Evaluation, Office of Criminal Investigations, other district laboratories, and external customers such as the Los Angeles Crime Lab, Customs laboratory, Drug Enforcement Agency labs, and other analytical testing laboratories.
- Performed a three-month detail at the Division of Field Science in Rockville, MD as a Scientific Coordinator drafting and reviewing regulatory policy, coordinating of assignments to the FDA field laboratories, compiling and assessing of field laboratory results for national quality control samples.
- Performed a one-month detail at the Seattle District Office as a Compliance Officer reviewing cases, writing warning letters, responding to consumer complaints, and providing technical assistance to industry and the public.
- Provided court testimony as a fact witness.
- Conducted method development and research with capillary electrophoresis and GC/MS. See Att. A.
- Performed details as a Supervisory Drug Chemist reviewing analytical worksheets, writing summary of results, and determining if any regulatory action needs to be taken.
- Author and Co-author on multiple publications and presentations.

Dr Patrizia Nestby PhD, MSc, FTOPRA

Principal Consultant

ACADEMIC QUALIFICATIONS.

MSc Regulatory Affairs – 2005
University of Wales, UK.

PhD in Neuropharmacology – 1998
Free University of Amsterdam, The Netherlands.

MSc Biomedical Sciences – 1994
University of Leiden, The Netherlands.

PROFESSIONAL SOCIETIES.

The Organisation for Professionals in Regulatory Affairs (TOPRA) – Fellow Member (FTOPRA).

EMPLOYMENT RECORD.

Regulatory Affairs Consultant, Director & Founder – Pioneer Regulatory Ltd
2018 - Current

Director Regulatory Affairs – Alnylam UK Ltd
2016 – 2018

Principal Consultant – Parexel Consulting
2008 - 2016

Associate Director Regulatory Affairs – ERA Consulting Ltd
2007 – 2008

Multiple Positions within Regulatory Positions – NV Organon
1998 - 2007

Previous Experience

Regulatory Affairs Consultant, Director and Founder - Pioneer Regulatory Ltd
Responsibilities:

- Providing consultancy services in the area of strategic and operational global regulatory affairs, including regulatory writing services.

Director Regulatory Affairs – Alnylam UK Ltd
Responsibilities:

- Leading global regulatory project teams for early and late-stage investigational medicinal products, consisting of small interfering RNA, and providing strategic global regulatory leadership as well as operational regulatory support.

Achievements Include:

- Defining an innovative pathway of drug development for a rare disease, preparing briefing documents and leading the EU multi-stakeholder scientific advice procedure.
- Leading a PIP procedure for a rare disease product up to approval.
- As global regulatory lead, leading the transition for a medicinal product from Phase II to Phase III, including execution of strategy for global clinical trial applications for confirmatory studies. Efficiently resolved a clinical hold situation, as imposed by the FDA, including preparing for/leading the meeting with the Agency.

Principal Consultant - PAREXEL Consulting
Responsibilities:

- Leading multidisciplinary and international teams; providing regulatory expertise on a broad range of projects through to supporting registration.
- Defining and implementing global strategy for MAA/NDA submissions; core dossier and local adaption writing and review (ICH regions).
- Preparing for and leading EU Scientific Advice procedure and FDA meetings, including authoring and review of briefing documents.
- Authoring and review of responses to questions from regulatory authorities during registration process, IBs, non-clinical and clinical IMPDs, IND applications, PIPs, RMPs, providing regulatory support for pharmacovigilance related as well as post-marketing activities.

Achievements Include:

- Leading regulatory and medical writing team tasked with preparation and submission of a complex NDA submission to FDA for a CNS product.
- On-site client assignment (2.5 years) as global regulatory lead for early/late stage products.
- Leading preparation and submission of a J-NDA to the Japanese regulatory agency for an anticoagulant product.
- Supporting the approval of the MAA for the first biosimilar monoclonal antibody in the EU.

Associate Director Regulatory Affairs – ERA Consulting Ltd
Responsibilities:

- Leading preparation of MAA and authoring sections of CTD modules, providing strategic regulatory advice, conducting due diligence activities, scientific advice procedures; authoring of regulatory documents such as IMPDs for CTAs, orphan medicinal product applications.

Director Regulatory Affairs, Global Venture Team Fertility - NV Organon
Responsibilities:

- The Global Venture Team Fertility was a project team responsible for the development and registration of two late stage biopharmaceutical products.
- Leading global regulatory affairs teams (EU, US, Japan) and defining and implementing worldwide regulatory strategy.
- Executing global regulatory and medical writing tasks, including those related to clinical trials and authoring of regulatory documents such as briefing documents for Agency interactions.
- Leading interactions with EMA in the EU and the FDA in the US.

Director CNS Drugs, Medical Biological Section - NV Organon
Responsibilities:

- Managing CNS team consisting of 5 academic regulatory professionals.
- Leadership of global regulatory affairs teams for a number of CNS compounds.
- Executing strategic and operational global regulatory activities during development and post-marketing.
- Participating in process improvement teams, including product information management, drug safety, clinical risk management and Information Technology.

Director Fertility Drugs, Medical Biological Section - NV Organon
Responsibilities:

- In addition to responsibilities as listed above under Director CNS Drugs, regulatory lead for authoring and approval process of a J-NDA to Japanese regulatory agency. Defining and implementing strategy for J-NDA submission as well as dossier writing and review. The product portfolio included small molecules as well as biotechnologically produced proteins.

Regulatory Affairs Scientist, CNS Team - NV Organon
Responsibilities:

- Performing regulatory affairs and medical writing activities as global project lead for early phase development products and for post-marketing maintenance of existing registrations.

Dr Martin Moxham BSc (Hons), PgDip, PhD, FTOPRA

Principal Consultant
Date Appointed to Position: January 2017

ACADEMIC QUALIFICATIONS.

Postgraduate Diploma in Computer Science (Distinction) - 2014
University of Hertfordshire, Hatfield, UK.

PhD in Biochemical Pharmacology – 1994
Royal Postgraduate Medical School, University of London, UK.

