

REGULATORY AFFAIRS/PRODUCT DEVELOPMENT/PRODUCT LICENSING

More than 14 years of experience in the pharmaceutical industry with exposure to brand and generic companies. Thorough knowledge of US FDA regulations combined with detailed exposure to product development, business development and product licensing experience.

EDUCATION:

- **Regulatory Affairs Certification, RAC (US): Regulatory Affairs Professional Society**
- **Regulatory Affairs and Quality Operations Post-Graduate Degree: Seneca College of Applied Arts & Technology, Toronto, Canada**
- **Bachelors Degree in Pharmacy, University of Madras, Madras, India**

PROFESSIONAL WORK EXPERIENCE:

Regulatory/Business Development Experience working for the following organizations:

- Novartis Pharmaceuticals, Mumbai, India
- Wockhardt Pharmaceuticals, Mumbai, India
- Apotex Inc, Toronto, Canada
- Mikart Pharmaceuticals, Atlanta, Georgia
- Hospira, New Jersey, USA
- Perrigo Company, New Jersey, New York and Allegan, Michigan
- GlaxoSmithKline, New Jersey, USA
- Pharmvista Inc. New Jersey, USA

Responsibilities in Regulatory Affairs:

- Experienced in filing DMF's, NDA's, sNDA's, 505(b)2 submissions, ANDA's, Supplements, and Annual Reports.
- Handled regulatory aspects of solid oral dosage forms, liquids, Sustained release, Injectables, Rx to OTC switches
- Meet and communicate with FDA for Type A, B or C meetings
- Experience in negotiating and filing for Rx to OTC switches
- Managed both Class 1 and Class 2 recalls for Pharmaceuticals and OTC
- Handled clearance of pharmaceutical, nutraceutical and API from US Customs and Border Patrol/FDA
- Performed due diligence on multiple applications across the world
- Handled regulatory aspects of product development from API to marketed product
- Perform QA inspections of facilities and provide regulatory impact of applications
- Managed multiple culturally diverse regulatory team across the world to obtain approvals

Responsibilities in Business Development/Product Licensing:

- Excellent working knowledge and experience on in-licensing and out-licensing
- Have licensed multiple pharmaceutical products, dietary supplements and medical devices to companies across the world
- Currently liaise with multiple vendors for Pharmvista since 2008.
- Launched products currently sold in the US markets as dietary supplement
- Advise multiple companies on licensing and product development
- Manage business worth more than \$2 million across 3 countries.

PROFESSIONAL AFFILIATIONS:

- Regulatory Affairs Professional Society, USA
- Pharmaceutical Sciences Group, Canada