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.

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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, the Netherlands, Australia 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.

Zeb Younes

Head of Product Development & Regulatory Consulting, Principal Consultant.

Zeb Younes is Head of Product Development & Regulatory Consulting, 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 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.

Dr Paul Griffin

Principal Medical Consultant.

Dr Paul Griffin is a Principal Medical Consultant at Scendea, offering invaluable technical, scientific, and clinical development guidance to our clients. With extensive experience as a Principal Investigator and Medical Monitor, Paul is a renowned expert in infectious diseases.

Paul's impressive professional portfolio includes senior roles such as Professor at The University of Queensland, as well as the Director of Infectious Diseases at the Mater Hospital. Paul holds notable qualifications, including a BS (Hons) in Microbiology and Immunology, an MBBS, and fellowships in Infectious Diseases and clinical microbiology.

Dr Austin Smith

Principal Medical Consultant.

Dr Austin Smith is a Principal Medical Consultant at Scendea, responsible for providing technical, scientific and clinical development advice to our clients. Austin has 15 years of experience in clinical practice in both radiation and medical oncology and over 20 years in pharmaceutical industry covering all aspects of clinical development.

Austin has extensive knowledge in a wide range of therapeutic areas. However, Austin has a particular peak of knowledge in the oncology and immunology space having practiced as a medical oncologist. Austin has held a variety of industry positions including at PPD, Theradex, Nanomab Technologies and LINK Medical. Austin has a Doctor of Medicine from the Royal College of Surgeons (Ireland) and is General Medical Council (UK) certified.

Dr James Parsley

Head of CMC & Principal Consultant.

Dr James Parsley is Head of CMC & Principal Consultant at Scendea. James is responsible for providing global CMC biological technical and regulatory advice to clients from early-stage development through to marketing authorisation and post marketing.

A former director at GSK, James has 20 years' experience in the pharmaceutical industry with a broad regulatory background in terms of regulatory disciplines and therapeutic areas. His main expertise is in CMC biopharmaceuticals. James holds a DPhil in Biochemistry from the University of Sussex and is a member of TOPRA for which he has previously lectured on both nonclinical and CMC biopharmaceutical regulatory affairs.

Erik Doevendans

Technical Head NL & Principal Consultant.

Erik Doevendans is Technical Head NL & 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.

Dr Angeles Escarti-Nebot

Head of Non-Clinical & Principal Consultant.

Dr Angeles Escarti-Nebot is Head of Non-Clinical & 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 Maria Beatrice Panico

Head of Clinical & Principal Consultant.

Dr Maria Beatrice Panico is Head of Clinical & Principal Consultant at Scendea, responsible for providing scientific and regulatory advice to our clients. Beatrice was formerly a Leading Senior Medical Assessor at the MHRA and represented the UK in the European working groups on new trial designs, safety and In Vitro Diagnostics. She is one of the authors of the CTFG Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials.

Prior to joining the MHRA, Beatrice worked as a clinical neurologist, clinical investigator, researcher in neuroscience and pharmacovigilance expert in the pharmaceutical industry. Beatrice was a member of the WHO working group on regulatory aspects of artificial intelligence and won the 2023 TOPRA Lifetime Achievement award for regulatory excellence. Beatrice is a medical doctor, fully qualified neurologist and has a PhD in neuroscience.

Penny Field

Technical Head (AUS) & Principal Consultant.

Penny Field is Technical Head (AUS) & Principal Consultant at Scendea, responsible for providing regulatory, CMC and clinical development strategies to clients. Penny has over 30 years' regulatory experience in the development and registration of biopharmaceuticals including prophylactic and immunotherapeutic vaccines, recombinant proteins (including mAB and biosimilars) and cell and gene therapies and has provided regulatory strategy, clinical guidance and scientific advice for a range of complex biologicals.

Penny has worked with CSL, Amgen and ERA Consulting and has also consulted to more than 30 companies to facilitate the product development and registration of prescription medicines. Penny holds a BSc (Hons) in Biotechnology and a MMSc in Drug Development.

Dan Cafaro

Principal Consultant.

Dan Cafaro is a Principal Consultant at Scendea responsible for defining and executing strategy for global regulatory affairs for medicinal products. Dan has extensive experience interacting with the FDA and the EMA and has over 30 years' experience in managing worldwide regulatory and development programs in the pharmaceutical and biotechnology industries.

Dan has held several senior leadership roles at Quark Pharmaceuticals, XOMA and Allergan and belongs to several professional societies including the Regulatory Affairs Professional Society (RAPS), The Organisation for Professionals in Regulatory Affairs (TOPRA), the Drug Information Association (DIA). Dan holds a BSc in Chemistry.

Dr Asha Kattige

Principal Consultant.

Dr Asha Kattige is a Principal Consultant at Scendea, responsible for providing technical advice in the areas of CMC, product development and international regulatory affairs, to facilitate the entry of clients' compounds into clinical trials and assist in the activities required for successful international marketing approvals.

Asha has over 20 years' experience in the pharmaceutical industry, holding senior positions at various companies including UCB, Teva, Quotient Sciences and Patheon. Asha has substantial experience in the fields of CMC, Product Development and Regulatory Affairs. Asha holds a PhD in Pharmaceutical Technology, has conducted research in parenteral and inhalation products and presented at various conferences.

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 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.

Stephen Kirk

Principal Consultant.

Stephen Kirk is a Principal Consultant at Scendea, responsible for providing nonclinical scientific and regulatory advice to our clients. Stephen was formerly head of nonclinical science at Allergy Therapeutics and prior to this, spent over two years as a senior toxicologist in the research and development group at KalVista Pharmaceuticals. Before joining the pharmaceutical industry Stephen spent over 20 years in various contract research organisations (Including Covance, Charles River and Aptuit) as a study director In toxicology and Immunotoxicology.

Stephen has a strong scientific background with more than 25 years experience In drug development. Stephen holds a BSc (Hons) in Immunology and a post-graduate certificate In Biopharmaceutical Development.

Shweta Menon

Deputy Head of Product Development & Regulatory Consulting, Principal Consultant.

Shweta Menon is the Deputy Head of Product Development & Regulatory Consulting, Principal Consultant at Scendea, responsible for providing company-wide operational leadership to project management teams alongside strategic, technical and regulatory advice and services to clients. Shweta has over 16 years' experience working in regulatory affairs including roles in GSK, Hospira and Teva.

Shweta has considerable experience in both pre- and post-authorisation submission activities in the EU and Global markets over a range of therapeutic areas for small molecules and biologics in addition to successfully project managing large scale partnerships and short-term engagements. Shweta holds a M.Pharm in Pharmaceutics.

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 Justine Ramsden

Principal Consultant.

Dr Justine Ramsden is a Principal Consultant at Scendea responsible for providing high-quality regulatory CMC technical advice and product development strategies. Justine has over 25 years of experience in the pharmaceutical industry, including over 22 years in Regulatory Affairs and has held senior positions in pharmaceutical companies including Alliance Pharmaceuticals and Piramal Critical Care.

Justine has extensive experience interacting with various EU regulatory bodies and has considerable experience in both pre- and post-authorisation submission activities in the EU and Global markets over a range of dosage forms and therapeutic areas. Besides her core CMC expertise, she has extensive experience in CMC writing, and strategic guidance and holds a PhD in pharmaceutical drug development.

Dr Natalie Thomas

Principal Consultant.

Dr Natalie Thomas is a Principal Consultant 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. Natalie holds a PhD in Biochemistry and Molecular Biology.

Aarti Pattni

Principal Consultant.

Aarti Pattni is a Principal Consultant at Scendea, responsible for the authoring and compilation of regulatory submissions to European and US agencies, in addition to providing strategic, technical and regulatory advice and services to clients within her role as project manager.

Aarti has experience working in various therapeutic areas including oncology and general medicines. Prior to joining Scendea, Aarti has been working with MSD in the Netherlands as an EU Liaison, Regulatory Affairs Europe, before this she worked for GSK, as a non-clinical Regulatory Associate and Regulatory Operations Associate in Ware and Stockley Park sites, respectively. Aarti holds a BSc in Biochemistry from King's College London.

Richard Scotland

Principal Consultant.

Richard Scotland is a Principal Consultant at Scendea, responsible for providing scientific, regulatory and clinical development strategies to our clients. Richard has over 30 years' experience in drug development, regulatory affairs, compliance, and clinical/medical management, within the fields of hematology, oncology, rare diseases, pediatrics and genetic disorders, CNS, and biologics.

Richard has extensive global strategic leadership experience within the pharmaceutical and biotech industry and holds a BA in Biology.

Ian Waterson

Principal Consultant.

Ian Waterson is a Principal Consultant at Scendea, responsible for providing nonclinical scientific and regulatory advice to our clients. Ian was formerly a Senior Non Clinical Assessor at the MHRA and has previously held positions in Sanofi and Covance working both as a Study Director and Toxicology Project Team Representative.

Ian has a strong scientific background with more than 29 years' experience in drug development and 8 years' experience as a MHRA regulator. Ian holds an MSc in Applied Toxicology and a BSc (Hons) in Life Sciences.

Leanne West

Principal Consultant.

Leanne West is a Principal Consultant at Scendea responsible for providing regulatory and clinical development strategies to clients. Leanne has over 28 years' experience in the biotechnology, pharmaceutical and CRO industries. Leanne has a broad level of experience across all phases of drug development and project management. Therapeutic areas include Infectious disease, oncology, women's health, cardiovascular disease and vaccines. Leanne has expertise in first-In-human trials and the regulatory hurdles required to move new agents into the clinic.

Leanne has held senior positions at Prescient Therapeutics, Novotech, Clinical Network Services and Novogen Limited and has also consulted multiple biotechnology companies to facilitate their clinical development. Leanne holds a BBiotechnology (Hons).

Dr Bertjan Ziere

Principal Consultant.

Dr Bertjan Ziere is a Principal Consultant at Scendea, responsible for providing regulatory and non-clinical development strategies to clients. Bertjan was most recently VP and Head of Preclinical Development & CMC at Leyden Laboratories BV and has over 15 years working as an independent consultant, focussing on non-clinical development, regulatory affairs, CMC and Quality Assurance.

Bertjan has a strong scientific background with more than 25 years of experience in pharmaceutical development and has provided strategic, scientific and regulatory guidance for a range of (bio) pharmaceuticals including vaccines, recombinant proteins, and gene therapies. He holds a PhD in BioPharmaceutical Sciences from the Universtity of Leiden, Netherlands.

Kelly Burns

Team Lead (AUS) & Senior Consultant.

Kelly Burns is Team Lead (AUS) & Senior Consultant at Scendea with over 8 years' experience working on early-phase clinical studies. Kelly has worked on regulatory documents across a broad range of therapeutic areas including infectious disease, respiratory disease, haematology, oncology, neurology, and immunological disorders.

Kelly started her career as a research scientist in reproductive biology and worked in skin pathology and histology before moving into clinical research. Kelly holds a BSc (Med.Sci) from the University of Newcastle Upon Tyne with first class honours in Physiology.

Dr Babaji Yadav

Principal Consultant.

Dr Babaji Yadav is a Principal consultant at Scendea, responsible for providing strategic Nonclinical/toxicology and clinical development advice to clients in support of global development programmes. He has over eight years of academic experience in pre-clinical oncology drug development, and ten years of industry experience in early phase clinical development and nonclinical consulting.

Babaji has prior experience in the Pharmaceutical, Biotech, and Clinical Contract Research Organization (CRO) industries, having worked at companies such as Sanofi-Aventis, Kazia Therapeutics, IQVIA, Clinical Network Services, and Novotech. Babaji is a registered EU/UK toxicologist and serves as an independent reviewer toxicologist on the Bellberry Human Research Ethics Committee (HREC) in Australia. Babaji holds a PhD in Pharmacology and Toxicology.

Iheoma Anosike

Senior Consultant.

Iheoma Anosike is a Senior Consultant at Scendea, responsible for overseeing the completion of deliverables for a number of Scendea's clients. Alongside her role as project manager, Iheoma works on the full scope of EU and US regulatory activities, managing various agency interactions and authoring technical/scientific documents for submission to regulatory authorities.

Whilst studying for her Master's degree in Advanced Chemical Engineering from Imperial College London, Iheoma gained experience in pharmaceutical process engineering and development for the production of medicines. Iheoma holds a BSc (Hons) in Biochemistry from the University of Birmingham. Iheoma is also a Regulatory Affairs Certification (RAC) holder.

Polly Kennard

Senior Consultant.

Polly Kennard is a Senior Consultant at Scendea. Polly is responsible for authoring and management of regulatory submissions to US and European agencies, as well as providing support to clients within her role as project manager.

Polly has many years of experience in pre-clinical drug development, in the CRO pharmaceutical and biotech industry. Polly has experience in the field of toxicology and safety pharmacology, and has worked in a number of therapeutic areas including neurological, respiratory and infectious diseases. Polly holds a BSc (Hons) in Pharmacology from the University of Hertfordshire and is a Member of the Royal Society of Biology, British Toxicology Society and American College of Toxicology.

Harriet Thomasson-Coombs

Senior Consultant.

Harriet Thomasson-Coombs is a Senior Consultant at Scendea. In her role as Senior Consultant, Harriet acts as project manager for our global clients, specialising in the preparation of CMC documents and interacting with key regulatory authorities on their behalf. Harriet has a wealth of experience in European and US procedures and enjoys supporting our clients in navigating these complex regulatory landscapes.
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 and a Regulatory Affairs Certification (RAC). Harriet won the 2023 TOPRA Horizon award for regulatory excellence.

Ellen Wilkinson

Senior Consultant.

Ellen Wilkinson is a Senior Consultant at Scendea providing technical advice and product development strategies to facilitate the entry of products into clinical trials and assist with successful international marketing approvals.

Ellen previously worked at the MHRA as an Assessor for Lower Risk Clinical Trials and also as a Clinical Safety Scientist, working on pharmacovigilance activities for U.K. clinical trials. Prior to joining the MHRA, Ellen has experience working within in-vitro academic research for the University of Arizona, USA, and holds a BSc (Hons) in Biomedical Sciences from the University of Bath.

Dr Bethany Aykroyd

Consultant.

Dr Bethany Aykroyd is a Consultant at Scendea providing product development and regulatory affairs consulting advice to support the development programmes of Scendea's clients. Bethany is responsible for authoring and preparing a range of documents for US and European agencies, interacting with regulatory authorities on behalf of clients and supporting them in her role as project manager.

Bethany holds a BSc (Hons) in Biomedical Science from the University of Essex, as well as an MPhil in Clinical Science specialising in rare diseases and a PhD in Physiology, Development and Neuroscience from the University of Cambridge. Bethany is also a Regulatory Affairs Certification (RAC) holder.

Dr Sinéad Blaber

Consultant.

Dr Sinéad Blaber is a Consultant at Scendea, responsible for medical writing and regulatory consultancy activities. She has over thirteen years' industry experience specialising in translational medicine. She is experienced in the design of clinical and non-clinical studies and in clinical and regulatory document preparation. She is passionate about driving the development of therapies with promise to cure or significantly improve patients' quality of life.

She previously held the position of Director of Clinical Development and Medical Affairs at Regeneus. Sinéad has a Bachelor of Biotechnology from the University of Technology, Sydney and a PhD in biotechnology from Macquarie University.

Ellie McNamee

Consultant.

Ellie McNamee is a Consultant at Scendea. Ellie is responsible for the authoring and compilation of regulatory submissions to European and US agencies and is also involved in creating weekly regulatory intelligence briefing reports which summarise the latest guidelines and news from various parts of the world.

Prior to joining Scendea, Ellie gained experience working in an academic research facility and contributed to a pre-clinical study within the area of infectious disease. Ellie holds an Integrated Master's degree in Biomedical Science from the University of Southampton.

Dr Leticia Monjas Gómez

Consultant.

Dr Leticia Monjas Gómez is a 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).

Badrudiin Olow

Consultant.

Badrudiin Olow is a Consultant at Scendea. Badrudiin is responsible for the authoring and compilation of regulatory submissions to European and US agencies and is also involved in creating weekly regulatory intelligence briefing reports which summarise the latest guidelines and news from various parts of the world.

Prior to joining Scendea, Badrudiin gained experience working for the local council as a COVID-19 test operative. Badrudiin holds a BSc (Hons) in Biochemistry and a MSc in Molecular Biology and Biotechnology from the University of Sheffield.

Mauricio Cano Mena

Associate Consultant.

Mauricio Cano is an Associate Consultant at Scendea. Mauricio is responsible for the authoring and compilation of regulatory submissions to the relevant regulatory agencies, in addition to providing consulting and procedural support to clients within his role as project manager.

Prior to joining Scendea, Mauricio worked at the Mexican branch of the pharmaceutical company Abbott Laboratories in the Quality Assurance department. He was responsible for diverse tasks to ensure compliance with the corresponding sanitary and regulatory authorities. Mauricio holds a BSc In Chemistry, Pharmacy & Biotechnology from Universidad del Valle de México and an Msc in Molecular Biology Research Extensive from the University of Queensland.

Basia Grodyńska

Associate Consultant.

Basia Grodyńska is an Associate Consultant at Scendea. Basia 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.

Basia has experience in science research, communications, and writing, with emphasis on microbiology, virology, phylogenetics and phylodynamics. She has worked to encourage greater career interest in STEM subjects, especially among women. Basia holds a BSc (Hons I) in Human Biology from Queen Margaret University and an MSc in Evolutionary Genetics from the University of Edinburgh.

Aylin Pelut

Consultant.

Aylin Pelut is a Consultant at Scendea, responsible for providing regulatory technical advice and product development strategies for Scendea's clients. Aylin works on the full scope of EU and US regulatory activities, managing various agency interactions and authoring technical/scientific documents for submission to regulatory authorities.

Prior to joining Scendea, Aylin gained experience within the pharmaceutical industry as a regulatory affairs specialist and has a deep understanding of the development process, from preclinical research to drug regulation and safety. Aylin holds a BSc in Biochemistry from the University of East Anglia and an MRes in Clinical Drug Development from the University College London.

Dilsher Gill

Associate Consultant.

Dilsher Gill is an Associate Consultant at Scendea, bringing a unique combination of scientific expertise and regulatory proficiency to his role. Dilsher's career path transitioned from teaching and academic research in molecular biology at the Queensland University of Technology, providing him with strong analytical skills.

He holds a BBiomedSC (Molecular Biology & Biochemistry) and a MPhil in Cancer Biology from the same institution. Dilsher's academic background, coupled with hands-on experience, equips him to excel in regulatory submissions and project management, contributing significantly to client success.

Dr Despoina Masmanidou

Associate Consultant.

Dr Despoina Masmanidou is an Associate Consultant at Scendea. Despoina is responsible for the authoring and compilation of regulatory submissions to European and US agencies. Additionally, she takes on project management responsibilities, offering consulting and procedural support to clients.

Prior to joining Scendea, Despoina forged a strong foundation in academic research environments. She contributed to research studies within the areas of cardiology, neurology and immunology, gained experience in medical writing, and created several electronic databases for the collection of clinical data. Despoina holds an MD and an MSc in the field of Clinical Research.

Mohammad Nohman

Associate Consultant.

Mohammad Nohman is an Associate Consultant at Scendea. Mohammad is responsible for authoring and compiling regulatory submissions to European and US agencies and being involved in creating weekly regulatory intelligence briefing reports which summarise the latest guidelines and news from various parts of the world.

Prior to joining Scendea Mohammad gained experience as a COVID-19 PCR Scientist at Cignpost Diagnostics and before then working at a CRO called Covance Labcorp as a Bioanalytical Study Analyst. Mohammad holds a BSc (Hons) in Biochemistry and a MSc in Immunology & Immunotherapy.

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

Zeb Younes BSc (Hons)

Head of Product Development & Regulatory Consulting, Principal Consultant
Date Appointed to Position: April 2023

ACADEMIC QUALIFICATIONS.

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

EMPLOYMENT RECORD.

Head of CMC and Principal Consultant, Scendea
2022 - 2023

Principal Consultant, Scendea
2021 - 2022

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 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 MD

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 Paul Griffin BS (Hons), MBBS

Principal Medical Consultant
Date Appointed to Position: November 2023

ACADEMIC QUALIFICATIONS.

Post-graduate Bachelor of Medicine, Bachelor of Surgery
University of Queensland- 1999 - 2002

Bachelor of Science (Honours) - Honours Microbiology and Immunology
University of Adelaide - 1998

Bachelor of Science- Majors; Infection & Immunity and Biochemistry/Molecular Biology.
University of Adelaide - 1995 - 1997

SPECIALIST QUALIFICATIONS.