BSc (Hons) Biochemistry (Toxicology) – 1988
University of Surrey, Guildford, UK.

PROFESSIONAL SOCIETIES.

The Organisation for Professionals in Regulatory Affairs (TOPRA) – Fellow Member (FTOPRA).

EMPLOYMENT RECORD.

Independent Consultant in Regulatory Affairs, iRegulatory
2014 – 2016

Director of Regulatory Affairs – Alkermes Pharma Ireland (previously Elan Pharma International)
2011 – 2014

Managing Director – iRegulatory
2001 – 2010

Registration Manager – Mitsubishi Pharma Europe
2000 – 2001

Regulatory Projects Manager – Akos International Consultancy
1999 – 2000

Senior consultant – ERA Consulting (UK)
July 2010 – May 2011

Senior/Principal Registration Officer, Lotus Notes Project Manager – Generics (UK)
1995 – 1998

Registration Executive – Smithkline Beecharm
1992 – 1995

Independent Consultant in Regulatory Affairs - iRegulatory
Responsibilities:

- Evaluation of the non-clinical data package for a cardiovascular product, for suitability to support an EU MAA submission.
- Updating Module 2 clinical summaries for an orphan ATMP (advanced therapy medicinal product).
- Medical writing of a scientific book chapter.
- Assistance with due diligence for a generic pharmaceutical product acquisition;
- Preparation of the clinical section of a drug development plan for a topical pharmaceutical product.
- Preparation of a detailed scientific overview and White Paper on a novel clinical trial design.
- Management consultancy on development of the infrastructure and business processes to support efficient RIM (regulatory information management) and eCTD preparation.
- Revision of the Investigator Brochure and IND Module 2 clinical summaries for a monoclonal antibody product, to incorporate new clinical data.
- Preparation of a briefing document for a Canadian Scientific Advice request, for an orphan ATMP.

Director of Regulatory Affairs - Alkermes Pharma Ireland
Responsibilities:

- Leader of the regulatory affairs team for the Athlone (Ireland) site, and member of the site leadership and global regulatory leadership teams.
- Lead for EU regulatory strategy within Alkermes, responsible for providing strategic regulatory input into Alkermes development programs (aripiprazole lauroxil and ALKS3831for schizophrenia, ALKS 5461 for major depressive disorder, ALKS 8700 for multiple sclerosis, ALKS 7106 for pain, and Vivitrol® for opioid dependence).
- Coordination of scientific advice procedures with the CHMP and national agencies in Germany, Netherlands, Sweden and the UK.
- Project management of preparation of responses to CHMP questions in relation to an EU Centralized MAA.

Managing Director - iRegulatory
Responsibilities:

- Leading and developing iRegulatory's EU regulatory consulting and contract regulatory publishing business.
- Preparation of non-clinical written and tabulated summaries for an oncology product for an MAA to be submitted via the EU Mutual Recognition Procedure.
- Project management of the conversion of a legacy EU MAA dossier to CTD format.
- Preparation of the clinical overview for an EU Centralized MAA for a biosimilar endocrinological product.
- Preparation of a briefing package for an EMA scientific advice meeting for another biosimilar endocrinological product.
- Consultancy on clinical aspects of an MAA for a biosimilar antiviral product for submission via the EU Centralised Procedure.
- EU regulatory gap analysis for an OTC nutraceutical product.
- Advising on EU regulatory strategy for line extensions for a cardiovascular product.
- Preparation of responses to questions during an EU SPC harmonization procedure for a cardiovascular product.
- Preparation of non-clinical and clinical overviews for EU MAAs for generic pharmaceuticals (multiple projects for multiple clients).
- Preparation of tabulated summaries of non-clinical study reports, for inclusion in an EU MAA for an analgesic product.
- Regular on-site consulting as an interim manager, including project management of an MAA to be submitted via the EU Mutual Recognition Procedure, and membership of the company's internal clinical trial protocol review committee.
- Development and delivery of public training courses on eCTD in UK, Denmark, Belgium and Poland.

Regulatory Projects Manager - Akos International Consultancy
Responsibilities:

- Preparation of clinical trial submissions in UK, France, Germany and Denmark.
- Preparation of a European Active Substance Master File for a veterinary product.
- Consultancy on an oncology product in mid-stage development, including attendance at scientific advice meetings with authorities in France, Sweden, Netherlands, Germany and UK.
- Project manager for an MAA for a biotechnology anti-infective product for submission via the EU Centralised Procedure.

Senior/Principal Registration Officer, Lotus Notes Project Manager - Generics [UK]
Responsibilities:

- MAA preparation and maintenance for generic pharmaceuticals in EU markets.
- Co-ordination of regulatory support for the Irish market.
- Due diligence for product acquisitions.
- Design and development of databases and workflow applications in Lotus Notes.

Registration Executive - SmithKline Beecham
Responsibilities:

- Assistance in the preparation of core regulatory submissions for Europe and non-US international markets for antibiotic and anti-viral products.

Dr Clare Ryder BSc (Hons), PhD

Head of Project Management and Principal Consultant
Date Appointed to Position: February 2021

ACADEMIC QUALIFICATIONS.

BSc Chemistry
University of Aberdeen

PhD Synthetic Organic Chemistry
University of Aberdeen

EMPLOYMENT RECORD.

Regulatory Affairs Director,
Head of Proprietary Product Development,
Global Regulatory Affairs
Orion Pharma - 2019 - 2021

Regulatory Affairs Associate Director
PPD - 2017 - 2019

Regulatory Affairs Senior Manager
PPD - 2016 - 2017

Advanced Regulatory Specialist
3M Health Care Ltd - 2005 - 2016

Senior Regulatory Executive, Respiratory
GlaxoSmithKline - 2002 - 2003

Senior Scientist
Elan Drug Delivery Ltd - 1999 - 2002

Scientist
Quadrant Healthcare - 1996 - 1998

AWARDS.

