BIOSPECTRA

100 Majestic Way, Bangor, PA 18013

Job Description

Job Title:

Regulatory Affairs Specialist

Job Summary:

The Regulatory Affairs Specialist is responsible for the preparation of all regulatory submissions to domestic and global regulatory agencies. This position is responsible for the compilation of BioSpectra product dossiers in accordance with ICH, eCTD and electronic submission requirements.

Essential Duties and Responsibilities:

- ✓ Prepares eCTD filings for submission to the US Food and Drug Administration (US FDA) and other global regulatory agencies
- ✓ Interprets regulatory standards and guidelines to provide information to support and quality system and departments, as appropriate
- ✓ Prepares Drug Master Files to submit to the US FDA or other global regulatory agencies and ensures each are current
- ✓ Compiles and completes all Regulatory Product Information Packets
- ✓ Prepares all product listing, facility registration, product label updates and facility identification for submission to the US FDA
- ✓ Other duties may be assigned as deemed appropriate by management

Qualifications:

- ✓ Bachelors of Science Degree in science related field
- ✓ Minimum of 2 years' experience in pharmaceutical regulatory affairs
- ✓ Clear understanding of cGMP and ICH guidelines
- ✓ Clear understanding of eCTD Submission Requirements
- ✓ Must be able to read, write, speak, and understand English
- ✓ Ability to effectively present information to management and other groups

Physical Requirements:

While performing the duties of this job, the employee is frequently required to stand or walk for long periods of time; sit; use fingers to make small equipment adjustments; reach with hands and arms; and talk or hear. The employee must regularly lift and/or move up to 10 pounds and occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vision, ability to adjust focus, ability to distinguish color change, and the ability to use a computer for extended periods of time.

Work Hours:

The Regulatory Affairs Specialist will be expected to work up to 40 hours per week. This is an hourly position requiring the Regulatory Submissions Specialist to record the working hours on a time card using the available time clock.

All BioSpectra job functions require the ability and willingness to work from all BioSpectra facilities and properties.