Dec 2012 - FRACP (Fellow Royal Australasian College of Physicians)

Dec 2012 - FRCPA (Fellow Royal College of Pathologists of Australasia)

Jan 2013 - FACTM (Fellow Australasian College of Tropical Medicine)

Dec 2016 - AFACHSM (Associate Fellow Australasian College of Health Service Management)

Feb 2018 - FIML (Fellow Institute of Managers and Leaders)

EMPLOYMENT RECORD.

Director of Infectious Diseases: Mater Hospitals
2013 - Current

Professor/Conjoint Professor: School of Medicine, Mater Clinical Unit, University of Queensland
2013 - Current

Principal investigator and Medical Director: Q-Pharm Pty Ltd/Nucleus Network
2011 - 2022

Medical Monitor and Safety Review Committee Member: Griffith University, Institute of Glycomics
2014 - 2019

Co-ordinator of Advanced Training for Infectious Diseases for QLD
2014 - 2019

Microbiology Advanced Trainee: Mater Pathology, Sullivan Nicolaides Pathology and Princess Alexander Hospital
2010 - 2013

Medical Officer: The Sunshine Coast Private, Caloundra Private and Nambour Selangor Private Hospitals and Last-minute locums
2007 - 2012

Registrar General Medicine: Mater Hospital
2010 - 2012

Infectious Diseases Advanced Trainee: Royal Brisbane Hospital and Prince Charles Hospital
2008 - 2010

Previous Experience

Director of Infectious Diseases - Mater Hospitals
Responsibilities:

- **University:** Recently promoted to Professor and Head of Clinical Unit. Year 4 coordinator. Regular tutorials to 3rd year medicine and surgery students including introduction of Infectious Diseases tutorials every rotation. Lectures to first and second year students. Regular attendance at Discipline of Medicine Examiners Teaching and Learning Meeting.
- **Mater Research:** Currently Principal Investigator on over 30 clinical trials at Mater Research including investigator-initiated trials and commercially sponsored trials
- **Clinical:** Public infectious diseases clinics and ward rounds including inpatients and consults. Private consulting on in-patients and in private rooms.
- **Director of Infectious Diseases:** Oversight of department including budget and recruiting. Department now consists of 5 physicians.
- **Teaching/mentoring:** Supervision of advanced trainees in Infectious Diseases. Participation in intern/RMO training formal education program. Regular tutorial for physician exam candidates as well as clinical exam preparation including tutorials, short and long cases. Educational supervisor for 2 basic trainees. Currently have more than 5 different projects underway with different groups of junior staff.
- **Antimicrobial Stewardship:** Responsible for creation and implementation of an antimicrobial stewardship program for the Mater that has included guideline and policy development.
- **Hospital in the Home:** Involved in the planning and implementation of this service at Mater, including guideline and policy development.
- **Infection Control:** Medical oversight and chair of the hospital acquired infection team. Regular attendance at multiple regular meetings include public, private and mother's hospitals. Outbreak management.
- Safety Health and Wellbeing: Responsible for coordinating and managing staff health.
- **Other:** Pandemic Influenza planning committee, Water quality committee, Sepsis management committee. Required to author and review multiple guidelines.
- **Highlights/Innovations include:** Establishing the antimicrobial stewardship and hospital in the home services. Commencing a regular tutorial for all third and fourth year medical students on the basics of Infectious Diseases and commencing a weekly departmental clinical meeting to facilitate collaboration within the department. Commencing an Infectious Diseases clinic at the refugee health service to simplify the experience for these complex patients. Responsible for the planning, validation and implementation of a new test for multi-resistant organisms and a novel environmental cleaning methodology utilising vaporised hydrogen peroxide with significant effect on reducing the burden of multi-resistant organisms in the hospital.

Professor/Conjoint Professor: School of Medicine, Mater Clinical Unit
Responsibilities:

Recently promoted to Professor and Head of Clinical Unit. Year 4 coordinator. Regular year 4 students attached to unit with at least weekly formal tutorials. Formal Infectious Diseases tutorial once per rotation to all year 3 and year 4 students in medicine and surgery (introduced by me 3 years ago). Long case tutorials and prepared long case tutorials with 3rd year medicine students (multiple per rotation). Examiner for year 3 medicine rotation.

Regular attendance at Division of Medicine Examiners Teaching and Learning meeting as well as participation in the 2019 Integration and Semesterisation Workshops. Brief presentation at orientation for year 3 and year 4 students. Also, regularly lecture to year 1 and year 2 students and have volunteered to examine many times in the year 1 exams.

Principal investigator and Medical Director: Q-Pharm Pty Ltd/Nucleus Network
Responsibilities:

Principal investigator and manager of medical services for Q-Pharm which became Nucleus Network, a specialised contract research organisation which undertakes a broad range of early through to late phase clinical trials for clients in the global pharmaceutical and biotechnology industries with a focus on infectious diseases. Trials undertaken include many new influenza vaccines including novel strains such as H7N9 and via novel delivery methods, malaria treatments, Ebola and HSV2 vaccines, in addition to Malaria human challenge studies. Principal investigator on over 150 clinical trials and investigator on well over 200 clinical trials. Responsible for the recruitment, training and supervision of numerous medical staff involved in the conduct of clinical trials.

Medical Monitor and Safety Review Committee Member: Griffith University
Responsibilities:

Safety review committee member on malaria human challenge studies. Ensure the safe conduct of malaria human challenge studies investigating antimalarial interventions at Griffith University.

Co-ordinator of Advanced Training for Infectious Diseases for QLD
Responsibilities:

Coordination of the selection process and allocation of advanced trainees state-wide for Infectious Diseases.

Medical Officer: The Sunshine Coast Private, Caloundra Private and Nambour Selangor Private Hospitals and Last-minute locums
Responsibilities:

Primarily to ensure ongoing clinical skill development in my own time worked 12 to 48 hour medical officer shifts at a variety of private hospitals with duties including responding to medical emergencies, care of intensive care unit (including intubated) patients, admissions and assisting in theatre. Various locum medical officer assignments including military placements such as RAAF Edinburgh, South Australia. This work was undertaken concurrently to full time training in Infectious Diseases and Microbiology.

Registrar General Medicine: Mater Hospital
Responsibilities:

To ensure maintenance of clinical skills, continued a clinical appointment at the Mater whilst completing my fellowship in Pathology

Relevant Highlights and Achievements

Recent awards include

- International Business Awards, Gold "Stevie" Award Winner in the "Media Hero of the Year" award.
- Paul Harris Fellow, Rotary International for exemplary work in community service.
- Mater Leadership Excellence award for demonstrating leadership excellence in the areas of safety, culture, innovation, leadership and care and wellbeing.

Current advisory board appointments include

- AstraZeneca International and National Advisory Board member for their COVID-19 vaccine
- AstraZeneca International Advisory Board member for their COVID-19 antibody therapy
- GSK Advisory Board and Spokesperson for their COVID-19 antibody therapy
- Pfizer National Advisory Board for their oral COVID-19 therapy
- MSD National Advisory Board for their oral COVID-19 therapy
- Seqirus Influenza Vaccine National Advisory Board

- Devised, conducted and published the first study utilising mass spectrometry to identify Vancomycin Resistance in Enterococci, a technique that is still in use in the clinical microbiology laboratory. I have been asked to present on this work at many meetings, it has featured in the mainstream media and was the subject of a brief to the Federal Government by the Health Policy Advisory Committee on Technology. For this work I was the recipient of the Royal College of Pathologists of Australasia Best Paper Award, and the publication has now been cited over 200 times.
- Devised, wrote the protocol, conducted and published the first study adding transmission blocking endpoints to a malaria human challenge study to be able to determine the transmission blocking effects of anti-malarial drugs. For this work I was the recipient of the American Society of Tropical Medicine and Hygiene International Clinical Research Award.
- Appointment to The Royal Australasian College of Physicians Advanced Training Committee in Infectious Diseases. Recently appointed as chair of the committee.
- Director and Scientific Advisory Board member for the Influenza Specialist Group/Immunisation Coalition.
- Australasian Society of Infectious Diseases, Hospital Infection Control Special Interest Group Committee Member.
- Examiner for the Royal Australasian College of Physicians.
- Professor, Head of Mater Clinical Unit, the University of Queensland.
- Published more than 80 peer reviewed publications and 10 book chapters, over 4200 citations with h-index of 27 with i10-index of 40.
- Principal investigator on over 150 clinical trials (Investigator on over 200 clinical trials in total). Includes 8 COVID-19 vaccine studies.
- Now over 20 years post graduate (MBBS UQ) and have been employed full time since obtaining the dual fellowships of Infectious Diseases Physician and Clinical Microbiologist over 10 years ago.
- Clinical Lead/Pathologist/Medical Advisory Board Member, Microba
- Consultant for Caliba Health Consultants
- International conference (ICTMM) management committee member and national conference organising committee member (ASID).
- Medical Monitor and Safety Review Committee member for numerous clinical trials.
- Institute BioSafety Committee appointment (prepare submissions to the OGTR for studies/licencing of genetically modified therapeutic products) for Clinical Network Services, Novotech and Beyond Drug Development, provide advice to international clients.
- Chair of Early Phase Clinical Trials Committee
- Responsible for overseeing approvals for early phase clinical trials
- Consultant to Health Care Management Advisors, National Laboratory Capability Audit, Mapping and Scoping project for the Federal Government.
- Heart of Australia Rural GP Education program speaker (volunteer travel to rural Queensland to provide education to rural medical practitioners).
- Speaker and consultant for numerous pharmaceutical companies, predominantly to educate about vaccines.
- Invited lecturer to teach Infectious Diseases to many other specialties including General Practice, Surgical Trainees, Sports Medicine and Dermatology.
- State Leadership Group Member for the Juvenile Diabetes Research Foundation.
- Extensive governance and leadership roles including antimicrobial stewardship/infection control and prevention/water quality/hand hygiene/ hospital in the home/chemical biological and radiological incident readiness/sepsis.
- Other relevant committee memberships include
- Statewide Infection Clinical Network Steering Committee Member
- Queensland COVID-19 Therapeutics Working Group (CTWG) Member
- COVID-19 Medicines and Pharmacy Planning Response Group (MPPRG) Member
- Queensland Health Disaster Management Advisory Network Member
- Lead the Mater's response to many major incidents (prior to COVID-19) including concern of hospital water quality and the settling of new refugees possibly exposed to Ebola, required extensive internal and external stakeholder engagement including the CEO and the Queensland Chief Health Officer to community groups such as the Liberian Ebola Task Force.
- Clinical innovation as evidenced by many initiatives including trial and implementation of novel environmental cleaning technology and rapid resistant organism testing methods.

Dr Austin Smith MD

Principal Medical Consultant
Date Appointed to Position: September 2021

ACADEMIC QUALIFICATIONS.

Doctor of Medicine
Royal College of Surgeons, Ireland

Diploma Pharmaceutical Medicine

Pharmaceutical Medicine CSST

AFFILIATIONS.

General Medical Council (UK)
Royal College of Physicians (UK)
Faculty of Pharmaceutical Medicine
American Society of Clinical Oncologists
European Society of Medical Oncologists
British Association of Cancer Research
European Association of Cancer Research

EMPLOYMENT RECORD.

VP, Clinical Development
LINK Medical Research AS - 2019 - Present

Medical Advisor
Nanomab Technologies Ltd - 2020 - Present

Medical Director
Theradex Oncology - 2010 - 2019

Lead Medical Director
PPD - 2007 - 2010

Various positions escalating positions across all **oncology functional disciplines** in both **adult and paediatric units**.
NHS/Independent Sector - 15 Years

Previous Experience

VP, Clinical Development - LINK Medical Research AS
Responsibilities:

Establish and promote clinical trial excellence in our existing clients, help new clients plan and optimise clinical development plans. Engage KOL networks to assist and align with LINK Medical therapeutic focus and sponsors research goals – Oncology, immunology / infectious diseases, metabolic medicines and promoting more paediatric research.

- Establish an Early Development Group to appraise and optimise clinical trial protocols.
- Act as Medical Lead for biopharma without internal medical resource to sett the vision and strategy for the portfolio pipeline.
- Attend and present at both company-sponsored meetings and regional biopharma meetings, both industry and academic.
- Being responsible for profit and loss business of managed teams.

Medical Director - Theradex Oncology
Responsibilities:

European Medical Lead for core activities and chief architect of the company's European business strategy. Managed Pharmacovigilance and regional Biostatistical Services.

- Assist with the acquisition of all new business and regularly attends/presents at pharmaceutical/biotech and academic meetings.
- Developed consulting business for sponsors with pre-clinical assets.
- Assist sponsors with interactions with regulatory and scientific advice meetings both at a national level in relevant European countries and at both the EMA and FDA.
- Overhauled pharmacovigilance department to become an independent profitable functional service offering.
- Part of Senior Management Team and Client Escalation Point.
- Ensuring the clinical team are compliant with processes and audit-ready.

Lead Medical Director - PPD
Responsibilities:

Served as a regional leader for all medical activities conducted outside the US. Directed medical monitor operations and safety expertise input and support to European and global research and clinical development projects in Phases I-III across all therapy areas.

- Managed 23 multidisciplinary physicians and support staff with the Medical and Pharmacovigilance Group.
- Achieved successful outcomes for numerous clients and reported these achievements into the Chief Medical Officer.
- Managed critical Medical Safety Initiative to identify and track signal detection across managed portfolios.

Associate Specialist in Medical Oncology - The London Clinic
Responsibilities:

As Associate Specialist, Dr Smith provided direct medical care of attending patients, co-coordinating Haematology & Oncology ward physicians. During this time also established a pioneering patient assessment team approach and also provided specialist input into business development initiatives.

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

Head of Nonclinical & Principal Consultant
Date Appointed to Position: September 2022

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.

Dr James Parsley BSc (Hons), DPhil

Head of CMC & Principal Consultant
Date Appointed to Position: April 2023

ACADEMIC QUALIFICATIONS.

DPhil in Biochemistry
University of Sussex

BSc (Hons) in Applied Biology
University of Bath

PROFESSIONAL SOCIETIES.

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

EMPLOYMENT RECORD.

Principal Consultant, Scendea
2022 – 2023

Director, CMC Regulatory Affairs Biopharmaceuticals, GlaxoSmithKline, UK
2017 – 2022

Manager, CMC Regulatory Affairs Biopharmaceuticals, GlaxoSmithKline, UK
2015 – 2017

Secondment to CMC Biopharmaceuticals, GlaxoSmithKline, UK
2013 – 2014

Submissions Manager, Nonclinical Regulatory, GlaxoSmithKline, UK
2004 – 2013

Secondment to GRA Labelling, GlaxoSmithKline, UK
2011 – 2012

Regulatory Affairs Associate II, Parexel International Ltd
2003 – 2004

Senior Regulatory Associate, GlaxoSmithKline, UK
2002 – 2003

Research Scientist and DPhil student, Institute for Animal Health, Pirbright, UK
1998 – 2002

Medical Technical Officer, Centre for Applied Microbiological Research
1996 – 1997

Previous Experience

Director, CMC Regulatory Affairs Biopharmaceuticals - GSK
Responsibilities:

Current Job description:
- Directs key, strategic CMC regulatory activities
- Represents Global CMC Regulatory, on Regulatory Networks and Matrix Teams providing and overseeing strategic direction and guidance to Project and Technical team stakeholders on both global project and key strategic business initiatives.
- Accountable for final content of CMC dossiers from FTIH through to Marketing Applications
- Line management responsibility of internal staff up to director level and contract staff across the portfolio.
- Participation in due diligence providing CMC regulatory support/ advice to in-licensing and divestment projects.
- Deliver CMC regulatory strategy to support quality incidents and major inspections (e.g. PAI's).
- Lead current, business critical activities across internal and external networks on behalf of GSK.

Experience:
- Thorough understanding of biopharmaceutical CMC regulations and how they relate to drug development, together with all major regulatory submissions and processes.
- I have acted as the CMC regulatory matrix team leader for a number of key assets, most recently a large team to accelerate and deliver a COVID therapeutic.
- I have worked on both early development and post approval assets with direct experience of coordinating global Clinical Trial and Marketing Applications, associated agency meetings and questions, global post approval change management and external collaboration interactions.
- I have been accountable for a considerable number of assets including Gene Therapy assets.

Submissions Manager - GSK
Responsibilities:

The Nonclinical Regulatory (NCR) Group is responsible for working directly with the Research and Development Scientists to write the nonclinical components of Clinical Trials, Marketing Applications and other communications with Regulatory Authorities Worldwide.

Experience:
- Thorough understanding of nonclinical regulations, pharmacology, pharmacokinetics and toxicology and how they relate to drug development, together with all major regulatory submissions and processes.
- I actively project managed a portfolio of projects for self and my team of staff.
- I worked on Marketing Authorisation Applications, New Drug Applications and international submissions.
- I authored and coordinated Investigator brochures, Investigational New Drug applications, Investigational Medicinal Product Dossiers and Paediatric Investigation Plans, responses to questions, briefing documents, marketed product updates/variations, renewals etc...

Secondment to GRA Labelling - GSK
Responsibilities:

Synopsis:
- I provided high quality labelling and regulatory pack management support for two key marketed products Ty(k/v)erb and Volibris
- Both products were approved via the centralized procedure in EU and I completed a number of Type II variations to update the SmPC in line with internal data or as a result of EU legislation.
- I acted as a key member of the Regulatory Matrix and Safety review teams working closely with the safety and medical physicians, scientists and regulatory colleagues.

Regulatory Affairs Associate II, Parexel International Ltd
Responsibilities:

Job description:
- Regulatory project lead/manager on assigned projects. Coordinated regulatory support to the project team, tracking project timelines and budget.
- Provided ongoing regulatory support, designed and completed/ compiled regulatory development plans and submissions.

Additional Experience:
- Exposure to clinical aspects of CTAs and MAAs such as Review of Drug Release Packages, Patient Information Sheets and Consent Forms to ensure compliance with ICH GCP; I Published the first centralised eCTD for Europe; Clinical MAA summary writing; Nonclinical Ethics Committee safety assessments; Labelling reviews; Ad hoc client requests; Sales and proposal work.

Senior Regulatory Associate - GSK
Responsibilities:

- Authoring of expert report style summaries of nonclinical data for version based regulatory database (Maintenance Library) and international submissions.

Research Scientist and DPhil student - Institute for Animal Health
Responsibilities:

- Research into the assembly of African Swine Fever Virus (October 1998 – April 2002)
- The interactions and subsequent conformational changes of the major capsid protein of the virus with a virally encoded, and cellular chaperones.
- Potential for vaccine development.

Medical Technical Officer - Centre for Applied Microbiological Research
Responsibilities:

- Development of novel acellular liposomal vaccine for Yersinia pestis (the causative agent of Plague).
- Research and pilot scale production of recombinant Yersinia pestis proteins for next generation vaccines.
- ACDP3 lab using ACDP2 recombinant organisms working to GMP and GLP regulations.
- Laboratory management and personnel training.
- Assay Development.

Additional Work-Related Information

External Speaking:

- Former presenter at the autumn TOPRA Introduction to Regulatory affairs Course on biopharmaceutical regulatory affairs and previously on nonclinical development.

Dr Maria Beatrice Panico MD, PhD

Head of Clinical & Principal Consultant
Date Appointed to Position: July 2023

ACADEMIC QUALIFICATIONS.

PhD in Neuroscience - 2004-2007
University of Tor Vergata, Rome

Fully qualified neurologist - 1999-2004
University of Tor Vergata, Rome

Degree in Medicine and Surgery - 1993-1999
Catholic University, Rome

EMPLOYMENT RECORD.