Center Gold Medal: awarded for the most distinguished first-class Honours

Thomson Prize: awarded for excellence in organic chemistry

Neish Prize: awarded for continuing research in organic chemistry

Previous Experience

Regulatory Affairs Director, Head of Proprietary Product Development, Global Regulatory Affairs - Orion Pharma
Responsibilities:

- Responsible for a team of senior regulatory staff focused on oncology and companion diagnostics, CNS, orphan/rare disease, respiratory, medical device, drug/device combination and animal health development programmes.
- Provide strategic guidance and oversight to support the development of regulatory strategies to enable expedited development programmes that meet regulatory authority expectations.
- Review and provide strategic leadership and input into regulatory documentation including IND/CTA, agency briefing materials, MAA/NDA CTD documents and responses to agency questions.
- Proactively engage with regulatory authorities throughout the development to actively influence and ensure clarity on agency expectations to facilitate decision-making.
- Support due diligence activities for potential in-licensing/out-licensing opportunities, assessing synergies, potential risks and opportunities to support Orion strategic goals including assessment for regulatory strategy, accelerated development, orphan designation and strategic fit.
- Responsible for resourcing strategy and for mentoring and personal/professional development of the regulatory team and for development of team processes.
- Active member of R&D Steering and business teams to support strategic decision-making and direction for development project teams including input to the strategic direction of Orion R&D to enable Orion to meet its strategic growth targets.

Regulatory Affairs Associate Director - PPD
Responsibilities:

- Provide regulatory consulting and strategic advice, technical expertise and co-ordination oversight for key client projects including budget management.
- Regulatory lead for client MAA submissions for biosimilar and biologic products via the centralised procedure, including pre-submission activities, EMA pre-submission meetings and Rapporteur meetings.
- Successfully co-ordinated the preparation and publishing of client submissions in EU, US, Canada and Australia liaising with document authors, reviewers, publishers and local regulatory teams to deliver the submissions on schedule. Defined processes for and led deficiencyresponse teams to support responses to agency questions during the review cycle.
- Experienced in organising and leading agency interactions including preparation of agency briefing materials, development of questions and leading preparation meetings (e.g. FDA, EMA, MHRA, BfArM,
- Health Canada, Australian TGA) and acting as agency contact for client submissions to the EMA.
- Line management and mentoring of global regulatory team and leadership of cross-functional technical teams and client contract manufacturing partners to deliver submission documentation to plan.

- Regulatory oversight lead for major PPD client partnership (consisting of around 50 ongoing clinical trials), ensuring consistent working practices across the regulatory function and quality in meeting client expectations/deliverables. Acting as a point of escalation and member of the partnership oversight committee.
- Supporting business development and senior management in pricing and securing new business including development and preparation of proposal text and budgets, presenting at bid defence meetings and supporting contract negotiations.
- Received PPD CEO Performance Excellence award in 2017 and CEO Customers Trust Award in 2018.

TOPRA Award Winner - November 2017

- **Contribution:** Individual recognition for the significant contribution made in leading and providing strategic input to the delivery of client Marketing Applications for biosimilar/biological products in the US, EU, Canada and Australia and developing streamlined processes for efficient delivery of submissions to aggressive timelines.
- **Support:** Team recognition (nominated by the client) for the extensive strategic and operational support PPD provided the client for provision of early engagement scientific advice through to support and execution of milestone submissions of US BLA, EU MAA and Canadian NDS. Responsible for project and budget management and delivery of the pre-submission and submission activities as part of this team.

Advanced Regulatory Specialist - 3M Health Care Ltd

- Regulatory Inhalation Expert responsible for delivering regulatory strategy and management for major inhalation projects, including development of new/generic products for global markets for internal and customer projects.
- Supervision of regulatory employees and leadership of technical teams to deliver submission documentation (all phases) on schedule including training, coaching and mentoring of both regulatory and technical staff.
- Responsible for the development and delivery of the entire MAA submission package for a generic inhalation product in a European Decentralised Procedure including, CTA Submissions, scientific advice meetings, submission of duplicate licences, co-ordination with a licence partner, and management of deficiency responses. Managed outsourcing of pharmacovigilance activities and ethics submission activities. Regulatory representative of product launch team. Achieved first to market in UK for generic Seretide®.
- Co-ordinated and managed the preparation of regulatory submission documentation for development projects including Phase I-III IND/IMPD, NDA/MAA, DMFs and briefing documents for scientific advice and regulatory authority meetings and responses to regulatory authority queries and deficiency questions.
- Responsible for the development of feasibility and full development project plans, resource estimation and development of scope, proposals and quotations for new business development opportunities. Supporting bid defence meetings.
- Managed the delivery of the CMC section for a new combination product for a customer development project advising on regulatory positioning to ensure single cycle review of CMC section in US.

Senior Regulatory Executive, Skincare - Boots Healthcare International
Responsibilities:

- Project co-ordinator responsible for the management of the skincare regulatory function delivering regulatory strategy for the registration/launch of new products and product maintenance. Development of claims support rationale and pack wording approval. Managing and coaching of junior regulatory staff.
- Project co-ordinator responsible for the registration and maintenance of products under the Nurofen brand. Preparation and submission of national/MRP applications and variations.

Senior Regulatory Executive, Respiratory - GlaxoSmithKline
Responsibilities:

- Responsible for providing regulatory support for marketed products. Preparation of CMC documents for EU and rest of world submissions, renewals and responses to questions and for national/MRP variations.

Senior Scientist - Elan Drug Delivery Ltd
Responsibilities:

- Responsible for the supply of materials for toxicology and clinical studies. Compiled and maintained CMC documentation. Development of dry powder microparticle formulations for use in a novel device.

Yoshinori Shinoki BS

Principal Consultant
Date Appointed to Position: July 2020

ACADEMIC QUALIFICATIONS.

BSc
Kyoto Pharmaceutical University

Registered Pharmacist

EMPLOYMENT RECORD.

