Senior Regulatory Affairs Executive

AREAS OF EXPERTISE

- **More than fifteen years' experience in vaccines, pharmaceuticals, biotechnology, and combination device products.**
- **Experience in regulatory strategy for worldwide drug development.**
- **Experience in writing all modules of the Common Technical Document (CTD) for marketing applications in Europe, US, and Japan (submission and follow-up).**
- **Experience in preparation of DMFs (Europe, US, and Canada) and Site Master File.**
- **Preparation of meeting with the EMA for scientific advice and/or pre-submission and also with the FDA for pre-IND meeting, end of phase II meeting and pre-NDA meeting.**
- **Completed several GMP, GLP, and GCP assessments and audits.**
- **Developed Quality Systems; SOPs, batch records, policies, and technology transfer documentation.**
- **Expertise in regulatory affairs and regulatory compliance to meet US and European standards.**
- **Experience in writing BLA, NDA, ANDA for US Submission.**
- **Experience in preparation and submission of clinical trials in Europe (new CTA application, IMPD), Canada (CTA), and US (IND process).**
- **Liaison with Regulatory Authorities (National European Member State, EMA, and FDA).**
- **Developed many training programs. Hot Topics Workshop instructor, providing cost-effective training worldwide as well as customized in-house training.**
- **Audit of Good Research Practice, Good Laboratory Practice, and Good Manufacturing Practice.**
- **Bilingual with the ability to interact effectively at all organizational levels to provide consulting services, domestically and internationally.**

INTRODUCTION

Consultant provides consulting services and cost-effective training worldwide. Started career in research in the US and later moved back to Europe, to work as a regulatory affairs manager in two different CROs based in the UK. There, gained extensive experience in European registration for a wide variety of products. Since then, consulting on FDA and European regulatory affairs. Recently, broadened experience with Japanese's submission. In addition, has extended expertise to Regulatory Compliance and Quality Assurance.

WORK EXPERIENCE:

1999 – Present
Industry Consultant
Example Engagements:

- More than fifteen years of industry experience in vaccines, pharmaceuticals, biotechnology, and combination device products.

- Expertise in regulatory affairs and regulatory compliance to meet US and European standards.
- Experience in regulatory strategy for drug development.
- Experience in writing all modules of the Common Technical Document (CTD) for marketing applications in Europe and US, submission and follow-up.
- Experience in writing BLA, NDA, ANDA for US submission.
- Experience in preparation and submission of clinical trials in Europe (new CTA application, IMPD), Canada (CTA) and US (IND process).
- Experience in preparation of DMFs (Europe, US and Canada) and Site Master File.
- Liaison with Regulatory Authorities (National European Member State, EMEA and FDA).
- Preparation of meeting with the EMEA for scientific advice and/or pre-submission and also with the FDA for pre-IND meeting, end of phase II meeting and pre-NDA meeting.
- Developed many training programs. Customized in-house training for onboard new employee (i.e. "The life of a Medicinal Product"). Twice a year provides a training (i.e. US Regulatory Regulation).
- Completed several quality assessments and audits (FDA - GMP Inspection and GLP Inspection).
- Developed Quality Systems for Good Research Practice, Good Laboratory Practice and Good Manufacturing Practice.
- Developed SOPs, batch records, policies and technology transfer documentation.
- Bilingual with the ability to interact effectively at all organizational levels to provide consulting services, domestically and internationally.

1996 – 1998
Valorum Inc, Research Triangle Park, NC, USA
Senior Regulatory Affairs Executive

Pharmakopius International Ltd, Reading, UK
Regulatory Affairs Manager

1995 – 1996
European Regulatory Affairs, Reading, UK
Regulatory Affairs Consultant

1994 – 1995
Applied Microbiology, Inc, New York, USA
Project Manager Assistant

1992 – 1994
Regeneron, Inc, New York, USA
Post-Doctoral Scientist

1987 – 1992
Laboratoire De Pharmacologie Et Toxicologie Fondamentales, Toulouse, France
PhD Program

INDUSTRY EXPERIENCE

Pre-IND meeting and IND submission
- Write and prepare the letter and the list of questions to request a pre-IND meeting with the FDA
- Write and prepare pre-IND Package
- Attend pre-IND meeting as a chairman, coordinator or scribe depending on the need from the Sponsor