Leading Senior Medical Assessor in Clinical Investigations and Trials Team - MHRA
2021 – 2022

Senior Medical Assessor Clinical Trials Unit (CTU) - MHRA
2019 – 2021

Accredited Medical Assessor Clinical Trials Unit (CTU) - MHRA
2013 – 2019

Safety Physician in Pharmaceutical Industry - Novartis Pharma, Switzerland & Servier, Italy
2011 – 2013

Clinical Neurologist and researcher in Neuroscience - University of Tor Vergata, Rome
1999 – 2011

Previous Experience

Leading Senior Medical Assessor in Clinical Investigations and Trials Team - MHRA
Responsibilities:

- Launching a pilot on risk-proportionate assessment of IVDs used for medical purpose in Clinical
- Trials of Investigational Medicinal Products (CTIMPs)
- Leader of pilot on coordinated assessment of Clinical Trial and Clinical Investigation applications

- Leader of discussion on potential legislative changes to assessment of safety in CTIMPs
- Leader of safety activities for clinical trials in the UK
- Involved in interdivisional discussions on AI and in-silico trials
- Responsible for safety aspects of all COVID19 trials in the UK

Senior Medical Assessor Clinical Trials Unit (CTU) - MHRA
Responsibilities:

- Assessment of clinical trial applications across all therapeutic areas
- Providing scientific and regulatory advice internally and externally
- Representing the unit and the Agency at national and international meetings
- Leading safety assessor
- Leader of project on coordinated assessment of Clinical Trial and Clinical Investigation applications
- Leader of project on assessment of In-Vitro Diagnostic Medical Devices (IVDs) used with medical purpose in CTIMPS
- Leader of project on increasing quality of data presented in Development Safety Update Reports (DSURs)
- Representing the Agency during the consensus meeting resulting in publication of international guidelines on Artificial Intelligence (SPIRIT-AI and CONSORT-AI)
- Representing the Agency at the WHO working group on AI in health

Accredited Medical Assessor Clinical Trials Unit (CTU) - MHRA
Responsibilities:

- Evaluating the safety and scientific validity of clinical trials across all therapeutic areas and all phases, including biologicals, advanced medicinal products and chemicals
- Coordinating national safety monitoring activities [substantial amendments, Development Safety Reports (DSURs), SUSARs, EudraCT alerts, Urgent Safety Measures (USMs) and safety signals]
- Collaborating with European National Competent Authorities through Voluntary Harmonised Procedure, review of new safety signals, safety assessor meetings and information requests
- Providing fast-track medical assessment of Ebola Clinical Trial Authorisation applications during the Ebola world health emergency
- Acting as Lead Safety Assessor during European safety review procedures
- Providing scientific and regulatory advice to external stakeholders
- Representing the CTU at internal and external meetings
- Discussing trial applications with advisory groups such as Clinical Trials Expert Advisory Group and Commission on Human Medicines
- Preparing answers to Parliamentary questions, Freedom of Information requests and queries from external stakeholders.

Safety Physician in Pharmaceutical Industry - Novartis Pharma
Responsibilities:

- Responsible for European Pharmacovigilance activities

Safety Physician in Pharmaceutical Industry - Servier
Responsibilities:

- Responsible for Italian Pharmacovigilance activities

Erik Doevendans MSc

Technical Head (NL) & Principal Consultant
Date Appointed to Position: November 2022

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.

Principal Consultant - Scendea
2019 - 2022

Owner and Consultant – BD Consultancy B.V.
2009 – 2022

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

Previous Experience

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.

Penny Field BSc (Hons), MMSc

Technical Head (AUS) & Principal Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

Master of Medical Science (Drug Development) – 2011
University of New South Wales

Research Honours (Biotechnology) – 1987
Murdoch University

BSc (Biology) – 1985
Murdoch University

EMPLOYMENT RECORD.

Senior Regulatory Affairs Manager - Seqirus
2018 – 2023

Principal Consultant - Bioregulatory Consulting
2002 – 2023

Senior Associate Consultant - ERA Consulting (Australia)
2006 – 2012

Regulatory Consultant - Amgen
1999 – 2001

Senior Regulatory Affairs Associate - CSL Limited
1996 – 1999

Regulatory Affairs Associate - CSL Limited
1990 – 1996

Previous Experience

Senior Regulatory Affairs Manager – Seqirus, In-Licensed Products Asia Pacific
Responsibilities:

- Working within the Commercial function to facilitate the selection, registration, extension of indications and maintenance of in- licensed medicines.
- Conducting due diligence, reviewing and preparation of marketing authorisations and writing responses to CMC, nonclinical and clinical evaluations to obtain approval of new medicines.
- Currently on the brand team responsible for the launch of a NCE for treatment of schizophrenia. Involved in the regulatory due diligence, approval, and post-marketing activities to successfully launch a novel agent.
- Managing the logistical issue regarding regulatory compliance for continuity of supply of registered products.

Principal Consultant – Bioregulatory Consulting
Responsibilities:

- Worked with small and medium sized biotechnology companies providing global regulatory strategy and preparing scientific documentation (pre-IND, IND, CTX and Orphan Drug applications) for submission to the FDA, EMA and TGA. Consulting work included:
  - Authored a clinical trial application (CTX) for a prophylactic HIV vaccine (DNA vaccine in combination with recombinant pox vaccine).
  - Provided regulatory strategy for the development of mAB against vascular endothelial growth factor (VEGF-A) and epidermal growth factor receptor (EGFR).
  - Consulted on the development and registration of E.coli derived recombinant proteins such as interleukin-1 receptor antagonist (IL-1RA), recombinant insulin, human growth hormone (rhGH), pegylated interferon alpha 2 and human granulocyte–colony stimulating factor (rhG-CSF).
  - Wrote the CMC section of an IND and an US Orphan Drug Designation for a NCE for the treatment of ovarian cancer.
  - Wrote an IND application for an immunotherapeutic HIV vaccine using recombinant fowl pox virus vaccine.
  - Supported the Phase I clinical trial of an allogeneic adipose derived Mesenchymal Stem Cells (MSC) by preparation of scientific documentation and provision of regulatory guidance.
  - Conducted gap analysis of a cell therapy for Provisional Registration in Australia.
  - Advised on regulatory strategy and product development for a CAR-T therapy for an oncology indication.
- Transitioned a change of sponsorship, for approximately 300 products in 26 countries, whilst ensuring regulatory compliance.
- Wrote dossiers for four vaccines for submission to UNICEF.

Senior Associate Consultant – ERA Consulting (Australia)
Responsibilities:

- Worked in collaboration with ERA Consulting to provide global regulatory advice for the development and registration of prescription medicines.
- Critically evaluated registration applications and conducted gap analysis of CMC data for biosimilars, biologicals and NCE.
- Prepared scientific documentation to facilitate the conduct of clinical trials.
- Prepared for, and attended, a pre-submission meeting with the TGA for a combination prescription medicine. Subsequently prepared a hybrid literature-based marketing application and gained TGA approval.
- Reviewed approximately 100 published papers and wrote a Clinical Safety Summary for a new indication for a prescription medicine.
- Involved in the development of fixed-dose combination product for neuropathic pain and the preparation of the pre-IND briefing package.

Regulatory Consultant – Amgen
Responsibilities:

- Worked with the US and UK Development Teams to write the CMC section for Kineret®, for the treatment of Rheumatoid Arthritis, which was submitted to EMA and TGA.
- Obtained ethics and clinical trial approval for two paediatric studies for Kineret®.

Senior Regulatory Affairs Associate – CSL Limited
Responsibilities:

- Provision of regulatory guidance and support to the influenza vaccine (Fluvax) Project Management Team to facilitate the annual production of influenza vaccine.
- Reviewed and rewrote the Fluvax dossier to achieve National Registration in Sweden. Responded to evaluation questions and negotiated with the Swedish Medical Products Agency regarding manufacture, product specification and post-marketing clinical trials.
- Project managed the successful registration of Fluvax in Denmark, the Netherlands and Belgium via the Mutual Recognition Procedure.

Regulatory Affairs Associate – CSL Limited
Responsibilities:

- Researched and wrote Drug Master Files (DMF) for four active ingredients (diphtheria toxoid, tetanus toxoid, inactivated pertussis and aluminium adjuvant) manufactured by CSL Limited.
- Prepared four abridged General Marketing Applications, cross-referencing these DMF, to successfully enable marketing in New Zealand.
- Submission of Marketing Application for an in-licensed product (BCG Vaccine).

Dan Cafaro BSc

Principal Consultant
Date Appointed to Position: August 2021

ACADEMIC QUALIFICATIONS.

BSc in Chemistry
University of California, Los Angeles.

PROFESSIONAL SOCIETIES.

mTOPRA
Regulatory Affairs Professional Society
The Organisation for Professionals in Regulatory Affairs (Europe)
Drug Information Association

EMPLOYMENT RECORD.

Chief Regulatory Officer & President US Operations
Quark Pharmaceuticals, Inc - 2019 - 2021

Executive Vice President - Regulatory Affaiirs/Quality/PharmDev
Quark Pharmaceuticals, Inc - 2018

Senior Vice President - Regulatory Affairs
Quark Pharmaceuticals, Inc - 2017

Vice President - Regulatory Affairs & Compliance
XOMA (US) LLC - 2007 - 2016

Vice President - Regulatory Affairs
XOMA (US) LLC - 1999 - 2007

Director - Regulatory Affairs
XOMA (US) LLC - 1996 - 1999

Manager - Product Development
Allergan. Inc - 1994 - 1996

Manager - Strategic Regulatory Affairs
Allergan. Inc - 1992 - 1994

Supervisor to Manager - International Regulatory Affairs
Allergan. Inc - 1987 - 1992

Associate to Senior Regulatory Writer (U.S. & Intl.)
Allergan. Inc - 1981 - 1987

Previous Experience

Chief Regulatory Officer & President US Operations - Quark Pharmaceuticals, Inc.
Responsibilities:

- Site head with direct responsibility for worldwide Regulatory Affairs, Quality, Pharmaceutical Development, Biostatistics, Data Management.

Vice President - Regulatory Affairs & Compliance - XOMA (US) LLC
Responsibilities:

- Overall responsibility for regulatory and quality programs for the organisation. Direct supervision of Regulatory Affairs & GxP Compliance and Quality Assurance. Member of the senior executive management team.

Director - Regulatory Affairs - XOMA (US) LLC
Responsibilities:

- Direction of the worldwide regulatory activities for the corporation and establishment of the regulatory and compliance infrastructure. Primary responsibility for leadership of the ophthalmic product development applications.

Special Concurrent Assignments:

Clinical Development - XOMA (US) LLC
Responsibilities:

- Shared responsibility with Chief Medical Officer for Medical Affairs, Biometrics, Clinical Operations, Data Management and Drug Safety.

Biodefense - XOMA (US) LLC
Responsibilities:

- Overall management oversight for Biodefense programs.

Manager - Product Development - Allergan, Inc.
Responsibilities:

- Initially hired to establish regulatory communications for Latin America. Preparation of international regulatory dossiers for ophthalmic, optical and dermatological products and review product labeling for worldwide regulatory compliance. Management of international and strategic regulatory affairs. Liaison for Santen/Allergan Joint Venture in Japan. Management of new product development activities for Optical division.

Special Concurrent Assignments:

Optical R&D Liaison - Allergan Joint Venture Japan
Deputy Management Representative for ISO 9001 Certification
Team Leader - Hydrogen Peroxide Technologies

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.

Dr Asha Kattige MPharm, PhD

Principal Consultant
Date Appointed to Position: August 2022

ACADEMIC QUALIFICATIONS.

PhD - Pharmaceutical Formulation and Technology
University of Sunderland

MPharm - Pharmaceutical Formulation and Technology
University of Mumbai, India

EMPLOYMENT RECORD.

Associate Director, Global Regulatory CMC Scientist - UCB
2021 – 2022

Senior CMC Project Manager (Grade 4), Regulatory - Britannia Pharmaceuticals Ltd
2018 – 2019

Inhalation Formulation and Analytics Manager - Legacy Actavis, Teva
2015 – 2018

Principal Formulation Scientist- Pharmaterials Ltd
2012 – 2014

Formulation Scientist Team Leader - Patheon UK Ltd
2007 – 2012

Formulation Scientist - Patheon UK Ltd
2005 – 2007

Research Officer, Department of Pharmacy and Pharmacology - University of Bath
2003 – 2005

Post doctoral Research Officer, Department of Pharmacy and Pharmacology - University of Bath
2001 – 2003

1995-1996: Research Assistant for German Remedies limited
1995 - 1996

Previous Experience

Associate Director, Global Regulatory CMC Scientist - UCB
Responsibilities:

- Responsible for developing and implementing the CMC&Devices regulatory strategy and submission plans for assigned projects/products to deliver timely approvals to meet business needs in regions assigned, and in line with the global regulatory strategy.
- Identifying supporting documents required for (global) submissions and negotiating the delivery of approved technical source documents in accordance with project timelines.
- Ensuring that the regional CMC/Medical Device regulatory strategy for the assigned projects/products are consistent with the GRA, S&TS teams and PV goals and objectives and meets HA requirements in assigned regions.
- Responsible for writing regional and global CMC/Medical Device documentation for submissions in line with agreed global regulatory strategy, and within agreed timelines.
- Ensuring effective communication of CMC/Medical Device regulatory strategy, risks, and overall plan for assigned products to GRA Teams, S&TS Teams and PV solution teams as agreed with the Lead.
- Responsible for highlighting anticipated and ongoing critical issues arising through the product life-cycle in a timely manner to GRA-CMC&Devices LT to enable communication to key stakeholders as appropriate.
- Involved in preparing or contributing to the preparation of the CMC/ Medical Device risk analysis (or regulatory Risk Capture Document) and supporting associated RA CMC challenge sessions.
- Led or provided support to all CMC/Medical Device related interactions to facilitate and ensure satisfactory resolution of CMC/Medical Device issues and negotiated approvals with HAs in regions assigned, for assigned projects/products.
- Led or provided support to cross-functional teams responsible for the preparation of responses to HA questions raised in regions for assigned projects/products.
- Regulatory Intelligence: Monitored and reacted as appropriate to changes in the CMC regulatory environment in regions assigned to support GRA-CMC&Devices.

Senior CMC Project Manager, Regulatory, Britannia Pharmaceuticals Ltd
Responsibilities:

- Responsible for supporting the development and project management of parenteral dosage forms focussing on neurology within pharmaceutical product portfolio from preclinical to commercialisation.
- Involved in MAA and NDA submissions, authoring of Drug Substance & Drug Product Module 3 sections of submissions and authoring/reviewing of responses to regulatory agencies (HPRA, Reference member states, FDA) requests for supplementary information.
- Provided CMC support for regulatory aspects of submissions for products across all development phases (PI-PIII) for EU, US, Australia and Japan.
- Assisted 3-4 IMPD applications for Europe.
- Liaising with product development, regulatory and clinical development to ensure key project milestones are delivered on time and on budget.
- Assisted global product development programs, led development and clinical manufacturing of API and drug products for assigned project(s)
- Worked to maintain a high level of Good Manufacturing Practice (GMP) according to MHRA, FDA and relevant Guidelines.
- Lead in the selection and management of suitable CMO/vendors.
- Oversight of Product Specification File and related documentation, review/ input into regulatory documentation.

Inhalation Formulation and Analytics Manager, (Legacy Actavis, Teva).
Responsibilities:

- Technical expert leading generic inhalation drug product development projects via outsource model and/or off-site internal laboratories
- Authoring of Drug Substance & Drug Product Module 3 sections of submissions and authoring/reviewing of responses to regulatory agencies (FDA) requests for supplementary information
- Provided input and review of CMC regulatory submissions, including but not limited to Pharmaceutical Development Reports.
- Assisted DCGI applications (4) for conducting pivotal pk studies in India and IMPD applications for Europe.
- Involved in ANDA submissions for generic inhaled combination products for US registration.
- Defined and led development strategies for new products and led contract negotiations to define project deliverables for 3rd party partners.
- Performed gap analysis, risk assessment to minimise risks and managed remediation plans where applicable.
- Led technology transfers of manufacturing processes from CMOs to commercial manufacturing sites.
- Responsible for creation of design planning, design input and risk management documentation in accordance with regulatory guidelines, including but not limited to 21 CFR Part 4, ICH Q8 and ICH Q9.
- Provided input and review of Development and Quality Agreements with 3rd party R&D sites.
- Liaised with 3rd Party R&D QA contacts, and supported QA technical audits of external contractors, notification of changes and complaints tracking, as well as supporting cGMP auditors.
- Responsible to ensure that all OOS results and unplanned deviations at 3rd Party R&D sites are fully investigated and documented and any corrective and preventative actions identified are tracked.
- Participated on Due Diligence reviews, as required
- Prepared for and participated in Health Authority scientific advice meetings.

Principal Formulation Scientist, Pharmaterials Ltd
Responsibilities:

- Directly supervised, coached, and developed around 5-6 staff when necessary in the performance of their duties in the laboratory and IMP GMP manufacturing suite.
- Involved in/Managed 6-7 inhalation projects involving formulation development and clinical manufacture of dry powder formulations and solutions for nebulisers
- Involved in developing "specials" oral formulation, designing product label, packaging and commercial manufacture
- Undertook and supervised new pre-formulation, pre-clinical, formulation development and scale-up studies and GMP manufacturing activities for client projects
- Provided technical support for early phases of drug development including clinical trials manufacture.
- Assisted in directing and managing all aspects related to the transfer of technology from the client to Quotient and vice versa.
- Documented and reviewed development reports.

Formulation Scientist Team Leader, Patheon UK Ltd
Responsibilities:

- Supervised and mentored/trained around 6-8 junior staff and provided technical expertise to various Formulation Development projects.
- Provided consultancy to clients specifically on parenteral formulation projects.
- Involved in writing proposals and quotes for new client business.
- Provided technical expertise and supervised projects involving Formulation and Process Development for intravenous, subcutaneous, microemulsions, ophthalmic and intrathecal, drug delivery for preclinical and clinical studies.
- Involved in Formulation Development for nasal and dry powder inhalers and nebulizers.
- Handled projects requiring Formulation development, Process optimisation of tablet and capsule formulations for preclinical and clinical studies.
- Implemented Design of Experiments and Quality by Design (QbD) approach for both intravenous and solid dose formulations.
- Involved in manufacture of stability and clinical trial batches within the laboratory area or in the pilot plant under cGMP conditions.
- Prepared technical documentation to support development work and manufacturing i.e. protocols, batch manufacturing records and reports.
- Undertook preformulation studies on new chemical entities.
- Attended client meetings (tele conferences and face to face meetings) and responsible for answering regulatory queries as required.
- Responsible for technology transfer between manufacturing facilities.
- Involved in the designing process of containment systems for safe handling of highly potent drug substances.

Formulation Scientist, Patheon UK Ltd
Responsibilities:

- Formulation and Process Development for intravenous drug delivery.
- Formulation Development and Optimisation of various oral formulations i.e. granulated capsule formulation, liquid-fill formulation for hard gelatin capsules, self emulsifying drug delivery systems, microemulsion formulation, solid dispersions and suspension formulations
- Manufacture of stability and clinical trial batches within the laboratory area or in the pilot plant under cGMP conditions.
- Prepared technical documentation to support development work and manufacturing (laboratory notebooks, batch records and process validation documentation) for internal and customer requirements.
- Performing preformulation studies on new molecule entities

Research Officer, Department of Pharmacy and Pharmacology, University of Bath
Responsibilities:

- Formulation development of anticancer drug infusions for parenteral use.
- Investigated the stability and compatibility of various drug infusions under clinical-use conditions to facilitate an outpatient chemotherapy dose-banding scheme.
- HPLC Method Development and Validation.
- Trained in the handling of cytotoxic drugs and working to GLP/GMP requirements.

Post doctoral Research Officer, Department of Pharmacy and Pharmacology, University of Bath
Responsibilities:

- Development, processing and optimisation of novel drug delivery systems for dry powder inhalers.
- Investigated the use of spherical pellets formulated using Extrusion Spheronization technique to deliver precise dosing and improve aerosolization of drug particles.
- Characterization using Twin stage impinger, Aerosizer, Scanning Electron Microscopy and Dynamic Vapour sorption.

Stephen Kirk BSc

Principal Consultant
Date Appointed to Position: September 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Immunology - 1989 - 1993
University of Glasgow

Certificate in Business Studies - 2011 - 2012
Open University

Post Graduate Certificate in Biopharmaceutical Drug Development - 2017 - 2019
University of Leeds

EMPLOYMENT RECORD.

Head of Nonclinical Science - Allergy Therapeutics
2022 – 2023

Senior Manager, Toxicology - KalVista Pharmaceuticals Ltd
2019 – 2022

The Non-Clinical Immunotoxicology Principal Investigator - Covance Laboratories Ltd
2009 – 2019

Interim Global Lead, Immunology and Immunotoxicology - Covance Laboratories Ltd
2016 – 2017

Study Director in the Toxicology Department - Aptuit Ltd
2006 – 2009

Study Director in the In Vivo Virology Department - BioReliance, Invitrogen Bioservices
2005 – 2006

Senior Research Scientist/Study Director, in the Department of Immunology/Immunotoxicology - Charles River Laboratories
2000 - 2005

Principal Scientist/Study Director, in the Department of Immunology, and Molecular Biology - Inveresk Research
1998 - 2000

Project Manager - Datavault Plc
1996 - 1998

Department of Immunology, Research Assistant - Western Infirmary
1993 - 1996

Previous Experience

Head of Nonclinical Science - Allergy Therapeutics
Responsibilities:

Responsibilities include design of nonclinical safety strategy for candidate therapies in development, overseeing study types including repeat dose toxicology, reproduction toxicology, local tolerance as well as PK, PD and TK studies and the establishment of mouse models of disease. Identification and oversight of CRO's utilised in safety evaluation. Providing nonclinical input to regulatory documentation such e.g., IND, CTA, IB etc. Working closely with research, and CMC groups to better understand properties of lead compounds. Providing regular updates to Project teams and Safety Review teams.

