



**Job Title:** Associate Director, Regulatory Affairs

**Date:** October 2010

**FLSA Exemption Status:** Exempt

**General Summary:** Provide Regulatory Affairs leadership, guidance and support to cross-functional development stage project teams and commercial product teams. Reports to the VP, Operations.

**Principle Duties & Responsibilities:**

- Establish regulatory policies and strategies in full compliance with applicable regulatory requirements for Pharmaceutical products or programs.
- Direct and prepare documentation in accordance with the highest regulatory standards for submission to regulatory agencies, with an emphasis on the US FDA.
- Lead the NDA filing team for Chelsea's first ever NDA approval.
- Serve as the regulatory representative on project as well as product/brand teams.
- Serve as the regulatory contact with FDA (review team and/or DDMAC), as appropriate.
- Accountable, as part of medical education and promotional review teams, for ensuring that medical education and promotional materials and activities are compliant with promotional/advertising regulations, state regulations, and healthcare authority guidance.
- Ensure that changes in regulatory requirements that can affect the company's business are appropriately communicated to project teams and senior management.
- Develop and manage regulatory timelines and budgets associated with Regulatory activities.
- Manage and collaborate with contractors and consultants, as needed.

**Education and Work Experience:**

A Bachelor's Degree in relevant field is required. An advanced degree and/or RACS certification is preferred. Eight or more years of experience across a breadth of Pharmaceutical Regulatory Affairs (RA) areas required. The most attractive candidates will have experience in NDA (eCTD) filing as well as post-approval RA oversight.

**Specialized Knowledge and Skills:**

Solid knowledge of current regulatory requirements and landscape across development and commercialization. Ability to creatively resolve issues with a "here's how to" rather than a "can't do that" approach. Adept at interacting with Regulators.

**Equipment and Applications:**

Proficient with Microsoft Office.

**Work Environment and Physical Demands:**

General office environment. Occasional travel is required. No special physical demands required.

**Disclaimer:**

The above declarations are not intended to be an all-inclusive list of the duties and responsibilities of the job described, nor are they intended to be such a listing of the skills and abilities required to do the job. Rather, they are intended only to describe the general nature of the job.