Job Description/Role Profile

Pre-Approval Regulatory Affairs Manager

Job Title:	Pre-Approval Regulatory Affairs Manager
Reporting To:	Director of Regulatory Affairs

Job Purpose Statement

Regulatory Affairs Manager is responsible for drafting, electronic submission and regulatory project management of new ANDA products throughout the drug development phase by coordinating cross functional team to provide timely documentation for the regulatory submission and activities from pre-submission to approval.

Main Accountabilities

- Responsible for preparation and submission of new ANDA product applications, amendment and supplements in eCTD format
- Serve as the Regulatory Project manager to deliver quality regulatory submissions to agreed project targets
- Provide operational regulatory input and guidance in cross-functional teams. Work flexibly within and across functional areas to provide broad regulatory support to ensure the delivery of product team and business objectives. Contributes to solutions to regulatory issues
- Serve as a member of new product development teams by assessing regulatory requirements required to achieve rapid market approval
- Support Regulatory Affairs Director (RAD) or assume assigned responsibilities for routine and non-routine contact with regulatory authorities and contract customers
- Monitor, interpret and validate current and changing regulatory legislation and share potential impact these activities may have on the product development program
- The individual in this role will also negotiate directly with the FDA and other regulatory authorities in an effort to resolve any regulatory issues which may occur
- Coaching and developing junior RA staff members to become proficient in regulatory decision making
- Ensure that appropriate, up-to-date records are maintained for compliance

Job Related Qualification/Skills

- Minimum B.S. degree in a scientific discipline is required
- Minimum of 4-6 years progressive experience within Pharmaceutical Regulatory Affairs
- Minimum 2 years hands on preparation and submission of ANDA applications, amendments and supplements in eCTD format
- Thorough knowledge of the ANDA drug development process
- Scientific knowledge to understand the drug development process
- Project Management with Cross-functional team experience
- Demonstrated knowledge of US FDA regulatory requirements, cGMP's, GFI and ICH for the manufacture, testing and release of pharmaceutical products
- Proven experience in interacting with various levels of the FDA
- Excellent verbal, written and communication skills
- Ability to manage people, materials and resources

Working Conditions/Physical Requirements

- Regulatory Affairs Manager works in an office environment