Senior Manager, Toxicology - KalVista Pharmaceuticals Ltd
Responsibilities:

Duties included design and implementation of nonclinical safety studies at various stages of drug development to support Phase 1 and Phase II studies. Interacting with CRO's and taking oversight of preclinical packages of work. Troubleshooting on study challenges where necessary and designing complimentary testing where required. Providing nonclinical input to regulatory documentation such e.g., IND, CTA, IB etc. Working closely with research, ADME and CMC groups to better understand properties of lead compounds and provide summary reports of toxicology, safety pharmacology and toxicokinetic data. Providing regular updates to Project teams and Safety Review teams.

The Non-Clinical Immunotoxicology Principal Investigator - Covance Laboratories Ltd
Responsibilities:

This role had an overarching view of all aspects of acquisition, analysis, reporting and interpretation of immunotoxicology data from repeat dose studies, biodistribution research and PK, PD and TK studies. This senior position was responsible for establishing and maintaining the highest level of quality in data capture and interpretation and reporting and providing advice and support to external and internal customers involved with preclinical immunotoxicology and safety assessment.

Additional roles also included subject matter expert on immunology for drug development teams, as well as part-time toxicology Study Director duties. Frequent interactions with clients via sales visits, conference attendance and poster / oral presentations.

Interim Global Lead, Immunology and Immunotoxicology - Covance Laboratories Ltd
Responsibilities:

Duties included, collation of revenue /sales figures, work capacity of group, growth prediction and new business opportunities. Additional duties also involved chairing of regular meetings of global groups to evaluate new service offerings and trouble-shoot areas with challenges.

Study Director in the Toxicology Department - Aptuit Ltd
Responsibilities:

Responsibilities included study management, report writing, study design and implementation, validation of immunotoxicology test systems, familiarity with present guidance and regulations, attending sales trips and conferences and liaising with potential sponsors and current clients.

Study Director in the In Vivo Virology Department - BioReliance, Invitrogen Bioservices
Responsibilities:

Responsibilities included, ensuring the day to day running of animal-based studies, protocol and report preparation, liaising with clients as well as peers and managers.

Senior Research Scientist/Study Director, in the Department of Immunology/ Immunotoxicology - Charles River Laboratories
Responsibilities:

Responsibilities included validation of immunoassays and immunotoxicology test systems, ensuring the smooth day to day running of the laboratory, including supervising over thirty scientists and analysts, project management, laboratory work schedules, report writing, experimental design and implementation.

Principal Scientist/Study Director, in the Department of Immunology, and Molecular Biology - Inveresk Research
Responsibilities:

Duties included validation of the flow cytometer and immunoassays, experimental design and implementation, data collation, report writing and providing sponsors with updates and reports.

Project Manager - Datavault Plc
Responsibilities:

Duties included organising removal and archiving of sensitive data for clients, mainly from the medical and financial sectors.

Department of Immunology, Research Assistant - Western Infirmary
Responsibilities:

Duties involved experimental design and implementation, animal handling and welfare, as well as report writing and data analysis. Duties also included part-time work as a teaching assistant in under-graduate laboratories.

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.

Shweta Menon MPharm

Deputy Head of Product Development & Regulatory Consulting, Principal Consultant
Date Appointed to Position: April 2023

ACADEMIC QUALIFICATIONS.

MPharm - Pharmaceutics
The Tamil Nadu Dr. M.G.R. Medical University, India.

PROFESSIONAL SOCIETIES.

TOPRA Member.

EMPLOYMENT RECORD.

Associate Program Director
Parexel International - 2018 - 2021

Senior Consultant
Parexel International - 2015 - 2018

Senior Regulatory Affairs Associate (Europe, Middle East & North Africa)
Hospira UK - 2012 - 2015

Senior Regulatory Affairs Officer (New Submissions-Europe)
Teva Europe - 2009 - 2012

Senior Regulatory Affairs Officer (Post Approval-Europe)
Teva Europe - 2007 - 2009

Regulatory Executive (First Registration and Post-Approval-Emerging Markets)
GlaxoSmithKline - 2005 - 2007

Regulatory Executive (Canada and UK)
Orchid Healthcare, India - 2004 - 2005

Previous Experience

Associate Program Director - Parexel International
Responsibilities:

- Establish team goals and structure for program with senior leadership/client, inspire individual ownership and accountability to achieve high client satisfaction and successful delivery.
- Ensure consistency across projects in program, provide oversight, manage senior stakeholders internally and externally.
- Lead and participate in applicable governance committee meetings and oversee Key Performance Indicators (KPI)s.
- Provide oversight on ongoing projects to ensure quality, delivery and ongoing client satisfaction.
- Conduct ongoing financial and process analysis and develop strategy to meet profitability targets across the program.
- Act as senior point of escalation for issues and arrange for follow through of resolutions via the appropriate departments.
- Maintain good ongoing client relationships to drive repeat business.
- Maintain a positive, results orientated work environment, building programs and modeling teamwork, communicating to the team in an open, balanced and objective manner.
- Provide reliable assumptions on business growth and achievable objectives.
- Liaise with other Program Directors / Associate Program Directors to drive cross-fertilisation of ideas and growth of accounts.
- Provide leadership, mentoring and coaching to team members.

Senior Consultant - Parexel International
Responsibilities:

Project Management:

- Accountable for deliverables, point of contact for issue escalation, tracking and implementation of project management tools.
- Help with issue resolution and first point of contact for work stream.
- To identify and track KPI's.
- Engage and drive discussions on defining processes, roles and responsibilities and process improvement.
- Understanding and outlining the scope of work and expectations.
- Unit tracking and bi-weekly or monthly status updates for Project Status Reports and financial planning trackers.
- Identify and address gaps in resource.
- Facilitate client decision making by framing issues, presenting options and providing objective business advice.
- Develop business solutions addressing specific client needs using best practices and knowledge of the client's business and key industry drivers.
- Actively participates in project scoping calls and proposal preparation.

Quality Deliverables:

- Produce quality work that meets the expectations of the client.
- Provide a broad range of consulting services and works within broad project guidelines to identify, refine, and address client issues and to achieve the client's objectives.
- Provides guidance to project team members on technical/process issues.
- Technical expert as required by the project deliverables and provide content expertise, strategic input and quality review.

Senior Regulatory Affairs Associate - Hospira UK
Responsibilities:

- Submission of marketing authorization applications via the European Centralised, Decentralised and Mutual Recognition (MR) procedures.
- Creation of Regional Regulatory Strategy for submissions.
- Participation in Scientific Advice meetings with regulatory agencies
- Review of Module 3- Chemistry, Manufacturing and Controls (CMC).
- Due diligence of Module 2- Quality, clinical and non-clinical overviews.
- Preparation of Module 1 including the administrative documents and product information text.
- Project management of new submissions to the Middle East and North African markets.

Senior Regulatory Affairs Officer - Teva Europe
Responsibilities:

- Preparation and submission of Centralised Procedure (CP) applications (including pre-submission activities like eligibility and NRG request).
- Preparation and submission of Decentralised Procedure (DCP) applications.
- Preparation of responses to questions for the above procedures and follow through to approval.
- Coordination of linguistic review for Centralised Procedure applications.
- Review and due diligence of CMC sections of dossiers being prepared for submission.

Regulatory Executive - GlaxoSmithKline
Responsibilities:

- Creation of work plan, logging and tracking the progress of all Established Products.
- Point of contact for Renewals, Regulatory Questions and Tenders and responsible for the coordination and preparation of these filings.
- Liaison with manufacturing sites to determine the availability of documents and accessing requirements.
- Liaison with document authoring groups to obtain CMC data for regulatory submissions.
- Liaison with internal groups regarding Samples, Certificates of Pharmaceutical Product and arranging the publishing of documents.
- Preparation of all supporting documents for the registration of New Chemical Entities, Line Extensions, Source transfers and variations.
- Therapy representative on internal matrix groups.

Regulatory Executive - Orchid Healthcare
Responsibilities:

- Preparation and submission of Abbreviated New Drug Submissions and Marketing Authorisation Application's to concerned agencies in Canada and UK.
- Review of Product Information text, patient information leaflets and outer packaging associated with submission.
- Preparation of response to queries received from respective Health Authorities.
- Co-coordinating activities with other departments to obtain documents related to submissions.
- Review of submission related documents to ensure that ICH and GMP compliance is maintained.
- Review of manufacturing and production documents.
- Initiation and coordination with Pharma Research and Contract Research Organisation's to procure samples for Bioavailability testing.

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.

Aarti Pattni BSc (Hons)

Principal Consultant
Date Appointed to Position: July 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Bio Chemistry (2ii)
University of London, King's College London

EMPLOYMENT RECORD.

Regulatory Consultant - DLRC, UK
2020 – 2022

Senior Specialist, Regulatory Affairs Europe, Associate Liason - Merck, Sharpe & Dohme, The Netherlands
2017 - 2020

Non Clinical Regulatory Associate, Global Regulatory Affairs - GlaxoSmithKline, UK
2015 – 2017

Regulatory Associate, Global Regulatory Affairs - GlaxoSmithKline
2015 – 2017

Cancer Pathway Tracker & Data Manager, Urology Centre - Guy's & St Thomas' Hospital, UK
2011 – 2014

Chemotherapy Administrative Manager - Guy's & St Thomas' Hospital, UK
2007 – 2011

Current Experience

Senior Consultant - Scendea
Responsibilities:

- Project Management experience, responsible for being the Client primary point of contact ensuring
  - Budgetary control and adherence
  - Generation of activity-specific timelines and strategy
  - Resource allocation and management within in scope and budget for the Client
  - Adherence to agreed project timelines and being able to identify, flag and resolve potential issues early on
  - Communication and scheduling implementation
  - Working with our Technical Leads to inform strategic account development plans
  - Writing of IND sections,
  - Providing regulatory strategy and project management for ATMP products,
  - Scientific Advice
  - ODDs, SMEs, pINDs, gap analysis and DDPs.

Previous Experience

Regulatory Consultant - DLRC, UK
Responsibilities:

- Project Lead for EU Orphan Drug Designation Application
- PIP and PSP applications
- Drafting of Non-Clinical components for US IND submissions, EU MAAs and IBs
- Post approval procedures including variations, PSUR/PBRER/DSUR, article 61.3 notifications, etc.
- EU Regulatory contact for Clinical Trials

Senior Specialist, Regulatory Affairs Europe, Associate Liason - Merck, Sharpe & Dohme, The Netherlands
Responsibilities:

- Manage submissions and interactions with the EU regulatory agencies. Troubleshoot and resolve any problem on the critical path to product registration.
- Provide regulatory support, guidance and expertise to HQ US-based internal groups to ensure that all applicable regulatory requirements are considered and appropriately incorporated into development programs and that products are developed in compliance with appropriate regulations and guidelines.
- Coordinate or oversee preparation of regulatory documentation in a timely manner to meet corporate objectives. Manage centralized procedures, work in conjunction with regional subsidiary staff for decentralized procedures and provide critical assistance for national submissions in the above-mentioned region.
- Serve as the Regulatory Affairs representative on assigned non-product related cross-functional teams.
- Responsible for coordinating the preparation, review and submission of regulatory dossiers in support of post-approval submissions in the EEA, Switzerland and non- EU CES countries.

Non Clinical Regulatory Associate, Global Regulatory Affairs - GlaxoSmithKline, UK
Responsibilities:

- Manage Established Drug Products Portfolio
- Compilation of new Non-Clinical components of dossiers and completion of periodic updates of documents to ensure that they reflect a contemporary understanding of each product
- Technical authoring of new non-clinical dossier components to support in-licensed/collaborative products.
- Generation of nonclinical submission components to support established pharmaceutical products and ad hoc requests for information.

Regulatory Associate, Global Regulatory Affairs - GlaxoSmithKline, UK
Responsibilities:

- Co-ordinate the preparation of regulatory submissions for renewals tenders, site registrations and country specific initiatives for delivery to the Emerging Markets and Asia Pacific region and specific European Markets.

- Checks with relevant groups (Global Chemistry Manufacturing and Controls, Global Labelling, GRA Therapeutic Groups) to understand any ongoing regulatory activities that may affect the submission package. Agree document strategy.
- Liaise with the different teams to ensure components (dossiers, samples, and certification) are delivered in a timely fashion. Admin MSRs (Market Specific Requirements).
- Samples – requesting drug substance, drug product samples and CoAs (Certificate of Analysis). Requesting publishing of dossiers
- Prepare the listed data package components according to the timeline in internal data systems or otherwise defined.
- Responsibility for ensuring that all standard license submissions are coordinated and provided to the countries within required timelines.
- Escalate all queries, urgent requests and delays to management for resolution where required.

Cancer Pathway Tracker & Data Manager, Urology Centre - Guy's & St Thomas' Hospital, UK
Responsibilities:

- Tracking cancer diagnostic and treatment pathways for all Urology patients
- Liaising with Consultant surgeons and nurses to discuss patient management
- Worked with Oncology Clinical Trials leads (consultants and specialist nurses) to ensure compliance with targets set by the Department of Health.
- Initiated a project to create a tracking system for patients
- Ensuring departmental compliance with Government targets for diagnosis and treatment – these targets were directly linked to funding for the NHS Trust
- Attended meetings for healthcare professionals across London where advice and guidance was shared regarding treatments for cancer patients.

Chemotherapy Administrative Manager - Guy's & St Thomas' Hospital, UK
Responsibilities:

- Implemented changes to improve the oncology service. Positive feedback from staff and improved patient experience by 70%. As a direct result, the Cancer Unit was recognized by industry professionals as one of the best in South London.
- Ran daily chemotherapy clinics
- Liaising between a range of professionals from Doctors to Ward Managers and liaised with other medical departments at both Guy's and St. Thomas' hospitals for patients' medication, diagnostic results, drug charts, blood results etc.
- Training of administrative members of staff at chemotherapy units across sites
- Managed team of four - including appraisals and performance tracking
- First point of contact for patient liaison.

Dr Justine Ramsden PhD, BSc (Hons)

Principal Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

PhD - School of Pharmacy & Pharmaceutical Sciences
De Montford University - 1997 - 2002

BSc (Hons) Pharmaceutical & Cosmetic Sciences
De Montford University - 1992 - 1996

EMPLOYMENT RECORD.

Director, Regulatory Affairs - Piramal Critical Care Ltd
2021 - 2023

Head of Regulatory - Alliance Pharmaceuticals
2016 - 2021

Regulatory Affairs Manager - Alliance Pharmaceuticals
2008 - 2016

Senior Regulatory Affairs Officer - Alliance Pharmaceuticals
2006 - 2008

Manager, International Regulatory Affairs - E-Z-EM Ltd
2005 - 2006

Advanced/Senior Regulatory Officer - 3M Health Care Ltd
2002 - 2005

Regulatory Affairs Officer - Simbec Research Ltd
2001 - 2002

Data Co-ordinator - Covance CAPS Ltd
1996 - 1997

Student Analyst - Parke-Davis & Co. Ltd
1993 - 1994

Previous Experience

Director, Regulatory Affairs - Piramal Critical Care Ltd
Responsibilities:

- Responsible for leading and developing complex EU regulatory strategy for new applications across multiple regions and delivering within the tight deadlines.
- Responsible for delivering all regulatory aspects across multiple application types (Centralised, MRP, DCP or national), from initiation to launch.
- Working with commercial teams to evaluate and identify potential for new and existing portfolio and ensuring successful execution of the plans.
- CMC expert responsible for providing technical regulatory strategy, review and mentoring for CMC requirements.
- Responsible for managing EU Regulatory Affairs team across multi-regions.
- Extensive communication with all EU regulatory authorities
- Management of Class I devices across EU and responsible for cross-department leadership to ensure the company is MDR compliant.
- Regulatory lead for multi-disciplinary product and project teams, providing expert regulatory strategy and advice.
- Management of regulatory resource across the teams to ensure delivery of the strategically important regulatory projects and optimising the budget for outsourced vendor activities.
- Leading the compliance activities to ensure regulatory compliance with internal and external requirements.
- Responsible for ensuring the development of the team and delivering a new development plan across the team.

Alliance Pharmaceuticals
Responsibilities:

- Responsible for leading a Global regulatory team for Rx and OTC medicines, medical devices, cosmetics, food supplements and chemicals.
- Responsible for leading and coordinating acquisition teams during due diligence and integration of both small and transforming acquisitions within a very high paced environment.
- Strategic development of the teams as regulatory department increased from a team of 9 to 22 personnel. Responsibility for implementing the changing team structures, managing the workload, priorities, department budget, training and development of the teams.
- Extensive experience of project managing complex CMC variations and providing strategic support and operational leadership for CMC challenges, as well as authoring CMC documentation.
- Extensive RA strategy including MRP applications, Regulatory Authority meetings/discussions
- Development of the Regulatory strategy for the implementation of MDR, for both Class I and Class II devices.
- Broad International experience for new product registrations and maintenance of different classifications of products across many regions including MENA and APAC.
- Responsible for the management and implementation of projects across the regulatory department, including a document management system, product information database, FMD and EVMPD.
- Development of the company strategy and responses for ECHA and the European Commission consultations for specific ingredient challenges, such as microplastics.
- Key team member for the company-wide Quality Management System, including responsibility for the core change control procedure.
- Responsible for managing internal and external contractors.
- Represented Alliance via trade associations (PAGB), providing company input for Brexit, paraffin and other ingredient issues, and various Regulatory Authority consultations.

Manager, International Regulatory Affairs - E-Z-EM Ltd
Responsibilities:

- Regulatory project manager responsible for the preparation of Module 3 documents and coordination of dossiers, in CTD format, for submission to Worldwide countries for both national procedures and MRP.
- Providing training and mentoring to the regulatory affairs team.
- Development of global regulatory strategy plans and ensured the successful and timely delivery of variations, renewals and clinical trial approvals of diagnostic products in Europe and other ROW countries.

Advanced/Senior Regulatory Officer - 3M Health Care Ltd
Responsibilities:

- Global coordinator for the Regulatory Drug Delivery Systems group providing regulatory advice and strategy at all stages of the project lifecycle for Global submissions.
- Responsible for developing the regulatory strategy and project plans for the partner companies and managing the ensuring the resource and projects were delivered according to the plans.
- Responsible for the line management of the regulatory team.
- Regulatory team leader for the preparation and coordination of MAA and NDA dossiers, in CTD format, for submission to European countries via the MR procedure, and other countries including the US and Canada.
- Responsible for the maintenance of inhalation products, including CMC and labelling variations and renewals.
- Provided regulatory support for the implementation of the Clinical Trial Directive, including obtaining the IMP ML, for 3M in Loughborough. Preparation of clinical trial applications for both Europe (IMPD) and the US (IND) in CTD format.
- Responsible for preparation of the regulatory section of the global new product development plans and ensuring the activities are carried out in accordance with the project plans.
- European coordinator for the maintenance of 3Ms inhalation aerosol products, including variations and renewals. Experience of working with the MHRA. European trainer for Documentum.

Regulatory Affairs Officer - Simbec Research Ltd
Responsibilities:

- Responsibilities included developing regulatory strategy for external clients, dossier preparation for all markets and the preparation, review and maintenance of clinical trial applications (CTX applications) in the UK.
- The role as also included providing regulatory advice and training services for regulatory affairs within the company and for external clients

Data Co-ordinator - Covance CAPS Ltd
Responsibilities:

- Reviewing of clinical data, interpreting and reviewing clinical trial protocols, within a framework of GCP.
- Project co-ordination and management of several Phase III clinical trials, maintenance of study documentation, liaising with clients and supervising the work carried out by the Data Co- ordinators and Data Technicians.

Student Analyst - Parke-Davis & Co. Ltd
Responsibilities:

- Formulation of OTC products, analytical quality control testing, stability of formulated products, set up and conducting of consumer evaluation trials, writing reports and SOPs, liaising with staff in other departments such as microbiology, QA, medical information and production.

Richard Scotland BA

Principal Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

BA., Biology
St Joseph's College, North Windham, ME - 1978

EMPLOYMENT RECORD.