Clinical Development Consultant
MEDISO, AMED – 2019 - Present

Senior Director
Parexel Consulting – 2015 - 2019

Senior Director &
Head of Clinical Development Services
Covance – 2010 - 2015

Asia Sourcing Manager
Eli Lilly Japan – 2008 - 2010

Manager - Oncology Therapeutic Area
Eli Lilly Japan - 2006 - 2008

Project Leader
Eli Lilly Japan - 2000 - 2007

Team Leader, SOP & Training
Eli Lilly Japan - 1996 - 1999

Clinical Team Leader - Endocrine
Eli Lilly Japan - 1992 1995

Planner, Business Planning
Sawai Pharmaceutical, Inc. – 1990 - 1992

Associate, Clinical Research
Sawai Pharmaceutical, Inc. - 1984 - 1990

Previous Experience

Clinical Development Consultant
Responsibilities:

- Clinical Development Expert
- Provide clinical consultation as technical advisors
- MEDISO (Medical Innovation Support Office (MEDISO) Sponsored by MHLW)
- AMED (Japan Agency for Medical Research and Development)
- Provide clinical consultation in cooperation with consulting firm located in US

Senior Director - Parexel Consulting, Parexel International
Responsibilities:

- Have responsibility to lead business and operations for Clinical and regulatory consultation
- Grow PAREXEL consulting business and organization
- Expanded list of regulatory related services, for example, eCTD publishing CMC related services and In-Country Clinical Caretaker (ICCC)
- Takes the role of external technical support of MEDISO and AMED and support product development to accelerate innovative regenerative medicines and medical devices.
- Manage totally 25 staffs.

Senior Director & Head of Clinical Development - Convance
Responsibilities:

- Had responsibility to lead business and operations for Clinical Development Services.
- Turned profitable country in 2013 and performed significant financial performance with strong profit in 2014
- Managed totally 100 staffs with some function leaders, PM, Regulatory, QC, Clinical Operations and Sales.

Asia Sourcing Manager - Eli Lilly Japan
Responsibilities:

- Had responsibility to lead planning and implementation of sourcing in Asian countries.
- Developed process, tools and criteria to develop effective sourcing and outsourcing plan.
- Developed preferred CRO for outsource of clinical monitoring in Asia.
- Managed totally 10 studies of outsource for monitoring in 2008.
- Achieved utilization of 50% flexible resource.

Manager, Oncology Therapeutic Area - Eli Lilly Japan
Responsibilities:

- Planned, coordinated and implemented the clinical plan for oncology projects including NME and new indication. Managed 8 projects and 9 clinical trials including one global study.
- Contributed portfolio management for oncology compound.
- Managed clinical research group over 30 people in oncology therapeutic area
- Contributed productivity gain projects called "Six Sigma".

Project Leader - Eli Lilly Japan
Responsibilities:

- Managed lifecycle management for compounds
- Led the clinical development leading to a successful launch.
- Managed budgets and resource plan for project.
- Responsible for various compounds, e.g. Tadalafil for ED and PAH, Olanzapine for schizophrenia and Gemcitabine for Billiary Tract Cancer
- Led successfully bridging study toward approval.
- Led successfully global study and projected Asian mega study which are first case in Lilly.

Team Leader, SOP & Training Team - Eli Lilly Japan
Responsibilities:

- Established company wide SOPs in accordance to newly established GCPs in Japan
- Planned and implemented training program for all clinical research employees.

Clinical Team Leader, Endocrine - Eli Lilly Japan
Responsibilities:

- Led registration clinical trial for line extension.
- Led the preparation of submission dossier.
- Led clinical team with my leadership.

Planner, Business Planning - Sawai Pharmaceutical, Inc.
Responsibilities:

- Developed and implement budget control system for all departments.
- Led long range company plan as project leader
- Developed marketing strategy and annual plan.

Associate, Clinical Research - Sawai Pharmaceutical, Inc.
Responsibilities:

- Developed and conducted PK-PD study in Cardiovascular therapeutic area
- Drafted study report and manuscript for the PK-PD study.
- Monitored and Managed over 30 sites under old GCP

Dr Jens van Wijngaarden MSc, PhD

Principal Consultant
Date Appointed to Position: July 2021

ACADEMIC QUALIFICATIONS.

PhD in Biomedical Science - 2011
University of Leiden, The Netherlands.

Masters (MSc) degree in Biomedical Sciences - 1995 - 2000
University of Leiden, The Netherlands.

EMPLOYMENT RECORD.

Representative of Directorates of Governmental Stakeholders for Future Regulatory Policy Making.
MEB (Dutch Medicines Registration Authority) – 2019 - 2021

Chair of the NL Committee on Advanced Therapeutic Medicinal Products (ATMPs).
2019 - 2021

NL project lead on the EU Committee Horizon 2020 project *"Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice (STARS)"*.
2018 - 2021

NL member of the EU-innovation network, fostered by the EU Heads of Medicines Agencies (HMA).
2017 - 2021

Member of the Appeal Committee
MEB (Dutch Medicines Registration Authority) - 2017 - 2021

Secretary of the NL Scientific Advice Committee
MEB (Dutch Medicines Registration Authority) - 2015 - 2021

Secretary and First Staff Advisor of the Medicines Evaluation Board
MEB (Dutch Medicines Registration Authority) - 2015 - 2021

Vice-secretary of the Medicines Evaluation Board
MEB (Dutch Medicines Registration Authority) - 2011 - 2015

EMPLOYMENT RECORD CONTINUED.

Senior Regulatory Project Leader, Pharmacotherapeutic Group 4.
MEB (Dutch Medicines Registration Authority) – 2010 - 2015

Regulatory Project Leader, Pharmacotherapeutic Group 4.
MEB (Dutch Medicines Registration Authority) – 2007 - 2010

Genetic counselor.
Leiden University Medical Center - 2018 - 2021

PhD Student and Research Fellow - Department of Endocrinology
Leiden University Medical Center - 2017 - 2021

RELEVANT EXPERIENCE.

