



Senior Manager/ Associate Director of Regulatory Affairs

Job Description

Dexcel Pharma USA is seeking a Senior Manager/ Associate Director of Regulatory Affairs to join the Company at its Parsippany, NJ corporate office. The position will be responsible for coordinating and ensuring quality regulatory submissions for the Company. This is an opportunity for an experienced individual to join a growing specialty pharmaceutical company and work directly with the senior management of the Company. The successful candidate will:

- Lead and manage a team of Regulatory Affairs professionals.
- Coordinate and review all regulatory submissions of the company including ANDAs and 505(b)(2) NDAs, as needed.
- Develop and implement regulatory strategies and filings throughout each product's lifecycle.
- Manage regulatory risks and ensure compliance with all applicable regulations.
- Ensure regulatory and cross-functional project strategies and submission timelines are in alignment for successful filing and timely approval.
- Actively monitor changes in applicable regulatory requirements and industry trends, and proactively identify and propose solutions for potential regulatory challenges.
- Maintain drug product labeling components for all commercial products.
- Author and review departmental SOPs, as well as any other additional SOPs that may impact regulatory affairs.

Qualifications

- Bachelor's degree in a scientific or technical field (e.g., chemistry, biology, pharmaceuticals, etc.) with 7+ years of work experience in US FDA regulated pharmaceutical development and manufacturing, including making submissions in eCTD format.
- A degree in regulatory affairs is preferred.
- Strong background in CMC documentation preferred.
- Must demonstrate strong leadership qualities: strategic thinking, decision making, problem solving, communication skills, attention to detail, project management, team building and development, professional integrity, influence and negotiating skills, adaptability and flexibility, and stakeholder management.
- Excellent organizational and time management
- Exceptional communication and interpersonal skills across all levels of the Company.
- Self-starter who can be effective with minimal supervision.
- Excellent writing and communication skills consistent with the ability to prepare concise, timely, and accurate reports/presentations.
- Previous experience in managing personnel is a plus.

Qualified candidates should submit their resumes directly to careers3@dexcelpharmausa.com.

*1 Upper Pond Road, Suite D250 Parsippany, New Jersey 07054
201-292-1292 www.dexcelpharmausa.com*