Independent Regulatory and Pharmaceutical Consultant
2018 - Present

Senior Vice President, Regulatory Affairs, Drug Safety/Pharmacovigilance, Biometry & Medical Writing (2016) - LFB USA, Inc.
2002 - 2018

SVP, Regulatory Affairs & Drug Safety / Pharmacovigilance (07/10) - LFB USA, Inc.
2002 - 2018

SVP, Regulatory Affairs & Executive Officer (3/06) - LFB USA, Inc.
2002 - 2018

Vice President, Regulatory Affairs (4/03) - LFB USA, Inc.
2002 - 2018

Senior Director, Regulatory Affairs (7/02) - LFB USA, Inc.
2002 - 2018

Director, Regulatory Affairs - Serono Laboratories
1995 - 2002

Manager, Regulatory Affairs - Genzyme
1993 - 1995

Director, Regulatory Affairs - Darby Pharmaceuticals
1991 - 1993

Manager, Regulatory & Clinical Affairs - Organogenesis
1991

Director, Regulatory Affairs - Astra Pharmaceutical Products
1990

Manager, Regulatory Affairs - Serono Laboratories
1987 - 1990

Manager, Regulatory Affairs - Damon Biotech
1985 - 1987

Drug Regulatory Affairs Associate - Delmed
1984 - 1985

Drug Regulatory Affairs Associate - Revlon Health Care Group
1981 - 1984

Drug Regulatory Affairs Assistant - Astra Pharmaceutical Products
1979 - 1981

Previous Experience

LFB USA, Inc.
Responsibilities:

- Lead an international team of Regulatory, Clinical and R&D personnel to seek and obtain the first ever European approval of a complex recombinant DNA-derived human glycoprotein produced in transgenic animals. The product was approved through the Centralized Procedure which enabled marketing of the product in all EU member States. Lead all direct interactions with EMA, experts and consultants.
- Lead a team in the U.S. in preparation and submission of the Company's first Biologics License Application (an electronic application) which was granted Fast track designation and Priority review. Negotiated with FDA acceptance of submission of the BLA on a rolling basis which enabled a more efficient review process and allowed us to utilize our limited resources in a focused manner.
- Developed the strategy for and lead all interactions with EMA and FDA pertaining to Scientific Advice, pre-IND meetings, end-of-Phase II meetings, as well as other meetings including Type A, B & C meetings.
- Actively participated in and drove when necessary the design of clinical trials to secure product registration.
- Coordinated and lead the FDA Advisory Committee which successfully supported the product licensure for this product. The de-risked asset is now being developed for another serious and life-threatening rare disorder affecting pregnant women and their neonates.
- Obtained orphan drug designation in the U.S. for the licensed product even though a similar human plasma-derived product had been granted such designation. The basis for the designation was that the recombinant product was inherently safer than human plasma-derived product. The orphan designation has afforded the firm waivers from Environmental Impact Assessments and application,product and establishment user fees, as well as market exclusivity.
- Developed the strategy and process for all electronic submissions to FDA and EMA.
- Lead a team in preparation and submission of the first ever New Animal Drug Application for the DNA construct used to generate the transgenic animals. This NADA was approved on the same day as the BLA. Time from submission of the NADA to approval was 6 days.
- Assumed responsibility in a lead role for establishing the Pharmacovigilance and Medical Information services on a global basis. The system was established in a very short period of time and was inspected by international health authorities without substantial issues. Have also had the PV system audited by internationally recognized PV experts to ensure compliance with EU and US requirements. Established Company-wide PV and product complaint training.
- Assumed responsibility for hiring, building and managing the U.S.-based Biometry and Medical Writing functions which enabled the submission of a BLA without any Biometry or Medical Writing issues
- Lead cGMP inspections of our firm by European and FDA (CBER and CVM) inspectors on multiple occasions. Ensured compliance with global requirements.
- Established Advertising and Promotion Review Committee (which includes review of publications) to ensure optimal messaging and compliance.
- Managed a group of personnel to deliver on the product development and registration goals. Guided personnel from the parent company with respect to U.S. registration activities for products already marketed in Europe.
- Mentored personnel on an international basis across all levels of the organization while establishing a positive, "can do" attitude. Also lead the successful submission of two BLAs (one a combination biologic/device product) and one New Animal drug Application (for the DNA construct stably integrated into the genome of animals) without any significant issues for FDA acceptance of the applications.

Director, Regulatory Affairs - Serono Laboratories
Responsibilities:

- Lead preparation, submission and product licensure of Rebif®, the first ever product (and remains to be the only product) to be licensed in the U.S. having overcome orphan drug market exclusivity based on a demonstration of clinical superiority from an efficacy perspective. The product was shown in a direct head-to-head study to be clinically superior to Biogen's lead product, Avonex®. The study was designed and powered to demonstrate clinical superiority of Rebif over Avonex on primary and co-primary study endpoints.
- Obtained licensure of Rebif approximately 18 months prior to expiration of U.S. market exclusivity for Avonex. With annual U.S. sales of Rebif now in excess of one billion dollars, the challenge and accomplishment of this Regulatory milestone was significant. Personally, I was one of a few within the organization who received a significant bonus from the CEO (one of the 77th richest men in the world). The achievement of product licensure of Rebif was the result of continuous negotiation and agreements with the FDA.
- Was actively involved in the preparation, submission of New Drug Applications and approval of several of the firms other recombinant DNA-derived products which were developed to replace existing human tissue extracted products. Development of these products resulted in improvements in routes of administration which were well received by the patient community.
- Was also actively involved in the development and introduction into the marketplace of a needle-free device for the administration of human growth hormone to pediatric patients. This combination was well received by patients and parents and offered a competitive advantage for this rare patient population.

Responsibilities:

- Day-to-day interactions with domestic and international health authorities
- Contribution to and implementation of global drug development strategy
- Management of staff and systems to facilitate efficient preparation of regulatory dossiers for product development and commercialization
- Review and approval of product advertising and promotional materials

Manager, Regulatory Affairs - Genzyme
Responsibilities:

At Genzyme, I was responsible for all regulatory activities related to the development of viral and non-viral gene therapy products, as well as transgenic product development. These responsibilities included interaction with the Food and Drug Administration and the National Institutes of Health which included submissions and public discussions of our gene therapy protocols before the Recombinant DNA Advisory Committee. On a day-to-day basis, my team interacted with FDA and NIH personnel, R & D personnel and management to ensure delivery on the strategic goals of the firm.

Director, Regulatory Affairs - Darby Pharmaceuticals
Responsibilities:

At Darby, I was the Head of Regulatory and had responsibility for all interaction with FDA. I was responsible for the scheduling, preparation of submissions and for securing the approval of New Drug Applications. Additional responsibilities included keeping management informed of changes in the Regulatory environment.

Manager, Regulatory & Clinical Affairs - Organogenesis
Responsibilities:

Primary responsibilities were to plan and initiate clinical studies for biological medical devices to be used in support of 510(k) notices and premarket approval applications. Additional responsibilities included the preparation and maintenance of investigational device exemption applications.

Director, Regulatory Affairs - Astra Pharmaceutical Products
Responsibilities:

Principal responsibilities were to manage personnel and regulatory projects leading to the submission of INDs, NDAs and ANDAs in accordance with planned strategies.

Manager, Regulatory Affairs - Serono Laboratories
Responsibilities:

Principal responsibility was to manage Regulatory personnel who, under my direction, prepared and filed INDs, NDAs, IDEs, PMAs, DMFs and other dossiers as required to permit investigation and/or registration of Company products in the U.S. and Canada. An additional primary responsibility was to liaise with the Food and Drug Administration to facilitate the timely development and registration of products.

It was my responsibility to inform Company personnel about GLP, GMP and GCP requirements to ensure that products were developed and produced in a sound and safe manner. By way of periodic audits against written Company policies/ procedures and government regulations compliance was assured.

Manager, Regulatory Affairs - Damon Biotech
Responsibilities:

Principal responsibilities included the coordination, compilation, review and submission of all Company regulatory documents in accordance with Federal, State and local laws, rules regulations and guidelines. Such submissions included DMFs, INDs, ELAs and PLAs and miscellaneous permit and license applications. Additional responsibilities included the coordination and preparation of adequate responses to requests made by government health authorities pertaining to Company applications.

Drug Regulatory Affairs Associate - Delmed
Responsibilities:

Principal responsibilities included the coordination, compilation, review and submission of Company regulatory filings that included DMFs, INDs and NDAs for drugs and 510(k) notices and IDE s for medical devices.

Drug Regulatory Affairs Associate - Revlon Health Care Group
Responsibilities:

Principal responsibilities included the coordination, preparation and review of the pharmacy and chemistry sections of INDs, NDAs, ANDAs and subsequent amendments/supplements. Additional responsibilities included the coordination, preparation and review of preclinical and clinical sections of INDs and NDAs.

Drug Regulatory Affairs Assistant - Astra Pharmaceutical Products
Responsibilities:

Principal responsibilities were to coordinate, compile and review INDs, NDAs and ANDAs. Supervised clerical personnel necessary for the preparation of large regulatory submissions. Was responsible for gathering and assembling information required for preparing annual and periodic IND, NDA and ANDA update reports.

Dr Natalie Thomas BSc (Hons), PhD

Principal Consultant
Date Appointed to Position: October 2023

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.

Director and Principal Consultant - Scendea
2019 - 2023

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.

Ian Waterson BSc (Hons), MSc

Principal Consultant
Date Appointed to Position: October 2022

ACADEMIC QUALIFICATIONS.

MSc Applied Toxicology - 2002 - 2007
University of Surrey

BSc (Hons) Life Sciences - 1993 - 1996
Napier University, Edinburgh

H.N.C. Applied Biology - 1991 - 1993
Sunderland University

PROFESSIONAL SOCIETIES.

Member of the British Toxicology Society.

EMPLOYMENT RECORD.

Senior Non-Clinical Assessor, MHRA
2018 – 2022

Accredited Non-Clinical Assessor, MHRA
2015 – 2018

Non-Clinical Assessor, MHRA
2014 – 2015

Senior Research Investigator, Toxicology - Covance Laboratories Ltd
2010 – 2014

Senior Research Investigator, Drug Safety Evaluation - Sanofi-Aventis
2010 – 2010

Research Investigator, Drug Safety Evaluation - Sanofi-Aventis
2005 – 2009

Principal Research Scientist, Toxicology - Sanofi-Synthélabo
2002 – 2005

Senior Research Scientist, Zootechnie - Sanofi-Synthélabo
2000 – 2002

Associate Research Scientist/Research Scientist, Toxicology -Sanofi Research Division
1994 - 2000

Senior Research Technician/Principal Research Technician, Toxicology - Sterling-Winthrop
1990 - 1994

Trainee Animal Technician to Leading Animal Technician - Hazleton Laboratories
1985 - 1990

Previous Experience

Senior Non-Clinical Assessor, MHRA
Responsibilities:

- Carry out the assessment of non-clinical data provided in marketing authorisation initial and variation applications or clinical trial applications and amendments including those with new, wide-ranging or complex issues making appropriate recommendations and decisions in line with the protection of public health.
- Manage own workload working in conjunction with service coordinators and other assessors to meet European, Agency or Divisional deadlines
- Promptly update Agency, divisional or team work management databases to reflect the progress of own work
- Prepare and present objective assessments or other scientific papers to expert advisory bodies
- Take a lead in providing reliable, timely and appropriate scientific and regulatory advice to companies at meetings and in writing reflecting contemporary regulatory guidance and relevant
- Mentors or coaches other staff to enhance their knowledge and contribution
- Provides ad hoc advice to colleagues in the division or Agency
- Continues to extend and deepen skills and knowledge in relevant scientific or professional areas
- Contribute to and influence assessment policy and practice and proactively identify where such contributions would be beneficial
- Contribute to and influence divisional procedures and proactively identify where such contributions would be beneficial
- Make individual contributions to representational or professional activities inside or outside the Agency.
- Develop good working relationships with colleagues and with internal and external stakeholders.
- Deal effectively with official correspondence to agreed timelines.
- Use own and Agency resources in line with Agency and divisional strategy to meet targets.

Accredited Non-Clinical Assessor, MHRA
Responsibilities:

- Assessment of new and variation applications and/or substantial amendments for national and European procedures.
- Assessment of responses for national and European procedures.
- Provide sound, robust, carefully considered scientific and regulatory advice to Advisory Committees, Companies, EMA, other Competent Authorities and other relevant stakeholders.
- Maintain all Agency information management systems with up to date information, contribute to the accuracy of the database and comply with Data Assurance Protocol and relevant SOPs.
- Provide regulatory and scientific advice to colleagues and stakeholders and dealing with enquiries including preparation of answers to official correspondence.
- Continue professional development in order to maintain and improve good regulatory and scientific / non-clinical / clinical expertise (as appropriate).
- Represent the Division or Agency at cross-divisional or external meetings and working groups.

Non-Clinical Assessor, MHRA
Responsibilities:

- Assessment of new and variation applications and/or substantial amendments for national and European procedures.
- Assessment of responses for national and European procedures.
- Provide sound, robust, carefully considered scientific and regulatory advice to Advisory Committees, Companies, EMA, other Competent Authorities and other relevant stakeholders.
- Maintain all Agency information management systems with up to date information, contribute to the accuracy of the database and comply with Data Assurance Protocol and relevant SOPs.
- Provide regulatory and scientific advice to colleagues and stakeholders and dealing with enquiries including preparation of answers to official correspondence.
- Continue professional development in order to maintain and improve good regulatory and scientific / non-clinical / clinical expertise (as appropriate).

Senior Research Investigator, Toxicology - Covance Laboratories
Responsibilities:

Specific responsibilities:

- Study Director: To plan, design, manage and report routine and non-routine toxicity studies in accordance with client's research strategy. To ensure that toxicity studies are conducted to the highest scientific standard and in full compliance with the principles of GLP to promote product advancement.
- Project Team Representative: Where required, to participate in compound-specific, multi-disciplinary Project Teams for clients. Prepare and/or review technical and scientific documentation that contributes to safety assessment of compounds (e.g NonClinical sections of IMPDs, CTDs etc.). To support a multi-disciplinary approach to safety assessment, including proactive involvement in problem resolution projects within Safety Assessment and collaboration with colleagues at external facilities to achieve co-ordinated progression of projects.
- Deputy Lead for Target Occupancy (in vivo pharmacology) studies: Manage the validation and reporting of new TO assays. Plan, conduct, manage and report routine and non-routine Target Occupancy studies.
- Training: Oversee the training of new Study Directors.
- Operational Implementation Manager: Manage the installation and validation of the In-Life data capture and Reporting software, from an operational perspective.
- Local representative in Safety Assessment for GTI evaluation strategy: Provide advice to clients both internally and externally on the approach to take for GTI assessment.
- Site representative in Global Report Format Team: To participate in a Global team to harmonise GLP report and protocol templates and the processes involved in protocol and report production, including eSubmission formatting.
- Site Toxicology Representative on NC3Rs project on microsampling.

Research Investigator, Drug Safety Evaluation - Sanofi-Aventis
Responsibilities:

Specific responsibilities:

- Study Director: To plan, design, manage and report routine and non-routine toxicity studies in accordance with the company's research strategy for drug development. To ensure that toxicity

Specific responsibilities:

- Study Director: To plan, design, manage and report routine and non-routine toxicity studies in accordance with the company's research strategy for drug development. To ensure that toxicity studies are conducted to the highest scientific standard and in full compliance with the principles of GLP to promote product advancement. Prepare and/or review technical and scientific documentation that contributes to safety assessment of compounds. Support a multi-disciplinary approach to safety assessment.
- Project Team Representative: Participate in compound-specific, multi-disciplinary Project Teams. Prepare and/or review technical and scientific documentation that contributes to safety assessment of compounds (e.g NonClinical sections of IMPDs, CTDs etc.). Support a multi-disciplinary approach to safety assessment, including proactive involvement in problem resolution projects within Drug Safety Evaluation.
- Lead User for in-life data capture computer system: Manage the installation and validation of the In-Life data capture system from a User's perspective.
- Local representative in Safety Assessment for GTI evaluation strategy: Working on a multi-disciplinary team to training and conduct GTI assessment from a Toxicology perspective.
- Local representative in DSE Global Expert Group for Genetic Toxicology: Acting as a site contact for global developments in genetic toxicology strategy.

Principal Research Scientist, Toxicology - Sanofi-Synthélabo
Responsibilities:

Specific responsibilities:

- Study Director: To plan, design, manage and report routine and non-routine toxicity studies in accordance with the company's research strategy for drug development. To ensure that toxicity studies are conducted to the highest scientific standard and in full compliance with the principles of GLP to promote product advancement. Prepare and/or review technical and scientific documentation that contributes to safety assessment of compounds. Support a multi-disciplinary approach to safety assessment.
- Deputy Project Licence Holder.

Senior Research Scientist, Zootechnie - Sanofi-Synthélabo
Responsibilities:

Specific responsibilities:

- Management: Responsible for management of animal unit and its staff, including providing fully resourced reams and trained personnel to complete all non-clinical study tasks.
- Training: Responsible for training and supervision/co-ordination of subordinate staff, including use of In-Life data collection system
- Reporting: Responsible for production of protocols and issuance of reports for internal projects.
- Technical Skills: Competent to complete and demonstrate routine and non-routine intrusive procedures requiring a Home Office Licence.
- Deputy Project Licence Holder
- Co-ordination of laboratory animal purchasing
- Management of rodent sentinel programme.

Associate Research Scientist/Research Scientist, Toxicology - Sterling-Winthrop
Responsibilities:

Specific responsibilities:

- Day-to-day management of In-Life phases of non-clinical studies, training, supervision of staff

Trainee Animal Technician to Leading Animal Technician - Hazleton Laboratories
Responsibilities:

Specific responsibilities:

- Trainee/junior technician: Responsibilities included maintenance and general animal husbandry; conduct of study procedures to GLP standards; conduct of Home Office licenced procedures.
- Animal Technician/Leading Animal technician: As above, but also development of supervisory skills, training, deputising for Senior Animal Technician and, eventually, management of the Inhalation Unit from an animal services aspect.

SELECTED PUBLICATIONS.

- Baldrick, P, Cosenza, M.E, Alapatt, T, Bolon, B, Rhodes, M, & Waterson, I. Toxicology Paradise: Sorting Out Adverse and Non-adverse Findings in Animal Toxicity Studies. The International Journal of Toxicology. 2020; 1-14

- Sewell, F, Waterson, I, Jones, D, Tricklebank, M.D, Ragan, I. Preclinical screening for antidepressant activity - shifting focus away from the Forced Swim Test to the use of translational biomarkers. Regul. Toxicol. Pharmacol. 2021; 125:105002.

Leanne West BSc

Principal Consultant
Date Appointed to Position: November 2023

ACADEMIC QUALIFICATIONS.

Honours Project
Thesis Title: Genetic fingerprinting by RAPD PCR of Dunaliella species
University of Wollongong - 1994

Bachelor of Biotechnology
University of Wollongong - 1991 - 1993

EMPLOYMENT RECORD.

Director Clinical Affairs and Operations- Prescient Therapeutics, Brisbane
2021 - 2023

Project Director - Novotech, Brisbane
2020 - 2021

Clinical Operations Manager - CNS, Brisbane
2018 – 2020

Senior Project Manager - CNS, Brisbane
2016 – 2018

Project Manager - CNS, Brisbane
2014 – 2016

Clinical Research Consultant- Self Employed
2011 - 2014

Clinical and Technical Affairs Manager - Novogen Limited, Sydney
2003 - 2010

Clinical and Technical Affairs Manager (UK/Europe) - Novogen Limited, UK
2000 - 2003

Clinical Logistics Manager - Parke Davis Pty Ltd, Sydney
1999 - 2000

Clinical Research Coordinator - Novogen Limited, Sydney
1997 - 1999

Clinical Research Associate- Novogen Limited, Sydney
1996

Scientific Officer - Wollongong Hospital (Haematology Department)
1995 - 1996

Scientific Officer - Illawarra Medical Laboratories, Wollongong
1991 - 1996

Previous Experience

Director Clinical Affairs and Operations - Prescient Therapeutics
Responsibilities:

- Responsible for Clinical Operations, Regulatory, CMC Operations
- Managing all aspects in the clinical development of two targeted therapies (PTX-100 and PTX-200) and the clinical development of OmniCAR, CAR-T.
- Regulatory management of two INDs and preparation of the CTA in Australia for OmniCAR
- Successfully prepared and recently awarded two Orphan drug applications for PTCL and TCL.
- Gained 2 years of experience in CAR-T regulations and supporting team on CMC aspects in this rapidly changing field.