Member of the MEB working group on the prescription status of medicines.
2008 - 2021

Member of the MEB working group on scientific advice.
2009 - 2021

Member of the MEB working group on Legal Affairs and transparency.
2010 - 2021

Member of the MEB working group for implementation of the new EU Pharmacovigilance legislation.
2011 - 2013

Tutor at the University of Utrecht.
2011 - 2021

NL regulatory project lead on Ebola-outbreak.
2012

Annual special mentioning as outstanding MEB employee of the year.
2009

Annual special mentioning as outstanding MEB employee of the year.
2010

Zeb Younes BSc (Hons)

Principal Consultant
Date Appointed to Position: July 2021

ACADEMIC QUALIFICATIONS.

BSc (Hons) Medical Biochemistry – 2001
Royal Holloway, University of London, UK

EMPLOYMENT RECORD.

Director, Regulatory Affairs CMC
Pharmalex UK Services Ltd. - 2017 - 2021

Associate Director ERA/Acting Director ERS
ERA Consulting - 2015 - 2017

Manager, Deputy Test Facility/Resources/Stability Services
SGS M-Scan - 2013 - 2015

Senior Team Leader, Product Stability and Formulation
Lonza Biologics PLC - 2009 - 2013

Associate Manager, Stability and Release, Analytical Development
Emergent BioSolutions - 2006 - 2009

QC Laboratory Manager
UCB Celltech - 2004 - 2009

Team Leader/Analytical Scientist/Research Assistant
Microscience - 2001 - 2004

Previous Experience

Director, Regulatory Affairs CMC - PharmaLex UK Services Ltd
Responsibilities:

- International Service Coordinator, Regulatory Affairs CMC Biologics for global CMC projects.
- Management of Biotech Regulatory Affairs CMC team.
- Leading, developing and coordinating an international team, international projects and international initiatives.
- Provide expert regulatory CMC consultancy to global biotech clients.
- Preparing and leading pre-submission, scientific advice and follow up meetings with Agencies.
- Preparing IND/IMPD for clinical trials and leading teams preparing EU Centralised MAA and BLA dossiers.
- Regulatory gap analysis.

Associate Director ERA/Acting Director ERS - ERA Consulting
Responsibilities:

- CMC consulting and strategy for various biotech projects.
- Team management.
- To project manage client work, to ensure timelines are met.
- To author and prepare regulatory dossiers, briefing packages, applications, source reports.
- To support and train customers and teams in various aspects of drug development.
- To set up and lead scientific advice meetings.

Manager, Deputy Test Facility/Resources/Stability Services - SGS M-Scan
Responsibilities:

- To establish, set up and maintain a new offering for stability services (staff, labs and infrastructure) characterisation and method development teams, this includes; operations, scheduling, staffing, new offering development, sales support and site compliance support.
- To manage all resources across site.
- To perform the role of GLP deputy test facility manager.
- Audit Support.
- Line management.
- Management of a GMP laboratory and ensuring compliance.
- Analytical representative for various customer projects / products covering all aspects of analytical development and providing customers with advice/guidance on analytical strategies and approaches. Management reviewer of study reports and protocols and final technical reviewer of deviations/investigations.

Senior Team Leader, Product Stability and Formulation - Lonza Biologics PLC
Responsibilities:

- To manage, co-ordinate, schedule and resource stability and formulation studies for various recombinant protein products and customers in a GMP laboratory.

- Line management and scheduling operations, ensuring completion of GMP and non GMP testing for various stability and formulation studies. Management of a GMP laboratory and ensuring compliance.
- Trouble shooter and lead in operational efficiency activities.
- Study Director.
- Analytical representative.

Associate Manager, Stability and Release, Analytical Development - Emergent BioSolutions
Responsibilities:

- Design, management and co-ordination of all formal development stability studies for protein subunit vaccines, live attenuated vaccines and ancillary products for EU site. Review and Analytical release of BMR for clinical use of products.
- Review and authorise analytical Master and executed Batch Manufacturing Records.
- Prepare CoAs for use of products in clinical studies.
- Design of stability studies.

QC Laboratory Manager - UCB Celltech
Responsibilities:

- Justifying the need for and setting up a laboratory to the principals of GMP including setting up the required documentation infrastructure and moving forward to maintain this status for testing mAbs and derivatives.
- Scheduling, lab metrics, troubleshooting equipment, performing investigations and OOE/OOS/OOT results.
- BLA Module 3 Preparation.

Bioanalytical Supervisor - UCB Celltech
Responsibilities:

- Management of project outsourcing activities.
- Management of stability studies.

Team Leader/Analytical Scientist/Research Assistant - Microscience
Responsibilities:

- Assay Development and Characterisation for protein subunit vaccine candidates and live attenuated vaccine candidates.
- Devise and develop novel assays for vaccine candidates and capture as test method procedures.
- Manage in-house stability and formulation studies for protein vaccine candidates.
- Perform stability testing for protein subunit vaccine candidates.
- Small scale purification.

SELECTED PUBLICATIONS.

- BioProcess International Articles
  - Manufacture and Regulation of Cell, Gene, and Tissue Therapies: Chemistry, Manufacturing, and Control Challenges, Issue Apr 2021
  - Manufacture and Regulation of Cell, Gene, and Tissue Therapies, Issue Nov 2020
- Particle Aggregation Analysis – Biologics & Particulates: Identification & Control in the Product Lifecycle. Drug Development and Delivery, Issue April 2015.
- Stability Testing Roundtable. Pharmaceutical Outsourcing, Issue September 2013.
- Novel protein vaccine candidates against Group B streptococcal infection identified using alkaline phosphatase fusions. FEMS Microbiology Letters 2003 222, 263-271

Dr Evyenia Shaili BSc (Hons), MSc, PhD

Senior Consultant
Date Appointed to Position: September 2021

ACADEMIC QUALIFICATIONS.

PhD Mathematical Biology and Biophysical Chemistry - 2014
University of Warwick, Coventry, UK

MSc Mathematical Biology and Biophysical Chemistry - 2009
University of Warwick, Coventry, UK

BSc (Hons) Biomedical Chemistry - 2008
University of Warwick, Coventry, UK

SCHOLARSHIPS.

