PRE-APPROVAL REGULATORY AFFAIRS SPECIALIST

Job Purpose Statement

This position 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 supplement in eCTD format.
- Assist the Regulatory Affairs Manager to deliver quality regulatory submissions to agreed project targets.
- Assist the Regulatory Affairs Manager for filing necessary applications through FDA electronic gateway.
- 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.

Qualification/Skills

- Minimum B.S. degree in a scientific discipline.
- Minimum of 2-5 years' progressive experience within Pharmaceutical Regulatory Affairs
- Minimum two years' hands on 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.

Working Conditions

- Works in an office environment.