Project Director- Novotech
Clinical Operations Manager - CNS
Responsibilities:

- Special interest in Early Phase studies
- Line manager for Project Managers providing mentorship and support for full service studies.
- Protocol development, clinical trials, data management, analysis and CSR.

Senior Project Manager - CNS
Project Manager - CNS
Responsibilities:

- Special interest in Early Phase studies
- Full service PM managing - Protocol development, clinical trials, data management, analysis and CSR. Budgets, timelines, risk and client servicing.

Clinical research consultant - Self Employed
Responsibilities:

- CNS Biodesk (Jan 2014 to May 2014) – Protocol writing
- Marshall Edwards Inc, San Diego, USA. (Jan 2011 – May 2014)
- Clintrace SAE reconciliation, narrative QC and closure for oncology products to close out IND.
- Closed out Clintrial database and produced data tables and listings to prepare Clinical Study Report for a Phase III ovarian cancer study.
- Responsible for Phase III Ovarian Cancer Clinical study report
- Preparation of ME-344 IND.
- Single remaining contact on behalf of Novogen R&D department.

Clinical and Technical Affairs Manager - Novogen Limited
Responsibilities:

- Senior Management - Clinical and Technical Affairs Manager (May 2003 – December 2010)
- Managed clinical program and staff for oncology studies- including preparation of clinical documentation, protocol design, writing, budgets, managing vendors and CROs, timelines, sites and monitoring.

- Responsible for study report writing for all studies- marketing and therapeutic programs.
- Clinical regulatory management for FDA and European components of Phase III IND study.
- Responsible for writing IND submissions, Special Protocol Assessment Application and a successful FDA Orphan Drug application for pancreatic cancer.
- Medical Liaison for Marketing and Medical Information to provide interpretation of clinical results or results from other publications.
- Provided clinical and technical support for Phytoestrogen products as well as compile dossier in CTD format for the TGA.
- Therapeutic areas – oncology, cardiovascular, endocrinology, anti-inflammatory.

Clinical and Technical Affairs Manager (UK/Europe) - Novogen Limited
Responsibilities:

- Managed clinical program in UK/Europe (Home office in Oxford).
- Regulatory - managed CTD submission of Promensil to UK regulatory agency.
- Medical Liaison for Marketing throughout Europe
- Provided clinical and technical support for Phytoestrogen products

Clinical Research Associate - Novogen Limited
Clinical Trials Coordinator - Novogen Limited
Responsibilities:

- Managed all of the clinical trials for the menopause and premenopausal indications for phytoestrogen product development, Novogens core R&D program.
- Developed systems and procedures for the clinical trial program.
- Provide clinical and technical support for Promensil, Novogens major product.

Scientific Officer - Wollongong Hospital (Haematology Department)
Responsibilities:

- Gained training in phlebotomy and transfusion medicine.

Scientific Officer- Illawarra Medical Laboratories
Responsibilities:

- Experienced in Haematology, Biochemistry, Immunology, Microbiology and Histology with a strong command of pathology terminology and understanding.

Dr Babaji Yadav PhD, MPharm, BPharm

Principal Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

PhD - Department of Pharmacology and Toxicology
University of Otago, New Zealand - 2008 - 2011

MPharm - Department of Pharmacognosy/Natural Products
Bharati Vidyapeeth University, India - 2003 - 2005

BPharm - Poona college of Pharmacy
University of Pune, India - 1999 - 2003

PROFESSIONAL SOCIETIES

UK Registered Toxicologist -
Royal Society of Biology and British Toxicology Society

Eurotox Registered Toxicologist -
Eurotox

EMPLOYMENT RECORD.

Associate Director and Principal Consultant (Nonclinical/Toxicology) - Novotech - Sydney
2021 – 2023

Senior Consultant - Novotech - Sydney
2021 – 2023

Consultant - Clinical Network Services - Australia
2018 – 2021

Associate Clinical Project manager - IQVIA - Sydney
2017 – 2018

Project manager - Kazia therapeutics (formerly Novogen ltd) - Sydney
2015 – 2017

Post-doctoral Research Fellow - Children's Cancer Institute Leukaemia Biology Program - Sydney
2012 - 2015

Lecturer - Alard College of Pharmacy, affiliated to University of Pune - India
2007 - 2008

Lecturer - Vishal Institute of Pharmaceutical education and research, affiliated to University of Pune - India
2007 - 2008

Research Trainee - Sanofi-Aventis Ltd, Analytical Development Department - India
2007 - 2008

Previous Experience

Associate Director and Principal Toxicologist - Novotech
Responsibilities:

- Provided strategic advice and technical expertise to clients who were mainly pharmaceutical or biotechnology companies.
- Guided project and program activities.
- Responsible for review of nonclinical toxicology packages, conducting gap analyses and risk assessments and preparing drug development plan to support the conduct of clinical trials and to support marketing applications for various modalities (e.g. small molecules, protein/peptides, oligonucleotides, vaccines, monoclonal antibodies, LBPs, herbal drugs, and cell and gene therapies etc.) and therapeutic indications (e.g. oncology, dermatology, infectious diseases, metabolic diseases, neuroscience etc.) mainly for Australia and USA.
- Performed literature reviews related to pharmacology and nonclinical toxicology for the drug and or excipient(s) under development in order to support their use in the clinical studies.
- Involved in writing regulatory documents such as investigators brochure and clinical protocol for submission to various regulatory bodies across the globe and writing of nonclinical modules of IND applications for submission to the US FDA.
- Assisted in preparing written responses to queries raised by regulatory agencies across the globe.
- Reviewed and/or designed and managed new drug toxicology programs, including a range of toxicology studies such as dose-range/MTD finding studies, repeat dose studies, acute single dose studies, safety pharmacology, genotoxicity studies and combination toxicology.
- Project management activities, including communication and co-ordination within the project team and the client to enable meeting project deadlines and budget targets.
- Aware of various regulatory guidelines by ICH, FDA, EMEA and WHO for requirements of non-clinical pharmacology and toxicology studies for conduct of clinical studies.
- Supported business development activities to win business and participate in marketing activities e.g. presentations at national/international conferences, and participation in webinars and panel discussions.
- Managed four line reports in last two years and involvement in providing leadership and management support to the nonclinical/toxicology group.

Associate Clinical Project manager - IQVIA
Responsibilities:

- Project managed Phase I and II clinical development of immuno-oncology drugs for biotech companies across the globe.
- Negotiated budget and contract with the sponsor.
- Reviewed, or developed as needed, all key documents/deliverables in the trial, e.g. regulatory and Ethics submissions, eCRF, Data Management Plan, Clinical Operational Plan, Integrated Project Management Plan, Safety Plan, Pharmacy Manual, Randomisation Plan, Statistical Analysis Plan and Clinical Study Report.
- Ensured frequent and effective communication with all study sites, consultants and other vendors in Australia and overseas if necessary.
- Managed investigational product distribution.
- Proactively managed the timely resolution of any identified problems with study sites, CRAs, consultants, other vendors and internal team.
- Supported sponsors in set-up, implementation, and execution of the assigned clinical study.
- Prepared and presented project information at internal and external meetings.
- Supported feasibility and site identification activity.
- Supported medical writing activity (PK/PD and Biomarker section of the clinical protocol).
- Produced and distributed status, tracking and financial reports for internal and external team members and senior management.
- Coordinated with other support staff within and across the global project management unit to identify and consolidate support processes.
- Served as the primary contact for internal project team and for external stakeholders.
- Undertook responsibilities for financial reporting on the project including tracking, revenue recognition and invoicing.
- Trained and mentored junior project support staff.

Research Project manager - Kazia therapeutics
Responsibilities:

- Successfully planned and completed IND enabling non-clinical pharmacology and toxicological studies for a lead oncology lead molecule with contract research organisations (CROs). These studies included acute/repeat dose toxicity studies in rodent and non-rodent species, toxicokinetic studies, safety pharmacology studies, genotoxicity studies, and immunotoxicity studies. Moreover, in vitro/ in vivo pharmacology and pharmacokinetic studies were also conducted using various models.
- Assisted in reviewing and quality controlling IND application for Cantrixil, another lead molecule for ovarian cancer. Cantrixil IND application was successful in June 2016.
- Assisted clinical/regulatory director in reviewing phase I clinical trial protocol for Cantrixil. The phase I clinical trial of Cantrixil commenced in Dec 2016.
- Assisted in managing and quality controlling HREC application for phase 1 study of Cantrixil.
- Assisted clinical research director in setting up a phase II glioblastoma study
- Liaised with internal and external cross functional teams (chemists, biologists, clinicians, chief medical officer, chief business development officer and CROs) to remain abreast of the project development and ensure project success. Worked with contract research and manufacturing organisations (CROs and CMOs) across the globe (USA, China, India & UK).
- Prepared and presented toxicological/drug safety data to internal (scientific advisory board) and external stakeholders.
- Demonstrated critical thinking and creative problem solving skills to ensure timely and successful implementation of projects.
- Participated in writing the pharmacology and toxicological section of the investigator's brochure (IB) and IND application for regulatory submissions.
- Participated in writing FDA annual reports for orphan drugs under development.
- Managed and collected all pre-clinical research data from contract research organisations and prepared ICH compliant reports for IND application.
- Set up and maintained budgets in liaison with the project director.

Post-doctoral research fellow - CCI, Leukaemia Biology program
Responsibilities:

My post-doctoral research was focused on improving treatments and studying mechanism of relapse in high risk acute lymphoblastic leukaemia (ALL) patients.

- Conducted pre-clinical testing of FDA approved anticancer drugs in consultation with haematologists from the Sydney Children's Hospital for personalised medicine programme.
- Assessed minimal residual disease (MRD) in patient diagnosis and relapse samples using RT-PCR based clonal biomarkers.
- Studied the mechanism of resistance to the standard of care drugs and found an alternative treatment to overcome the resistance in selective high risk ALL patients enrolled in international ANZCHOG study 8, ANZCCSG study *7*, COG-AALL0434 and Interfant 06 clinical trials using patient derived pre-clinical models.
- Managed and performed whole genome sequencing, RNA sequencing and gene expression analysis to identify mechanism of relapse in high risk ALL patients using tumour samples obtained at diagnosis and relapse.
- Trained and supervised post-graduate students and research assistants in relevant technical skills and research projects.
- Worked in collaboration with national and international collaborators on oncology projects.
- Maintained budget for the grants and assisted in grant application and write annual reports to funding bodies.
- Invited speaker at Gavan Institute of Medical Research, Sydney to deliver a seminar on patient-derived xenografts for cancer therapeutics development.
- Published two first author scientific manuscripts in international refereed journals.
- Appointed as an examiner by the School of Medical Sciences, UNSW to examine honours thesis and seminars.
- Invited to deliver a presentation at Children's Cancer Institute seminar series
- Invited by Children's Cancer Institute to be a part of a video produced for the fund raising and promotional activities of the institute.

Lecturer - Alard College of Pharmacy, affiliated to University of Pune
Responsibilities:

- Developed and delivered lecture materials and conducted practical courses for undergraduate students of pharmacy for pharmacology and anatomy/ physiology.
- As an in charge of the scientific committee, trained and mentored several students to participate and present search work at national level conferences.
- Provided administrative support including module co-ordination and participation in College governance structures.
- Participated in planning and organizing a one-day workshop on "Recent trends in pharmaceutical Biotechnology" at Alard College of Pharmacy. Was personally involved in selecting and inviting experts/speakers in the field of pharmaceutical biotechnology.
- Presented research papers in several national conferences.
- Selected to attend a government funded national level quality improvement program (QIP) by All India Council for Technical Education (AICTE), India.

Research Trainee - Analytical Development Department, Sanofi- Aventis Ltd
Responsibilities:

- Successfully developed and validated new analytical methods for testing of the novel finished products in pipeline (diabetes and hypertension) as per ICH guidelines.
- Analysed pilot scale batches from the manufacturing department for in process quality control.
- Prepared standard operating procedures (SOPs) as per GLP guidelines.
- Conducted stability testing studies for marketed finished products.
- Provided technical support to the quality control department for testing and timely release of the marketed products for diabetes and hypertension (Sanofi trade names- Cardace, Daonil and Frisium).

Dr Bertjan Ziere PhD, MSc

Principal Consultant
Date Appointed to Position: May 2024

ACADEMIC QUALIFICATIONS.

PhD Degree - Division of Biopharmaceutics, Leiden-Amsterdam Center for Drug Research
University of Leiden, the Netherlands

Master Degree: Bio-Pharmaceutical Sciences (BFW)
University of Leiden, the Netherlands

EMPLOYMENT RECORD.

VP of Preclinical Development & CMC - Leyden Laboratories BV
2021 - 2024

Managing director and Principal Consultant- Ziere Consultancy BV
2016 – 2024

Managing director and Principal Consultant- Biologics Development Consultancy BV
2007 - 2016

Managing Director - Ziere Consultancy BV
2006 - 2007

Senior Director Operations - Biotech Company
2003 - 2006

Director Research & Development - Biotech Company
2001 - 2003

Senior Scientist Preclinical Research and Development - Pharmaceutical Company
1999 - 2001

Post-doctoral fellow - University of Leiden and Giba Geigy, ADDR, UK
1993 - 1999

Previous Experience

VP of Preclinical Development & CMC - Leyden Laboratories BV
Responsibilities:

- Member of leadership team of Leyden Laboratories BV
- Pharmacology & toxicology of all products
- Chemistry, Manufacturing and Control of all products
- Formulation and delivery of products to nasal and lung mucosa
- Bioanalytical assay development and validation to measure compound (and metabolites) in complex matrices (serum, nasal mucus, BALF, etc.) from preclinical and clinical studies

Managing director and Principal Consultant - Ziere Consultancy BV
Responsibilities:

- Strategic advice on pharmaceutical development and pharmacology/toxicology
- Regulatory strategy
- Guidance on (scientific advice) meetings with regulatory authorities
- Assessment of business-plans and development-plans (VCs, companies)
- Writing of expert-reports (QOS, modules 3, 2.4 and 2.6) for biotech products
- Auditing of CMO's / CRO's for Biotech and Pharmaceutical companies
- Interim / project management of complex scientific and pharmaceutical programs
- Management and outsourcing of nonclinical studies

Managing director and Principal Consultant - Biologics Development Consultancy BV
Responsibilities:

- Strategic advice on pharmaceutical development and pharmacology/toxicology
- Regulatory strategy
- Guidance on (scientific advice) meetings with regulatory authorities
- Assessment of business-plans and development-plans (VCs, companies)
- Writing of expert-reports (QOS, modules 3, 2.4 and 2.6) for biotech products
- Auditing of CMO's / CRO's for Biotech and Pharmaceutical companies
- Interim / project management of complex scientific and pharmaceutical programs
- Management and outsourcing of nonclinical studies

Managing Director - Ziere Consultancy BV
Responsibilities:

- Assessment of business- and development plans (gap-analyses) for biotech companies
- Strategic advice on pharmaceutical development (in biopharmaceutical industry)

- Writing of expert reports
- Interim management
- Auditing of CMO's and CRO's for Biotech and Pharmaceutical companies
- Management and outsourcing nonclinical studies

Senior Director Operations - Biotech Company
Responsibilities:

- Head of five pharmaceutical departments:
  - Production: Upstream Processing (USP)
  - Production: Downstream Processing (DSP)
  - Research and Development (R&D)
  - Preclinical Development (toxicology/pharmacology)
  - Regulatory Affairs
- General management, planning and budget control of Operations (USP/DSP, R&D,
- Preclinical Development, Regulatory Affairs), including outsource management and contracts (CMO's / CRO's)
- Line management of directors and managers
- Development and implementation of quality systems within the company (GLP,GMP)
- Member of Operational Management Team: Strategy, Partnering, Financing, Project Management

Director Research & Development - Biotech Company
Responsibilities:

- Management of R&D organisation
- Support of Manufacturing Operations development and QC testing
- Design and management of Preclinical Development studies

Senior Scientist Preclinical Research and Development - Pharmaceutical Company
Responsibilities:

- Design and management of Preclinical Research and Development studies (pharmacology, toxicology studies)

Iheoma Anosike BSc (Hons), MSc

Senior Consultant
Date Appointed to Position: July 2023

ACADEMIC QUALIFICATIONS.

MSc Advanced Chemical Engineering – 2019
Imperial College London, UK

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

PROFESSIONAL SOCIETIES.

Regulatory Affairs Professionals Society (RAPS): Regulatory Affairs Certificate (RAC) – Drugs

EMPLOYMENT RECORD.

Associate Consultant - Scendea
2019 – 2021

Customer Generation Executive – MVF
2018 – 2019

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

Current Experience

Consultant - Scendea
Responsibilities:

- Establishment and maintenance of a high level of technical knowledge in product development and international regulatory affairs .
- Creation and delivery of high-quality regulatory documentation for clients.
  Examples include:
  - MAA/BLA Module 3 authoring (mAb Biosimilar)
  - Initial IND authoring for a range of product classes, including biologics
  - IMPD authoring for a range of product classes, including small molecules
- Development of strategic drug development approaches for regulatory and CMC.
  Examples include:
  - Authoring of regulatory strategy reports for biologics and small molecules
- Management of projects and provision of practical support to ensure timely completion of all project tasks as assigned within the allocated timelines and budgets.

Examples include:

- MAA/BLA Module 3
- IND and CTAs (Phase 1 to Phase 3)
- EU scientific advice meetings (EMA and national agencies) and Innovation Task Force Briefing Meetings (ITF BM)
- FDA meetings
- EU Paediatric Investigation Plans, Orphan Drug Designations, PRIME, SME status

- Active participation in internal and external meetings to obtain relevant information for dissemination to the Scendea team and external stakeholders.
- Participation in meetings with internal and external stakeholders on matters related to current and future projects, contracts and new business opportunities.
- Preparation of written estimates, quotations and contracts for Clients as required.
- Assist in the development and maintenance of Standard Operating Procedures (SOP) and other relevant training materials. Examples include:
  - Delivery of formal training sessions to the Scendea team
  - Regular ad hoc training provided to new team members as required
- Ensure that all client material is treated and maintained in full respect of client confidentiality.

Previous Experience

Associate Consultant - Scendea
Responsibilities:

- Development and maintenance of a high level of technical knowledge in product development and international regulatory affairs.
- Support creation and delivery of high-quality billable related documentation for clients.
- Support strategic drug development strategies in the area of regulatory affairs.
- Create timelines and organise internal resourcing for projects to ensure the timely completion of project related activities.
- Support the preparation of written estimates, quotations and contracts for clients.
- Ensure completion of all project tasks as assigned within the allocated timelines and budgets.
- Generate and summarise relevant information from in/external meetings and disseminate to the Scendea team and external stakeholders.
- Assist development and maintenance of Standard Operating Procedures (SOP) and other relevant training materials.
- Review and collate information pertaining to the latest developments in regulatory affairs for internal and external distribution.
- Ensure all client material is treated and maintained in full respect of client confidentiality.

Kelly Burns BSc

Team Lead (AUS) & Senior Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Physiological Science
University of Newcastle Upon Tyne

EMPLOYMENT RECORD.

Consultant - Scendea
2022 - 2023

Medical Writer - Novotech Australia (Previously Clinical Network Services)
2013 – 2022

Clinical Trials Assistant - Novotech Australia (Previously Clinical Network Services)
2013 – 2014, 2015 - 2017

Histology Scientist - Sullivan Nicolaides Pathology
2012 – 2013

Reproductive Biology Student - University of Newcastle Upon Tyne
2011 – 2012

Previous Experience

Consultant - Scendea
Responsibilities:

- Creation and delivery of high-quality regulatory documentation for clients. **Examples Include**: Initial IND authoring for a range of product classes
- iPSP, PIP, and IMPD authoring for a range of product classes
- Creation and delivery of high-quality clinical documentation for clients. **Examples Include**: Authoring of CSRs, authoring of Investigator Brochures, authoring of DSURs
- Consultation for the development of a study design based on preclinical data, therapeutic area, and phase of development – including authoring of clinical study protocols – across a range of therapeutic areas. **Examples Include:** Vaccines, oncology, neurology, dermatology, and respiratory, musculoskeletal, cardiovascular, inflammatory, and orphan diseases

Medical Writer - Novotech (Previously CNS)
Responsibilities:

- Preparation of clinical and regulatory documents, including but not limited to integrated statistical/clinical study reports, protocols, investigator brochures, regulatory submissions, drug development plans, drug safety update reports, manuscripts for publication, and other documents as required.
- Liaison with clients, external consultants, colleagues, and review of current literature sources to ensure document development is in alignment with client goals, local regulations, and Good Clinical Practice.
- Consultation for the development of a study design based on preclinical data, therapeutic area, and phase of development.
- Working across multiple therapeutic areas based on local and international client requirements.