2009 - 2012: EPSRC Doctoral Training Award for PhD

2008 - 2009: EPSRC Doctoral Training Award for MSc

2005: AstraZeneca-Warwick Scholarship for BSc

EMPLOYMENT RECORD.

Regulatory Affairs Manager, Oncology
Amgen, London - 2018 - 2021

Senior Associate
PAREXEL International, London - 2016 - 2018

Scientific Officer
European Medicines Agency, Paediatric Medicines Office, London - 2015 - 2016

Trainee
European Medicines Agency, Orphan Office, London - 2014 - 2015

Postdoctoral Research Assistant
University of Warwick, Coventry - 2014 - 2014

Previous Experience

Regulatory Affairs Manager, Oncology - Amgen
Responsibilities:

European Regulatory Delegate/Lead for oncology products in early development.

Core responsibilities include:

- Plan, manage and execute European regulatory submissions to advance the clinical development, including pediatric waivers and scientific advice applications
- Advance product pipeline by obtaining and maintaining Clinical Trial Authorisations (CTA) within the European Union. This includes preparation and management of all the stages of the CTAs such as the initial submission, RTQ (Response To Questions), substantial amendments, temporary halts
- Development of European product regulatory strategy to support MAA of products in early development, in close collaboration with global regulatory team, European commercial and market access teams. Communication of regulatory strategies to management and other relevant stakeholders
- Perform regulatory research to obtain relevant histories, precedent and maintain an awareness of new and developing legislation/ policies and communication of any impact to the wider team
- Manage and coordinate a clinical trial group comprised of junior members of staff with a primary role to conduct the administrative tasks needed for CTAs.

Senior Associate - PAREXEL
Responsibilities:

Supported clients in a number of European and US regulatory submissions.

Key projects included:

- Authoring clinical and non-clinical sections for centralized MAAs or BLAs. In particular:
  - Clinical writer for Module 2.7.3 (Summary of Clinical Efficacy) for a novel biologic for the treatment of plaque psoriasis and played a central role in the justification of drug posology through critical analysis and discussion of the clinical study data within relative sections of 2.7.3. In addition, played a key role in authoring responses to Day 120 CHMP questions.
  - Non-clinical writer for the Pharmacokinetics Written Summary (Modules 2.6.4 and 2.6.5) for a novel chemical drug
  - Non-clinical writer for the Toxicology Written Summary (2.6.6 and 2.6.7) within the Nonclinical Overview for a hybrid application regarding a new formulation of an authorised drug
  - Clinical writer for an extrapolation report for a BLA submission for a biosimilar
- Provided scientific and regulatory input in the preparation of a briefing document for a Scientific Advice procedure
- Supported activities required for Marketing Authorisation Transfer (MAT) between two large pharmaceutical companies
- Provided internal advice in projects dealing with orphan designations and PIP submissions.

Scientific Officer - EMA, Paediatric Medicines Office
Responsibilities:

- Assessed Paediatric Investigational Plans (PIPs) for medicinal products in a number of therapeutic areas, including oncology, immunology and haematology
- Liaised with expert working groups to assess aspects of the PIP such as: appropriateness of formulation, the approach to PK/PD modeling and the proposed non-clinical studies
- Led discussion meetings with the FDA to facilitate alignment in paediatric drug development between US and Europe for certain PIPs
- Participated and led meetings with applicants to discuss procedural and scientific matters in relation to their applications (e.g. pre-submission meetings).
- Led and coordinated the construction of an inventory with off-patent medicines that could be developed for certain paediatric respiratory conditions.

Trainee - EMA, Orphan Office
Responsibilities:

- Acted as EMA coordinator for a number of procedures for orphan designation, which entailed the scientific review of applications as per the eligibility criteria laid out by the orphan regulation. Presented the analysis and main outcomes at the COMP plenaries for further discussion and decision
- Developed and coordinated a survey completed by the COMP members that identify trends in recurrent issues arising during discussions of orphan designation procedures. Results led to the creation of a decision-making flowchart for designation procedures, used internally. In addition some of the conclusions of this project were implemented in the Commission notice on orphan medicinal products, adopted in 2016
- Conducted literature reviews on relevant animal models used for studying rare neurological diseases, which formed the foundation of an article published at a peer-reviewed journal ("Nonclinical data supporting orphan medicinal product designations: lessons from rare neurological conditions", Drug Discov Today, 23(1):26-48.

Postdoctoral Research Assistant - University of Warwick
Responsibilities:

- Research focused on platinum-based photoactivatable complexes to be used in photochemotherapy (as initiated in PhD)
- Participated in efforts to commercialise, secure industrial partners and obtain funding for research
- Established collaborations with different research groups to study the antimicrobial activities of the compounds synthesized
- Co-supervised laboratory activities and projects of other students
- Authored and peer-reviewed articles.

Amy Cooke MSc, BSc (Hons)

Consultant
Date Appointed to Position: November 2018

ACADEMIC QUALIFICATIONS.

MSc Cancer Biology – 2017
University of Kent

BSc (Hons) Biomedical Science – 2016
University of Kent

PROFESSIONAL SOCIETIES.

The Organisation for Professionals in Regulatory Affairs (TOPRA) - Member

EMPLOYMENT RECORD.

Associate Consultant – Clinical Network Services
2017 – 2018

Marketing Intern – Charles River
2016 – 2017

Previous Experience

Marketing Intern, Charles River
Responsibilities:

- Searching scientific databases
- Accurately recording data
- Formatting documents

Dr Rehma Chandaria MPharm, MSc, PhD

Consultant
Date Appointed to Position: October 2018

ACADEMIC QUALIFICATIONS.

PhD Tissue Engineering and Regenerative Medicine – 2017
University of Nottingham, UK

MSc Drug Discovery Skills – 2011
King's College London, UK

MPharm Pharmacy – 2008
Cardiff University

PROFESSIONAL SOCIETIES.

