Senior Regulatory Analyst, Regulatory & Medical Affairs

AREAS OF EXPERTISE

- **ANDAs, NDAs, INDs in eCTD Format**
- **CMC Management**
- **R&D and Quality Guidance**
- **OTC Drugs, Medical Devices, Cosmetics**
- **International Partnership Procedures**
- **Product Launch Support**

INTRODUCTION

Consultant is a pharmaceutical regulatory professional with a career of increasing responsibilities for NDA/ ANDA products, OTC Drug products, Medical Devices and Cosmetics. Consultant has over 16 years of experience in the pharmaceutical industry with over 10 years of experience in regulatory affairs and pharmaceutical development with primary focus on Chemistry, Manufacturing and Controls (CMC). Establish communication and develop rapport with FDA to gain approvals, support product launches to meet business requirements. Expert in providing strategic regulatory guidance and planning leading up to development and post-approval changes. Proficient in prioritizing and driving projects independently in a timely manner, yet flexible to multitask when necessary. A team player who is attentive to detail and able to work in a fast-paced environment.

WORK EXPERIENCE

05/2012-Present
Industry Consultant
Duties:

- Managed and led Regulatory Affairs team for PDI Healthcare for Pharma/OTC products and Medical Devices and Cosmetic Products. Responsible for the registrations, compliance and regulatory strategies for their NDA, OTC, Medical Device and cosmetic products.
- Managed all the activities with the newly acquired NDA which included labeling supplements, clinical supplements (PAS), IND submissions and amendments, NDA Annual Reports and IND Annual Reports.
- Helped PDI set-up processes to support the NDA. Created about eight SOPs to support Regulatory Affairs functions.
- Helped Quality teams achieve GMP compliance. Led the Quality team to set-up a Stability program in-house per ICH guidelines.
- Filed a sNDA in December 2012 for a new claim. Have filed and updated an open IND. Have written and filed a 510K premarket notification registration for a new medical device that has been forecasted to increase sales of approximately 20M and on track for market authorization by 4Q14.
- Work closely with legal and quality to ensure compliance to SOPs, FDA and EPA regulations. Helped create regulatory databases for a Master List of all products manufactured by PDI/ NP (more than 400 products). Also drove the creation of ingredients database and claims database for the OTC and cosmetic products. Was instrumental in writing, implementing and training on 8 new SOPs and processes.

04/2007 – 05/2012
Roxane Laboratories, Inc., Columbus, OH
Senior Regulatory Analyst, Regulatory & Medical Affairs
Duties:

- Managed, authored, reviewed and filed about 20 ANDAs, numerous amendments, supplements and annual reports. Regulatory Manager and Lead for all International Third Party projects. Filed and helped approval of five ANDAs involving International Partnerships which was first of its kind for the company.
- Filed over 20 ANDAs out of which 6 ANDAs were in eCTD format. Filed over 50 Annual reports out of which about 25 were filed in eCTD format. Have filed numerous supplements/ amendments to the FDA.
- Managed 30-40 projects at different stages of development. Provide regulatory guidance on products from development through approval and post approval marketing. Led and drove CMC deficiency meetings to gain approval in a timely manner. Managed, authored, reviewed and filed post approval supplements, CBE-supplements and Annual Reports. Support new product launch meetings by providing regulatory guidance. Provide regulatory assessment of all changes (Change Management Unit (CMU)) related to both new and approved products. Mentored colleagues and direct report on proper regulatory assessment of the CMU changes.
- Proficiently used Trackwise and Documentum for assessing and approving changes to analytical methods, specs, and stability reports.

2003 – 2007
Boehringer-Ingelheim Roxane, Inc., Columbus, OH
Chemist, QC Launch
Duties:

- Led successful analytical transfer of methods from Germany to Columbus to support a major launch.
- Supported analytical transfer and testing of nasal products.
- Always strived for right first time. Never had any investigation caused by personal error during my tenure in the lab.
- Conducted Gap Analysis on analytical methods before they were transferred over to the QC lab.
- Supported analytical transfer of an important brand product for the company.
- Worked on a very low dose solid powder for inhalation product.
- The technologies acquired during my tenure included Particle Size Distribution and Delivered Dose in addition to HPLC.

2001 – 2003
Bigbot, Inc., Columbus, OH
Manager, Information Systems
Duties:

- Started as Programmer/Analyst and then as Manager, Information System.
- Worked with programmers to develop software for the company.

1994 – 1996
Torrent Pharmaceutical, LTD., Ahmedabad, India
Scientist, Analytical Development Laboratory, R&D
Duties:

- Supported analytical testing for development lots produced by Formulation Development group.
- Worked on raw material testing, finished product testing including but not limited to all oral formulations, topical formulations, injections and cosmetics.

EDUCATION

Banaras Hindu University, India
Masters: Chemistry

NIIT, India
Honors Diploma: Systems Management

ADDITIONAL TRAINING

Columbus State Community College, Columbus, OH
Courses: Visual Basic, C++, Java, Oracle