Senior Medical Writer - Novotech (Previously CNS)
Responsibilities:

- Working closely with the project team to ensure adherence to project plans, timelines, and budgets.
- Maintain awareness of current trends in protocol design and drug development strategies.
- Identify opportunities for improvement and advancement within the organisation.
- Professional development of new and junior medical writers, including training, support, and mentoring.

Key Achievements:

- Developing and reviewing Standard Operating Procedures, work instructions, systems, and processes to ensure consistency, quality, and efficiency to accommodate 4-fold growth within the medical writing team.
- Nominated by my colleagues three times for a company award based on outstanding behaviour and achievement.

Therapeutic Areas:

- Vaccines, oncology, respiratory, neurological, ophthalmology, musculoskeletal, cardiovascular, dermatology, inflammatory diseases, gastrointestinal.

Project Administrator/Clinical Trials Assistant - Novotech (Previously CNS)
Responsibilities:

- To assist in implementation and coordination of clinical trials.
- Maintenance and management of all study documentation.
- Providing administrative support to project managers, clinical research assistants, and biometrics.
- Management and inventory of trial supplies.
- Ensure compliance with all guidelines and local regulations.

Histology Scientist - Sullivan Nicolaides Pathology
Responsibilities:

- Staining, orientation, macro description, and blocking of specimens.
- Processing of specimens.
- Maintenance of laboratory equipment.

Polly Kennard BSc

Senior Consultant
Date Appointed to Position: September 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Pharmacology - 2013 - 2017
University of Hertfordshire

EMPLOYMENT RECORD.

Senior Toxicology Scientist - Benevolent AI
2022 – 2023

Senior Associate Toxicology Scientist - Pre-Clinical Department, Jazz Pharmaceuticals (Formerly Gw Pharmaceuticals)
2020 – 2022

Scientist - Pharmacology Department, Covance (Formerly Envigo)
2017 – 2020

Assistant - Department Of Pharmacy, Pharmacology and Postgraduate Medical Research, University Of Hertfordshire
2015

Previous Experience

Senior Toxicology Scientist - Benevolent AI
Responsibilities:

Part of the safety team within the pre-clinical department. I helped oversee the toxicology studies in line with the company's regulatory submissions. I analysed and interpreted data that came through from cros. I assessed the safety of potential drug targets prior to development

Senior Associate Toxicology Scientist - Pre-Clinical Department, Jazz Pharmaceuticals
Responsibilities:

I was part of the toxicology team within the pre-clinical department. I helped to oversee the toxicology studies in line with the company's regulatory submissions. I analysed and interpreted data that comes through from cros.

Scientist - Pharmacology Department, Covance (Formerly Envigo)
Responsibilities:

I was part of the drug discovery and safety team, specialising in respiratory and infectious diseases. I have developed new in-vivo models in rodents for infections such as mrsa and influenza. I have also developed a pyretic model in the rat. I would run safety pharmacology studies in line with oecd guidelines and government regulations.

Assistant - Department Of Pharmacy, Pharmacology and Postgraduate Medical Research, University Of Hertfordshire
Responsibilities:

I was part of a team investigating the effect of social housing on reflex allodynia on diabetic and control rats. My role would include measuring sucrose intake, food and water consumption and the amount of gravel displaced during burrowing. I then presented our findings at the national pharmacology conference 2015.

Harriet Thomasson-Coombs MChem

Senior Consultant
Date Appointed to Position: September 2022

ACADEMIC QUALIFICATIONS.

MChem, Master of Chemistry with a year in Industry - 2016
University of York

PROFESSIONAL SOCIETIES.

Regulatory Affairs Professionals Society (RAPS) - Regulatory Affairs Certificate (RAC) Drugs

EMPLOYMENT RECORD.

Associate Consultant – CNS (Rebranded to Scendea)
2018 – 2019

Associate Scientist (Chemistry) – Domainex Ltd
2016 – 2018

Industrial Trainee – MRCT (Now LifeArc)
2015 – 2016

Previous Experience

Consultant - Scendea
Responsibilities:

- Establishment and maintenance of a high level of technical knowledge in product development and international regulatory affairs
- Creation and delivery of high-quality regulatory documentation for clients.
  Examples include:
  - MAA/BLA Module 3 authoring (mAb Biosimilar, Cell Therapy)
  - Initial IND authoring for a range of product classes, primarily biologics
  - IMPD authoring for a range of product classes, including small molecules
- Development of strategic drug development approaches for regulatory and CMC
  Examples include:
  - Authoring of regulatory strategy reports for biologics and small molecules
  - Active discussion of strategic options when authoring of responses to clinical hold and agency information requests

- Management of projects and provision of practical support to ensure timely completion of all project tasks as assigned within the allocated timelines and budgets
  Examples include:
  - MAA/BLA Module 3
  - IND (Phase 1 to Phase 3)
  - EU scientific advice meetings (EMA and national agencies)
  - FDA meetings
  - EU Paediatric Investigation Plans, Orphan Drug Designations, PRIME, SME status
  - MHRA scientific advice meetings and application to the Innovative Licensing and Access Pathway (ILAP)
- Active participation in internal and external meetings to obtain relevant information for dissemination to the Scendea team and external stakeholders
- Participation in meetings with internal and external stakeholders on matters related to current and future projects, contracts and new business opportunities
- Preparation of written estimates, quotations and contracts for Clients as required
- Assist in the development and maintenance of Standard Operating Procedures (SOP) and other relevant training materials. Examples include:
  - Delivery of formal training sessions to the Scendea team
  - Regular ad hoc training provided to new team members as required
- Ensure that all client material is treated and maintained in full respect of client confidentiality.

Associate Consultant - Scendea
Responsibilities:

- Development and maintenance of a high level of technical knowledge in product development and international regulatory affairs. Completion of other tasks relevant to Scendea project delivery under supervision
- Support creation and delivery of high-quality billable related documentation for clients
- Support strategic drug development strategies in the area of regulatory affairs
- Support the preparation of written estimates, quotations and contracts for clients
- Ensure timely completion of all project tasks as assigned within the allocated timelines and budgets
- Generate and summarize relevant information from in/external meetings and disseminate to the Scendea team and external stakeholders
- Assist development and maintenance of Standard Operating Procedures (SOP) and other relevant training materials
- Ensure all client material is treated and maintained in full respect of client confidentiality

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

Ellen Wilkinson BSc (Hons)

Senior Consultant
Date Appointed to Position: May 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Biomedical Sciences
University of Bath, UK

EMPLOYMENT RECORD.

Assessor - Low Risk Clinical Trials, MHRA
2022 - 2023

Clinical Safety Scientist, Clinical Trials, MHRA
2020 - 2022

Database administrator, Clinical Trials Unit, MHRA
2019 - 2020

International Research Assistant: University of Arizona, College of Medicine, Phoenix, USA
2017 - 2018

Current Experience

Senior Consultant (Clinical focus) - Scendea
Responsibilities:

- Provide project management, strategic, technical, and regulatory advice/services to clients in all areas of the development of products ensuring:
  - Budgetary control and adherence
  - Generation of activity-specific timelines and strategy
  - Resource allocation and management within in scope and budget for the Client
  - Adherence and delivery to agreed project timelines and being able to identify, flag and resolve potential issues early on
  - Communication and scheduling implementation
  - Working with our Technical Leads to inform strategic account development plans
- Lead meetings with internal and external stakeholders on matters related to any current and/or future projects, contracts, or new business opportunities
- Contribute to technical authorship and review of development regulatory documents including but not exhaustive of; Regulatory Strategy Plans, Clinical and Drug Development Plans, Clinical Trial Applications, Pre-INDs, INDs, Scientific Advice and Meeting Briefing Documents, Orphan Drug and Paediatric plans/ applications, Protocols, Investigator Brochures, IMPDs, CSRs, Marketing Authorisation Applications, New Drug Applications, Biologic License Applications, according to area of expertise

- Review written estimates, quotations, and contracts for Clients as required
- Champion the client's view for development of products with other contractors such as CROs
- Represent Scendea clients in regulatory agency interactions and provide regulatory solutions to agency objections
- Exceed expectations relating to the quality, delivery time and cost of services, and empower others to do the same

Previous Experience

Assessor - Lower Risk Clinical Trials, MHRA
Responsibilities:

- Efficient triage, risk-based assessment, and authorisation of lower-risk clinical trial application (CTA) amendments across pharmaceutical (quality, CMC) and scientific functions:
- Quality documents reviewed: IMPD, MA, Labelling, QP declarations, Certificates of GMP
- Scientific documents reviewed: IB and SmPC
- CTA documentation reviewed: CTA form (Annex I), Substantial amendment form (Annex II), Cover letter, IRAS Amendment Tool
- • Adhering to strict regulatory timelines for review and working in a high-pressure environment.
- • Confident in liaising with internal and external stakeholders to make recommendations and decisions in line with UK regulatory requirements.
- • Routinely provide regulatory support to the clinical trials (CTs, medicines) and clinical investigations (medical devices) teams.
- • Collaborate within a multi-disciplinary team to address issues with regulatory compliance.
- • Project management of a pilot to combine assessment of initial applications for CTs for medicines and clinical investigations for medical devices to ensure delivery of project goals. Involves authoring SOPs, internal/external guidance, and comms, as well as leading meetings for feedback and process review.

Clinical Safety Scientist - Clinical Trials, MHRA
Responsibilities:

- Extensive knowledge of ICH and UK safety reporting guidelines for CTs.
- Routine benefit-risk assessment of Development Safety Update Reports (DSURs).
- Signal detection and risk management of safety reports for CTs, including COVID-19 trials, with statistical business intelligence software. Generate and present monthly metrics of safety activities.
- Monitor compliance of and validate Suspected Unexpected Serious Adverse Reaction (SUSAR) reports and Urgent Safety Measures (USMs). Knowledge of MedDRA terms and medical terminology.
- Routinely advise reporters on queries regarding safety submissions to the MHRA, working closely with post-marketing.
- Updating PV database, submission, and reporting systems for the MHRA and conducting UAT for updated IT systems as a business user.
- Lead a project to combine assessment of initial applications for CTs for medicines and clinical investigations for medical devices; involved case management, presentations, maintaining SOPs, improving processes, andbuilding relationships with internal/ external stakeholders.
- Deputise for Senior Safety manager and conduct training for new colleagues.
- Author written divisional reports for ongoing project activities.
- Collaborate with EU regulatory competent authorities to address emerging safety signals.

Database administrator - Clinical Trials Unit, MHRA
Responsibilities:

- Management of UK data on the European Medicines Agency (EMA) EudraCT database, ensuring consistency
- between UK and EU systems.
- Successfully handling a backlog of XML/database system errors in collaboration with the Health Research
- Authority (HRA) and EMA, whilst providing information to member states regarding EudraCT alerts.
- Managing regulatory submissions (initials, amendments, temporary halts, USMs and End of Trials) received by
- the MHRA through work allocation within a multidisciplinary team and answering queries on UK/EU regulatory
- guidance.
- Presenting metrics at unit meetings and generating statistics for freedom of information (FOI) requests.
- Training of new joiners within the clinical trials team.
- Responding to helpline queries working in conjunction with GCP/ GMP inspectors, Toxicologists, Medics and
- Pharmacists.

International Research Assistant - University of Arizona, College of Medicine
Responsibilities:

- Managed and budgeted research focused on microbiology, immunology, and oncology.
- Techniques involved included: qPCR, monolayer and 3-D cell culture, western blots, confocal microscopy, and
- cell viability/ toxicity assays.
- Presented written and statistical reports to colleagues at weekly meetings, whilst adhering to strict writing
- deadlines.
- Received the IDSOG (The Infectious Diseases Society for Obstetrics and Gynecology) Trainee Travel Scholar
- Award for presenting at the Philadelphia, USA, meeting in 2018. Presented scientific posters at several US
- National Conferences.
- Authored 2 first author publications and provided strategic advice for ongoing pre-clinical studies.

Dr Bethany Aykroyd BSc (Hons), MPhil, PhD

Consultant
Date Appointed to Position: September 2022

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

EMPLOYMENT RECORD.

Associate Consultant – Scendea
2021 – 2022

PROFESSIONAL SOCIETIES.

Regulatory Affairs Professionals Society (RAPS) - Regulatory Affairs Certificate (RAC) Drugs

Current Experience

Consultant - Scendea
Responsibilities:

- Develop and maintain a high level of technical knowledge in the area of product development and international regulatory affairs.
- Author, review and deliver high-quality regulatory documentation to clients. Examples include: IND modules, IMPD, Scientific Advice Briefing Documents (FDA, EU and MHRA), Orphan Drug Designation, DSUR, Investigator's Brochure.
- Interacting with global regulatory agencies to facilitate regulatory submissions.
- Manage projects and providing practical support to ensure the timely completion of all project tasks as assigned within the allocated timelines and budgets.
- Participate in meetings with internal and external stakeholders on matters related to current and/or future projects, contracts or new business opportunities.
- Support with the formulation of drug development strategies.
- Participate in internal and external meetings to obtain relevant information for dissemination to the Scendea team and external stakeholders.
- Prepare written estimates, quotations and contracts for clients.
- Assist in the development, maintenance and delivery of relevant training materials. Examples include: providing regular ad hoc training to new team members and delivering formal training sessions to the Scendea team.
- Ensure that all client material is treated and maintained in full respect of client confidentiality.

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.

Dr Sinéad Blaber BBiotech (Hons), PhD

Consultant
Date Appointed to Position: May 2023

ACADEMIC QUALIFICATIONS.

BSc (Hons) Biotechnology
University of Technology, Sydney

PhD in Stem Cell Research
Macquarie University, Sydney

EMPLOYMENT RECORD.

Director of Clinical Development and Medical Affairs - Regeneus Ltd
2020 - 2022

Biomedical Translation Bridge (BTB) Project Manager - UniQuest Pty Limited
2019 - 2020

Clinical Project Manager - Clinical Network Services Pty Limited
2018 - 2019

Clinical Research Scientist - Regeneus Ltd
2014 - 2017

Research Fellow - Regeneus Ltd
2012 - 2014

Research and Development Scientist - Regeneus Ltd
2009 - 2012

Laboratory Demonstrator - University of Technology, Sydney
2008 - 2010

Previous Experience

Director of Clinical Development and Medical Affairs - Regeneus Ltd
Responsibilities:

- A multi-factorial role spanning clinical development, medical affairs, and business development, that was integral to the strategic and scientific direction of the company.
- **Key activities in this role include:**
- Preparation of presentations and materials to support business development meetings and due diligence processes.
- Pitching Regeneus' products in business development meetings.
- Maintaining current information on competitors' products.
- Phase II clinical trial design for lead cell therapy product, ProgenzaTM.
- Third party vendor vetting and selection.
- Lead liaison with regulatory consultants on interactions with the USA FDA.
- Contributing to Pre-IND meeting information package submitted to FDA.
- Design and execution of high-quality nonclinical studies to support product development.
- Project Manager and lead liaison with Australian Department of Defence on $300,000 iCERA grant received to investigate the therapeutic potential of our bioactive secretome product, SygenusTM.
- Conference presentations.
- Responsible for establishing and managing relationships with KOLs.
- Developing and distributing social media content.
- **Core skills:** product pitching, clinical trial design, communicating with varied audiences from KOLs to regulatory bodies, social media content preparation.

Biomedical Translation Bridge (BTB) Project Manager - UniQuest Pty Limited
Responsibilities:

- Project manager responsible, on behalf of UniQuest, for delivering the BTB Program, a Medical Research Future Fund (MRFF) initiative to fund and nurture health and medical research to commercial proof-of-concept stage with potential to attract further capital and support.
- **Key activities in this role included:**
- Critical appraisal of over 300 therapeutic and medical device applications for competitive positioning, unmet medical need, scientific merit, and clinical, regulatory, commercialisation and intellectual property (IP) strategies.
- Mentoring of 23 medical research institutes/small biotechnology therapeutics companies on their IP, scientific, clinical, regulatory and commercialisation strategies and competitive positioning to strengthen their prospects of achieving commercial proof-of-concept.
- Project management of five awardees including setting and assessing progress against milestones, decision points, and budget targets totally over $14 million.
- Internal and external stakeholder management including quarterly reporting on milestones and budget targets for awardees and the overall Program.
- **Core skills:** Mentoring, strategic planning, expanded therapeutic and medical device knowledge, expanded knowledge on government grant schemes, milestone and budget management.

Clinical Project Manager - Clinical Network Services Pty Ltd
Responsibilities:

- Clinical project manager responsible for multiple simultaneous studies across numerous therapeutic areas including pediatric oncology, autoimmune conditions, and infectious diseases. Studies included double-blind and open-label Phase I trials of novel Investigational Products from biotechnology companies and Phase II-III trials of established pharmaceuticals.
- **Key activities in this role included:**
- Relationship management of medical staff including Principal Investigators and Medical Monitors.

- Overall leadership of trials including management of Clients, Phase I units, internal teams (CRAs, medical writers, biostatisticians, clinical programmers, data managers, unblinded team members) and third-party vendors (bioanalytical labs, safety laboratories, EDC providers).
- Ensuring the team (internal and external) meet agreed timelines and budgets.
- Preparation of study documentation including project management plans, safety management plans, safety monitoring committee charters, pharmacy manuals and trial trackers.
- Oversight of all study activities including CRAs and their monitoring activities, EDC builds, preparation of randomisation plan and specification documents, production of randomisation lists (in unblinded project manager role), SAPs, SARs and CSRs.
- Ensuring adherence to all ICH GCP, HREC and TGA guidelines.
- **Core skills:** Leadership, managing multiple competing priorities, problem solving, expanded therapeutic area knowledge.

Clinical Research Scientist - Regeneus Ltd
Responsibilities:

- Key person responsible for providing scientific expertise to the Human Health team for multiple commercial cell therapy products. Additionally, I performed a combined project manager and CRA role solely responsible for: a first-in-human, Phase I/II, double-blind placebo-controlled osteoarthritis trial; an adipose tissue procurement study; and jointly responsible for multiple data collection studies from commercial patients. Over 100 patients were enrolled in these studies across nine sites. Product lead for a novel topical secretion-based treatment for inflammatory skin conditions.
- **Key activities in this role included:**
- Identification, engagement and management of over 15 KOLs in multiple therapeutic areas.
- Presenting to Investigators and clinical staff at Investigator meetings.
- Providing scientific advice via analysis and interpretation of published and in-house data.
- Presentation of results through manuscripts, public messaging, and oral presentations.
- Maintaining current information on competitors' products.
- Contributing to product marketing and development strategies.
- Contributing to clinical development plans for promising lead product candidates.
- Preparation of critical clinical trial documents including clinical trial protocols, CRFs, PICFs, CTRAs, SOPs, source data worksheets.
- Reviewing and contributing to IBs, SAPs, SARs and CSRs.
- Site selection, negotiating study budgets and contract agreements for seven sites.
- Trial oversight including management of all trial staff (internal and external).
- Assisting in the preparation of, and adherence to, the clinical trial budget ($2.5 million).
- Identification, contract negotiation and management of third-party vendors.
- Ensuring adherence to all ICH GCP, HREC and TGA guidelines.
- Training nursing staff in Investigational Product preparation and administration.
- Conducting site qualification, monitoring and closeout visits to ensure completeness and accuracy of data collected and site compliance.
- **Core skills:** Tailoring writing and presentations for different audiences, critical thinking, clinical trial design, teamwork.

Research Fellow - Regeneus Ltd
Responsibilities:

- Lead scientist for Regeneus Ltd in their partnership with Macquarie University. Research produced in this position contributed to three patents. **Responsibilities included:**
- Supervising three PhD and two honours students; one later co-founded a life sciences company.
- Managing an eight-person laboratory including a $400,000 yearly budget.
- Performing data collection, troubleshooting and quantitative data analysis.
- Representing the collaboration via conference presentations and university meetings.
- **Core skills:** Public speaking, writing, mentoring, budget management, intellectual property submissions and management.

Research and Development Scientist (0.2 FTE) - Regeneus Ltd
Responsibilities:

- Junior scientist involved in conducting research and contributing to the research direction, via:
- Development and validation of processing protocols for cell therapy procedures.
- Improving the cell yield by 25% via amendments to the processing protocol.
- Preparation and CD marker characterisation of adipose cell populations in >200 samples.
- Development and implementation of multi-plex cytokine analysis of serum and secretions.
- **Core skills**: Data collection and analysis, grasping complex scientific concepts quickly, problem solving, protocol validation.