General Pharmaceutical Council
– Registered Pharmacist – 2009

EMPLOYMENT RECORD.

Consultant – Clinical Network Services
2018 – Present

Translational Research Scientist – Autolus Ltd
2016 – 2018

Locum Community Pharmacist – Self-employed
2009 – 2012

Scientist – GlaxoSmithKline
2011 – 2011

Previous Experience

Translational Research Scientist, Autolus Ltd
Responsibilities:

- Development, validation and transfer of bioanalytical assays for use in patient monitoring in clinical trials.
- Writing and reviewing validation reports used in IND applications.
- Writing and reviewing SOPs.
- Working with the regulatory affairs team to write and review regulatory submissions such as CTA amendments and pre-IND briefing books.
- Ensuring compliance with GCP within the translational research laboratory.
- Representing translational research within a matrix clinical study team including clinical, medical, regulatory and project managers.
- Authoring and uploading documents to the Wingspan eTMF.
- Working with an external data management company to review and approve data transfer specifications.
- Performing flow cytometry, qPCR and Luminex multiplex cytokine assays to GCLP regulations.

Scientist, Immuno-Inflammation, GlaxoSmithKline
Responsibilities:

- Isolation of T cell and monocytes from donated human blood for the purpose of validating epigenetic drug targets.
- Laboratory methods used include cell culture, electroporation and lipofection of siRNA, qPCR, western blotting and MSD multiplex cytokine assays.

Locum Community Pharmacist
Responsibilities:

- Dispensing and checking prescriptions.
- Offering advice regarding minor ailments and use of prescription and over-the-counter medication.

Harriet Thomasson MChem

Consultant
Date Appointed to Position: November 2018

ACADEMIC QUALIFICATIONS.

MChem, Master of Chemistry with a year in industry
2016 – University of York

EMPLOYMENT RECORD.

Associate Scientist – Domainex Ltd
2016 – 2018

Industrial Trainee – MRCT (Now LifeArc)
2015 – 2016

Previous Experience

Associate Scientist - Domainex Ltd
Responsibilities:

- Clear and concise scientific writing, regularly summarising and presenting work to clients.
- Close analysis of key data to ensure a high standard of quality throughout compound production, purification and testing.
- Assessment of synthetic tractability and medicinal chemistry interest of target compounds.
- Expedient synthesis of bespoke clinically relevant compounds.

Dr Hannah Lewis BSc (Hons), MRes, PhD

Consultant
Date Appointed to Position: October 2018

ACADEMIC QUALIFICATIONS.

PhD Cardiovascular Research – 2018
King's College London, UK

MRes Cardiovascular Research – 2014
King's College London, UK

BSc (Hons) Physiological Sciences – 2013
Newcastle University, UK

PROFESSIONAL SOCIETIES.

British Societies for Cardiovascular Research
– Member

Previous Experience

Research Scientist (PhD)
Responsibilities:

- Contribution to the design and conduction of experiments investigating the impact of post- translational protein modification in both physiological and pathophysiological murine models.
- Statistical analysis of a variety of non-clinical data sets.
- Scientific techniques: Immunohistochemistry, immunoblotting, histology, in vivo analysis including murine echocardiography, cell culture, qPCR, small animal model generation.
- Preparation and production of research outputs including presentations for conferences and manuscripts for publication.
- Organisation and delivery of a national conference.

Bethany Rose Louise Aykroyd (Hons), MPhil, PhD

Associate Consultant
Date Appointed to Position: June 2021

ACADEMIC QUALIFICATIONS.

PhD in Physiology, Development and Neuroscience - 2021
University of Cambridge.

MPhil in Clinical Science (Rare Diseases) - 2017
University of Cambridge.

BSc (Hons) Biomedical Science - 2016
University of Essex

AWARDS.

2019	**Conference Travel Grants (totaling £4,695) –** awarded from seven scientific societies to present at four national and international conferences from 2019-2020.
MAY 2017	**Vice Chancellor's & Wolfson College PhD Scholarship -** Full financial support for the 250 highest ranked PhD applicants for 2017 entry.
MAY 2016	**Cambridge Newton College Masters Scholarship (£12,000) -** Fewer than 70 are awarded to the most outstanding UK MPhil applicants for 2016 entry.
JULY 2016	**John Shire Memorial Prize -** Most outstanding student in the School of Biological Sciences, University of Essex.
JULY 2016	**Glaxo Smith Kline Prize -** Most outstanding BSc Biomedical Science student.
APRIL 2015	**Wellcome Trust Vacation Scholarship -** £2,000.

Previous Experience

PhD in Physiology, Development and Neuroscience
University of Cambridge
Responsibilities:

Scholarship awarded for being one of the top 250 PhD applicants for 2017 entry across all subjects. After identifying a gap in the literature, I built on knowledge gained from my MPhil research to understand more about the importance of placental endocrine signalling during pregnancy.

Major achievements include:

- Coordinated with stakeholders to ensure project completion leading to the publication of my research as first author, in a peer-reviewed scientific journal. Further publications pending.
- Presented my findings at six national and international conferences and formed networks with researchers and clinicians from around the globe.
- Chaired the organisation of an interdisciplinary academic research conference.
- Supervised multiple undergraduate and postgraduate students.

MPhil in Clinical Science (Rare Diseases)
University of Cambridge
Responsibilities:

Scholarship awarded for being one of the top UK MPhil applicants for 2016 entry across all subjects.

- Course modules included: Epidemiology, Medical Statistics, Practical Aspects of Clinical Research, Genetics and Rare Diseases.
- Brainstormed rare disease clinical case studies and analysed research advancements in academic publications.
- Negotiated and designed a six-month research project outside of the predetermined options.
- Presented my research at three national research conferences.

BSc (Hons) Biomedical Science
University of Essex
Responsibilities:

Scholarship awarded for being one of the top UK MPhil applicants for 2016 entry across all subjects.

- Highest final degree mark from the School of Biological Sciences in 2016 (out of 242 students).
- First class obtained in each year.
- Successfully planned and applied for a Wellcome Trust funded summer research project.