- Write and prepare the IND in a eCTD format (modules 1, 2, 3, 4 and 5)
- Submit IND electronically
- Maintenance of IND as amendment and annual report

Product and therapeutic area
- Two (2) HIV viral vector vaccine with the Division of Vaccines and Related Products Applications
- Several (7) stem cell products with the Office of Cellular, Tissue and Gene Therapies
- Three (3) investigational products with the Division of Cardiovascular and Renal Products
- Two (2) investigational products with the Division of Dermatology and Dental Products
- One (1) investigational products with the Division of Gastroenterology and Inborn Errors Products
- Two (2) investigational products (one biosimilar and one small molecule) with the Division of Pulmonary, Allergy and Rheumatology Products
- One (1) investigational products with the Division of Bone, Reproductive and Urologic Products
- One (1) for a biosimilar to Humira

Pre-NDA meeting and information package submission
- Write and prepare the letter and the list of questions to request a pre-NDA meeting: FDA Division of Anesthesia, Analgesia, and Addiction Products, FDA Division of Division of Gastroenterology and Inborn Errors Products
- Write and prepare pre-NDA Package

Orphan designation Application
- Write and prepare the orphan designation application
- Write and prepare orphan grant application

Product and therapeutic area
- One HIV viral vector vaccine
- One stem cell product
- Two (2) cardiovascular investigational product
- One dermatological investigational product
- One small molecule GI tract
- One for DMD indication

Clinical Investigator's brochure
- Write and prepare/update IB from nonclinical and clinical study reports

Product and therapeutic area
- One HIV viral vector vaccine
- One Rotavirus Vaccine
- One stem cell product
- Two dermatological investigational product

Clinical protocol
- Write and prepare a draft clinical protocol to be edited by the principal investigator

Product and therapeutic area
- One dermatological investigational product

BLA, NDA and ANDA submission

- Write and prepare a BLA modules 2 and 3 for a blood product
- Write and prepare a BLA modules 2 and 3 for 1 stem cell product
- Write and prepare Module 3 for a BLA application from batch records and SOPs and Module 2 for two conjugate vaccines, submission through mutual recognition and centralised procedure in Europe and US and follow-up
- Write and preparation Modules 2, 3 and 4 of a CTD for an Hepatitis B vaccine
- Write and prepare Module 3 and Module 2 for a 505(b)(2) NDA for a opioid product
- Write and prepare 505(b)(2) NDA modules 1, 2, 3, 4 and 5 for a combination device-drug (reformulation of an existing product) – and submit electronically
- Prepare four (4) 505(b)(j) ANDA modules 1, 2, 3 and 5 and submit electronically
- Preparation of 8 DMFs for conjugate vaccine products and silver API

BLA, NDA and ANDA Post Approval submission

- Use several amendments to update a BLA NDA modules 2 and 3 for several vaccine products (Flu-type)
- Convert and update Module 2 and Module 3 for 4 antibiotic products
- Convert a PreApprovalSupplement into a Type 2 Variation for European submission for a vaccine product

DMF submission

- Review and submit electronically 5 DMF for a European API facility
- Review and submit electronically 3 DMF for an Argentinian API facility
- Assist in FDA inspection
- Prepare and submit electronically Drug Establishment Registration and Self Identification
- Maintenance of all DMFs

Electronic Submission

- All IND and NDA/BLA were prepared for electronic submission
- Lorentz Software for publishing
- Submission via the FDA Gateway Portal

Regulatory Compliance

- Evaluation of the process validation for a monoclonal antibody with emphasis on leachables and extractables.
- Preparation of SOPs, Batch Records and technology transfer to GMP manufacturer for a viral vaccine delivery system.
- Audits of research laboratories (GLP oriented) for IND purposes and preparation of manufacturing plant (GMP oriented) for FDA pre-approval inspection.
- Review all CAPA for all vaccine products for a Big Pharma

EDUCATION

1988 – 1992
Laboratoire De Pharmacologie et Toxicologie Fondamentales, Toulouse, France
Ph.D.: Option Cell Biology and Biochemistry

LANGUAGES

- French – Fluent
- English - Fluent