Laboratory Demonstrator - University of Technology, Sydney
Responsibilities:

- Instructed wet labs and tutorials for undergraduate subjects including Metabolic Biochemistry and Introductory Pharmacology & Microbiology
- Developed and conducted bacterial workshops for visiting high school students
- **Core skills:** Tailoring course content, public speaking.

Ellie McNamee MSc

Consultant
Date Appointed to Position: March 2024

ACADEMIC QUALIFICATIONS.

Integrated MSc Biomedical Sciences
The University of Southampton - 2017-2021

EMPLOYMENT RECORD.

Associate Consultant
Scendea - 2022 - 2024

Laboratory Research
The University of Southampton - 2020-2021

Previous Experience

Associate Consultant - Scendea
Responsibilities:

- Development of technical knowledge in international regulatory affairs and product development
- Supporting the authoring, review, and quality control of technical regulatory documents
- Examples include INDs, ODDs, CSRs, IBs, PIPs, and DSURs
- Project management of regulatory submissions and documents within allocated timelines:
- Management of ODDs, RPDs, DMFs, INDs, EMA SA requests, FDA meeting requests, and annual reports
- Interacting with regulatory agencies to facilitate regulatory submissions (MHRA, EMA, FDA)
- Summarizing relevant information from in/external meetings and disseminating to the Scendea team and external stakeholders
- Ensuring timely completion of all project tasks within agreed timelines and budgets
- Preparation of written estimates, quotations, and contracts for clients
- Examples include business proposals, statements of work (SOW), and ad hoc budgets
- Preparation of weekly regulatory intelligence briefing reports summarising updates to international regulatory guidance

Laboratory Research - The University of Southampton
Responsibilities:

- Research group at the Biofilm Innovation Centre working in a Containment Level 2 laboratory.
- Following SOPs to process clinical samples.
- Designing, optimising and implementing proteomics protocols and analysing acquired data.
- Constructed risk assessments, reports and presentations.
- Input and maintenance of clinical data in spreadsheets.
- Use of software including DAIME, ImageJ, Empiria Studio, Image Studio for image analysis and GraphPad Prism for statistical analysis.

Dr Leticia Monjas Gómez MSc, PhD

Consultant
Date Appointed to Position: September 2022

ACADEMIC QUALIFICATIONS.

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

Masters Degree in Organic Chemistry- 2021
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.

Associate Consultant
Scendea - 2021 - 2022

Postdoctoral Researcher
University of Gothenburg, Sweden - 2018 - 2020

Postdoctoral Researcher
University of Gothenburg, Sweden - 2017 - 2018

PhD Candidate
University of Gronigen, The Netherlands - 2012 - 2016

PROFESSIONAL SOCIETIES.

Regulatory Affairs Professionals Society (RAPS): Regulatory Affairs Certificate (RAC) – Drugs

Current Experience

Consultant - Scendea
Responsibilities:

- Develop and maintain a high level of technical knowledge in product development and international regulatory affairs
- Create and deliver high-quality regulatory documentation for clients
- Examples include authoring of IND Modules, IMPD, Pre-IND Briefing Book, EU Scientific Advice Briefing Document, Orphan Drug Designation, Fast Track Designation, Investigator's Brochure, DSUR
- Create drug development strategies in the area of regulatory affairs
- Manage projects and provide practical support to ensure the timely completion of all project tasks as assigned within the allocated timelines and budgets
- Examples include project management of IND, EU scientific advice meeting (EMA and national agencies), FDA meetings (e.g., pre-IND meeting), Orphan Drug Designation, Fast Track Designation
- Participate in meetings with internal and external stakeholders on matters related to any current and/or future projects, contracts, or new business opportunities
- Prepare written estimates, quotations, and contracts for clients

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.

Badrudiin Olow BSc (Hons), MSc

Consultant
Date Appointed to Position: February 2024

ACADEMIC QUALIFICATIONS.

MSc Molecular Biology and Biotechnology - 2021 - 2022
University of Sheffield

BSc Biochemistry - 2015 - 2020
University of Sheffield

EMPLOYMENT RECORD.

Associate Consultant - Scendea
2022 - 2024

Test Operative, NHS Test and Trace - North Lincolnshire Council
2021 – 2021

Current Experience

Consultant - Scendea
Responsibilities:

- Project Management experience in a range of regulatory activities for over 16 clients since joining Scendea
- Support the authoring and delivery of high-quality regulatory documentation. Examples include IND Modules, IMPDs, Scientific Advice briefing packages, Orphan Drug Designation (ODD) applications, Fast Track Designation (FTD) applications, Investigator's Brochures, DSURs, CSRs, Protocol Synopses, PIPs etc.
- Management of regulatory activities ensuring completion within the allocated timelines and budgets
- Support the preparation of strategic drug development plans in the area of regulatory affairs
- Preparation of written estimates, quotations, and contracts in collaboration with the Business Development team
- Act on behalf of clients as the point of contact in communication with regulatory agencies
- Management of workshops relating to CMC, nonclinical and clinical strategy
- Attend and summarise the discussions in EMA and National Agency meetings, to be disseminated to external stakeholders

Previous Experience

Associate Consultant - Scendea
Responsibilities:

- Establish and maintain an elevated level of technical proficiency in the fields of product development and international regulatory affairs.
- Ensure assigned tasks are completed within allocated timelines and budgetary constraints.
- Facilitate project delivery by diligently executing assigned tasks while providing support to colleagues as needed.
- Preparation and delivery of high-quality regulatory documentation to meet client requirements.
- Assist in developing strategic drug development plans with an emphasis on regulatory affairs.
- Contribute to the preparation of accurate and detailed estimates, quotations, and contracts for Scendea clients.
- Synthesize key information from internal and external meetings and effectively communicate insights to internal team members and external stakeholders.

Test Operative, NHS Test and Trace - North Lincolnshire Council
Responsibilities:

- Communicating COVID guidelines and policies regarding positive tests to members of the public, demonstrating how they should perform an INNOVA rapid COVID test on themselves ensuring they are comfortable and understand the process
- Processing these tests utilizing extraction fluid in a safe aseptic manner to acquire positive and negative results
- Ensuring tests are processed safely and efficiently while guaranteeing potentially infectious samples are handled responsibly by following NHS regulations
- Performing data entry uploading results through the online council website so that members of the public are aware as soon as possible as to the status of their results

Aylin Pelut BSc (Hons), MSc

Consultant
Date Appointed to Position: April 2023

ACADEMIC QUALIFICATIONS.

MSc in Clinical Development
University College of London, UK

BSc (Hons) in Biochemistry - 2020
University of East Anglia, UK

EMPLOYMENT RECORD.

Global Regulatory Affairs Specialist - RECKITT, UK
2020 - 2023

Work Experience - Roche Pharmaceuticals, Switzerland
2020 - 2020

Previous Experience

Global Regulatory Affairs Specialist - RECKITT
Responsibilities:

- Collaborated within a team to obtain global government approvals for pharmaceutical products in both UK and worldwide.
- Handled queries raised by health authorities regarding marketing authorisation applications and coordinated response documents in accordance with regulatory guidelines.
- Delivered training and created a database to track and organise questions and responses received by health authorities for multiple products across the globe.
- Worked alongside R&D to develop regulatory strategies in order to identify risks in regulatory guidelines and product launch across the globe for products of interest.
- Ensure the compliance of the prepared CTD documents, the correct labelling of packaging and patient information leaflets for each product launch to gain regulatory approval.
- Presented successes and challenges of the regulatory process in regard to obtaining global marketing authorisation to key stakeholders.

Work Experience - Roche Pharmaceuticals
Responsibilities:

- Observed daily routine of a project manager, specialised in oncology and discuss key responsibilities within the role
- Observed briefings with medical affairs managers where day to day tasks and management were discussed

Mauricio Cano MSc, BSc

Associate Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

Master of Molecular Biology Research Extensive- 2021 - 2022
The University of Queensland, School of Chemistry and Molecular Biosciences

Bachelor's Degree in Pharmacy, Chemistry & Biotechnology - 2011 - 2015
Universidad del Valle de México

EMPLOYMENT RECORD.

Casual Associate Animal Technician - The University of Queensland, Biological Resources
2023

Quality Process Analyst - Abbott Laboratories de México
2016 - 2020

Research Assistant - Universidad del Valle de México, Campus Coyoacán
2013 - 2017

Research Assistant - Biology Institute, Universidad Nacional Autónoma de México
2015 - 2016

Current Experience

Associate Consultant - Scendea
Responsibilities:

- Establish and maintain an elevated level of technical proficiency in the fields of product development and international regulatory affairs.
- Ensure assigned tasks are completed within allocated timelines and budgetary constraints.
- Facilitate project delivery by diligently executing assigned tasks while providing support to colleagues as needed.
- Preparation and delivery of high-quality regulatory documentation to meet client requirements.
- Assist in developing strategic drug development plans with an emphasis on regulatory affairs.
- Contribute to the preparation of accurate and detailed estimates, quotations, and contracts for Scendea clients.
- Synthesize key information from internal and external meetings and effectively communicate insights to internal team members and external stakeholders.

Dilsher Gill MPhil, BSc

Associate Consultant
Date Appointed to Position: October 2023

ACADEMIC QUALIFICATIONS.

MPhil – Cancer Biology - 2023
PACT Group, Queensland University of Technology (QUT)

Bachelor of Biomedical Science (Infection & Immunity) - 2020
QUT

EMPLOYMENT RECORD.

Biology Laboratory Demonstrator & Teacher - QUT
2021 - 2023

MPhil Project Researcher - QUT
2021 - 2023

Current Experience

Associate Consultant - Scendea
Responsibilities:

- Establish and maintain an elevated level of technical proficiency in the fields of product development and international regulatory affairs.
- Ensure assigned tasks are completed within allocated timelines and budgetary constraints.
- Facilitate project delivery by diligently executing assigned tasks while providing support to colleagues as needed.
- Preparation and delivery of high-quality regulatory documentation to meet client requirements.
- Assist in developing strategic drug development plans with an emphasis on regulatory affairs.
- Contribute to the preparation of accurate and detailed estimates, quotations, and contracts for Scendea clients.
- Synthesize key information from internal and external meetings and effectively communicate insights to internal team members and external stakeholders.

Previous Experience

Casual Associate Animal Technician - The University of Queensland, Biological Resources
Responsibilities:

- Perform routine checks on the well-being of different breeds of mice by ensuring they look bright, alert and responsive and do not display signs of disease and/or health conditions that could negatively affect their quality of life.
- Provide mice with enough food, water, enrichment and a clean cage.
- Handling, sexing and weaning of mice.
- Recording of new litters and updating the information of weaners on the cage cards and electronic system accordingly.

Quality Process Analyst - Abbott Laboratories de México
Responsibilities:

- Generation of specifications for printed packaging materials.
- Review and approval of regulatory texts for printed packaging materials.
- Generation, coordination, and follow-up of Quality Technical agreements with suppliers.
- Regular follow-up of projects to ensure timely launch of products into the market.
- Generation, coordination, and review of product Annual Quality Review reports.
- Generation of Standard Operating Procedures.
- Generation of Change Controls on Trackwise SolTRAQs system.
- Packaging material sampling and inspection.
- Generation of Supplier Quality Records and Impact Assessments.
- Generation, coordination, and review of First Lot Quality Review reports.
- Spanish-English and English-Spanish translations of Standard Operating Procedures, Manufacturing Procedures, Packaging Procedures and product Annual Quality Review reports.

Research Assistant - Universidad del Valle de México, Campus Coyoacán
Responsibilities:

- Performed amputations and looked after Ambystoma mexicanum, Danio rerio and Polypterus senegalus specimens for studies on their regenerative capabilities.
- Assessed the regenerative capabilities of Polypterus senegalus pectoral fin employing cell death detection techniques (Neutral red, acridine orange, cell tracker, TUNEL assay) and tissue staining of complete fins and histological sections (Alcian blue, alizarin red and Herovici stain).
- Stock-taking and ordering of reagents and consumables.
- Waste management and disposal.
- Stand-in laboratory technician in support of students during lab sessions.

Research Assistant - Biology Institute, Universidad Nacional Autónoma de México
Responsibilities:

- Transcription, classification, and analysis of information for the creation of a DNA extraction database for cephalopods.
- Selection, analysis and sequence alignment of cephalopod COI employing BioEdit software to establish genetic relationships between species.
- DNA extraction, electrophoresis, and PCR from cephalopod tissues.

Previous Experience

Biology Laboratory Demonstrator & Teacher - QUT
Responsibilities:

- Support a professor in the molecular biology department to conduct and teach LQB186 Human Cell & Molecular Biology and QLB601 Cancer Biology.
- Assist in teaching and lecturing students on the fundamental principles and processes of biological systems through the application of modern experimental techniques used in molecular biology, biochemistry and cancer biology.
- Provide detailed feedback on students' assignments, class participation, quizzes, data analysis and final examinations.
- Apply a variety of teaching methods to support students in achieving desired grades in line with their academic goals.
- Ensure respectful, sensitive and effective communication with diverse cultural groups and student with varying abilities.

MPhil Project Researcher
Responsibilities:

- Utilised advanced research methodologies and conducted intricate data analysis to investigate specific proteins in prostate cancer cells.
- Investigated and determined the functions and significance of selected target proteins in the context of prostate cancer.
- Designed and innovated a novel biochemical test to detect prostate cancer proteins and contribute to improved diagnostics in the field.
- Collected and analysed data generated from investigations, employing statistical methods and relevant software tools.
- Stayed up-to-date with the latest advancements and discoveries in cancer biology through literature reviews.

Basia Grodyńska BSc (Hons), MSc

Associate Consultant
Date Appointed to Position: January 2024

ACADEMIC QUALIFICATIONS.

MSc Evolutionary Genetics - 2022 - 2023
University of Edinburgh

BSc Human Biology - 2019 - 2021
Queen Margaret University

Current Experience

Associate Consultant - Scendea
Responsibilities:

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Dr Despoina Masmanidou MD, MSc

Associate Consultant
Date Appointed to Position: November 2023

ACADEMIC QUALIFICATIONS.

Master of Science (MSc) in Clinical Research - 2021 - 2023
Erasmus University Rotterdam

Medical Doctor- 2013 - 2019
Aristotle University of Thessaloniki

EMPLOYMENT RECORD.

Researcher - MSc Thesis Work
2022 - 2023

Teacher Assistant - Netherlands Institute for Health Sciences
2022 - 2023

Physician - Private Dermatology Practice - Dr. Maria Voyatzi
2020 - 2021

Research Assistant - Hippocration General Hospital
2018 - 2019

Current Experience

Associate Consultant - Scendea
Responsibilities:

- Establish and maintain an elevated level of technical proficiency in the fields of product development and international regulatory affairs.
- Ensure assigned tasks are completed within allocated timelines and budgetary constraints.
- Facilitate project delivery by diligently executing assigned tasks while providing support to colleagues as needed.
- Preparation and delivery of high-quality regulatory documentation to meet client requirements.
- Assist in developing strategic drug development plans with an emphasis on regulatory affairs.
- Contribute to the preparation of accurate and detailed estimates, quotations, and contracts for Scendea clients.
- Synthesize key information from internal and external meetings and effectively communicate insights to internal team members and external stakeholders.

Previous Experience

Researcher - MSc Thesis Work
Responsibilities:

- Research position in the departments of Neurology and Immunology.
- Plan, coordinate, and execute a cohort study.
- Perform data collection, data analysis, and medical writing.
- Build the departments' joint electronic patient database in Castor EDC.
- Collaborate with and gave presentations to the multiple sclerosis centre ErasMS.

Research Assistant - Hippocration General Hospital
Responsibilities:

- Contributed to the research studies of the 3rd Cardiology department.
- Assessed the diagnostic and prognostic value of echocardiographicmarkers in aortic valve stenosis.
- Interviewed survey participants and coded qualitative interview data.
- Conducted literature review.
- Wrote and edited medical articles.
- Published two articles in scientific journals.

Teacher Assistant - Netherlands Institute for Health Sciences
Responsibilities:

- Responsible for courses like "Advanced Clinical Trials", "Study Design", etc.
- Support students during course activities.
- Coordinate the hybrid teaching sessions.
- Update and edit the course material on the university's online learning platform.

Physician - Private Dermatology Practice - Dr. Maria Voyatzi
Responsibilities:

- Examined and consulted patients.
- Performed medical treatments and cosmetic therapies.
- Operated high-tech medical devices.
- Undertook office administration duties.

Mohammad Nohman BSc (Hons), MSc

Associate Consultant
Date Appointed to Position: January 2024

ACADEMIC QUALIFICATIONS.

MSc Immunology & Immunotherapy - 2015 - 2016
University of Birmingham

BSc Biochemistry - 2012 - 2015
University of Wolverhampton

EMPLOYMENT RECORD.

Science Technician - St George's School, Birmingham
March 2023 - December 2023

Scientist - Cignpost Diagnostics
2021 - 2022

Study Analyst - Covance Labcorp
2021 - 2022

Current Experience

Associate Consultant - Scendea
Responsibilities:

- Establish and maintain an elevated level of technical proficiency in the fields of product development and international regulatory affairs.
- Ensure assigned tasks are completed within allocated timelines and budgetary constraints.
- Facilitate project delivery by diligently executing assigned tasks while providing support to colleagues as needed.
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- Assist in developing strategic drug development plans with an emphasis on regulatory affairs.
- Contribute to the preparation of accurate and detailed estimates, quotations, and contracts for Scendea clients.
- Synthesize key information from internal and external meetings and effectively communicate insights to internal team members and external stakeholders.

Previous Experience

Science Technician - St George's School, Birmingham
Responsibilities:

- Planned and readied materials and equipment for a variety of different subjects for a large number ofstudents performing experimental assessments.
- Investigated factors affecting laboratory experiments and chemicals, providing innovative solutions toresolve the issue as well as expert guidance to teachers and students.
- Created and implemented processes, laboratory records, CLEAPPS and SOPs in the science department including tracking, usage and disposal of sample and equipment inventory for ease of use and improvement of lab workflow.
- Managed lab classrooms and prep rooms, updating them to appropriate H&S standards. Liaising with different regulatory bodies to get this accomplished in a timely manner.
- Managing and providing training to a small team of LSAs to assist with day to day operations and takeover when I am not present.

Scientist - Cignpost Diagnostics
Responsibilities:

- Manual preparation and analysis of PCR samples using different assays (VIRPATH, RNA STAR and Kingfisher extractions) and different buffer types (MTM AND MLB)
- Interpretation and reporting of COVID-19 PCR data. Assisted senior managers with managing KPIs ofthe lab.
- Assisted technical managers in implementing quality documents and working strategies to improveworkflow along with having an in-depth hand in the improvement, implementation and updating of SOPs.
- Guaranteeing UKAS laboratory standards were upheld in accordance with ISO standards (ISO 15189)
- Facilitated the UKAS accreditation and audits of multiple BSL 2 laboratories.
- Managing day to day operations of the lab allowing for an effortless working environment.
- Isolating any issues that would occur within the lab (e.g. contamination) and providing a seamlesssolution which would not disrupt workflow. Managing reception and disposal of samples in accordance with SOPs from high profile clients. Each with their own reporting timeline.
- Liaising with appropriate teams to ensure accurate reporting of sample results, establishing and maintaining open communication which facilitated smooth operations.
- Making sure equipment used in the lab were kept to the utmost standard. Adhering to company policy about communicating the quality of equipment and when repair or maintenance is required.
- Ensuring correct storage for reagents. Performing validation experiments so the lot no. is suitable for continual use.

Study Analyst - Covance Labcorp
Responsibilities:

- Undertook bioanalytical method development/validation and sample analysis for both regulatory and non-regulatory studies (GCP and GLP).
- Executed a variety of sample prep and extraction techniques (LLE, SPE, SLE, PPT, homogenization andserum screening).
- Trained upcoming new scientists to an exceptionally high standard on multiple different assays and techniques, allowing them to deliver the same quality of work as myself.
- Took a proactive approach on equipment functionality, troubleshooting, resolving and preventing issues as soon as possible relaying issues to the broader team.
- Implemented changes both inside and outside the lab into the department which streamlined workflow allowing for greater efficiency.
- Performed meticulous QC checking of experiments, results and analytical data from peers to verify compliance with GLP.
- Gone above and beyond my role assisting study directors with tabulation of data, producing graphs and figures. Along with constructing reports to be sent to clients.

CONTACT

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