



Crown Laboratories, Inc.

Job Title:	Regulatory Affairs Specialist
Reporting To:	Regulatory Affairs Manager
Organizational Unit:	Regulatory Affairs
Direct Reports:	None
Budgetary Responsibilities:	None

Job Purpose Statement

Regulatory Affairs Specialist is responsible for compiling, organizing and tracking all documentation from contributing departments to be included in new ANDA product submissions throughout drug development, submission and approval.

Main Accountabilities

- Responsible for compiling, organizing and tracking of documentation for new ANDA product application, amendment and supplements in eCTD format to achieve one cycle approval from the FDA.
- Generates, facilitates and maintains all related regulatory documents from pre-approval to submission and approval ensuring timeliness, quality and accuracy.
- Assist the Regulatory Affairs Manager to deliver quality regulatory submissions to agreed project targets
- Perform quality control review of submissions
- Assist the Regulatory Affairs Manager for filing necessary applications through FDA electronic gateway as appropriate
- Assist in developing procedures to ensure regulatory compliance
- Familiar with standard concepts, practices, and procedures of FDA
- Relies on experience and judgment to plan and accomplish goals

Job Related Qualification/Skills

- Minimum B.S. degree in a scientific discipline is desired
- 1-3 years progressive experience within Pharmaceutical Regulatory Affairs
- Previous hands on experience of preparation and compilation of ANDA applications, amendments and supplements in eCTD format
- Working knowledge of the ANDA drug development process

- Scientific knowledge to understand the drug development process
- Experience with cross-functional teams
- Working knowledge of US FDA regulatory requirements, cGMP's, GFI and ICH for the manufacture, testing and release of pharmaceutical products
- Excellent organizational, verbal, written and communication skills
- Proficient in MS Office Suite (Word, Excel, Outlook, PowerPoint)

Working Conditions

This job operates in a professional office working environment. This role routinely uses standard office equipment such as computers, phones, photocopiers and fax machines

Physical Requirements

While performing the duties of this job the employee will be required to spend long periods of time on the phone and seated at a workstation