Iheoma Anosike BSc (Hons), MSc

Associate Consultant
Date Appointed to Position: November 2019

ACADEMIC QUALIFICATIONS.

MSc Advanced Chemical Engineering – 2019
Imperial College London, UK

BSc Biochemistry (Hons) – 2018
University of Birmingham, UK

EMPLOYMENT RECORD.

Customer Generation Executive – MVF
2018 – 2019

Admissions Compliance and Development Team Member – University of Westminster
2017 – 2017

Previous Experience

Customer Generation Executive
Responsibilities:

- Negotiating with customers and responding to objections
- Accurately recording and reviewing data
- Meeting targets in number of qualified leads generated

Admissions Compliance and Development Team Member
Responsibilities:

- Conducting visa checks against regulatory frameworks
- Creating staff training documents
- Advising applicants on university application process

Dr Leticia Monjas Gómez MSc, PhD

Associate Consultant
Date Appointed to Position: April 2021

ACADEMIC QUALIFICATIONS.

PhD in Medicinal Chemistry - 2016
University of Groningen, The Netherlands.

Masters Degree in Organic Chemistry - 2012
Complutense University of Madrid, Spain.

Degree in Chemistry - 2010
Complutense University of Madrid, Spain.
Bachelor research: University of Groningen, The Netherlands (Erasmus fellowship)

EMPLOYMENT RECORD.

Postdoctoral Researcher
University of Gothenburg, Sweden - 2018 – 2020

Postdoctoral Researcher
University of Gothenburg, Sweden - 2017 - 2018

PhD candidate
University of Groningen, The Netherlands - 2012 - 2016

Previous Experience

Postdoctoral Researcher
Prof. M. Grøtli group - University of Gothenburg, Sweden
Responsibilities:

- Developed small-molecule modulators for metabolic diseases: design, synthesis and structure-activity relationship studies.
- Project coordinator: assigned and prioritised work, delegated tasks to team members, communicated with collaborators, scheduled meetings.
- Organised and analysed research results (4 groups consisting of chemists, biochemists and biologists), and chemicals database.

Postdoctoral Researcher
Dr. C. J. Wallentin group - University of Gothenburg, Sweden
Responsibilities:

- Chemistry: synthesised derivatives of a marine natural product as potential antibiotics.
- Communicated with collaborators (computational chemists, biologists).
- Disseminated scientific results/review: scientific article, book chapter, oral presentation at a national scientific meeting.

PhD Candidate
Prof. A. K. H. Hirsch group - University of Groningen, The Netherlands
Responsibilities:

- Designed and synthesised vitamin derivatives to study vitamin transporters in bacteria: starting point for the development of antibiotics.
- Project management to meet deadlines, prioritisation of work and coordination with collaborators (mainly biochemists and biologists)
- Communicated scientific results: 11 scientific articles (written together with collaborators), 7 oral presentations and 7 poster presentations at national and international conferences.
- Generated results that secured funding for one PhD student and one postdoc in the research group to continue the project.

Dr Sarah Kendall BSc (Hons), MRes, PhD

Associate Consultant
Date Appointed to Position: October 2020

ACADEMIC QUALIFICATIONS.

PhD Cardiovascular Science - 2017 - 2020
Kings College London, UK.

BSc (Hons) Biochemistry - 2012 - 2016
The University of Surrey, UK.
Placement Year - Weill Cornell Medical College NYC, USA

EMPLOYMENT RECORD.

Randall Division Representative
Kings' College London - 2018 – 2019

Activities Organiser's Assistant
Southbourne School of English - 2016

Research Assitant
Weill Cornell Medical College - 2014 - 2015

Previous Experience

Randall Division Representative
Responsibilities:

- Contributing to decision-making processes regarding on-going changes in the School of Basic and Biomedical Sciences (BMBS).
- Diversity, development, and inclusion committee representative and the school board of post-graduate coordinators.
- Part of the committee responsible for the inaugural careers day that attracted 150 participants, as well as the first annual BMBS postgraduate symposium.
- Engaging with the student body, and organising of monthly social events.
- Devising and executing a retreat day for research staff and students.

Activities Organiser's Assistant
Responsibilities:

- Working in an internationally diverse language school, organising activities to integrate children of different nationalities.
- Developing activities to adapt to children's specific needs, promoting key British cultural values and adjusting communication methods to compensate for language barriers.
- Managing activity budget and student payments, as well as adapting activities to ensure financial viability.

Research Assistant
Responsibilities:

- The project primarily investigated the interaction of two cardiac proteins; Filamin C and Hspb7.
- Demonstrated ability to work independently within the Todd Evans Laboratory, using scientific techniques including PCR, cloning, transfection, western blots and co-immunoprecipitation.
- Proven contribution of ideas and results to a PhD project, while developing key communication skills to enable accurate presentation of complex ideas to a large group.
- Developed ability to utilise different computational programs and analyse complex data.

University of Surrey Ambassador
Responsibilities:

- Employed as a widening participation and careers ambassador, to promote and market the university to potential students.
- Contributed to articles in the university newspaper.
- Communicated efficiently with thousands of people, both in person and by email.
- Networked with employers, organising events for them to present at the university.
- Developed skills to work both independently, with different groups of students and in a team environment.
- Demonstrated the ability to devise, distribute and analyse large surveys.

CONTACT

Info@Scendea.com

HEAD OFFICE.

Scendea Ltd
20 The Causeway
Bishop's Stortford, Hertfordshire,
CM23 2EJ
United Kingdom

Tel: +44 (0)1279 656 305

EU OFFICE.

Scendea (NL) B.V.
De Cuserstraat 93
1081 CN Amsterdam
The Netherlands

Tel: +31 (0)208 949 169

US OFFICE.

Scendea (USA) Inc.
Suite 110
5764 Pacific Center Blvd.
San Diego, CA 92121
USA

Tel: +1 619 793 4511
Fax: +1 858 295 1477

SCENDEA

COLLABORATE | INNOVATE | SUCCEED