Crown Laboratories, Inc.

Job Title:	Regulatory Affairs Director
Reporting To:	VP of QA/RA

Job Purpose Statement

Provide the planning and leadership to the Regulatory Department by ensuring that appropriate structures, systems, competencies and values are developed.

Main Accountabilities

- Overall responsibility for the management of the regulatory department and ensure that new chemical entities , new dosage forms and new indications are registered in a timely manner.
- Establish on-going liaison with key opinion leaders and government officials to ensure that significant developments are identified and monitored
- Provide operational regulatory input and guidance in cross-functional teams. Work flexibly within and across functional areas to provide broad regulatory support to ensure the delivery of product team and business objectives. Contributes to solutions to regulatory issues
- Serve as a member of new product development teams by assessing regulatory requirements required to achieve rapid market approval
- Analyze product development and research, monitored for legislative and regulation updates to ensure compliance
- Evaluated, reviewed and processed documentation and corporate records to verify compliance
- Monitor, interpret and validate current and changing regulatory legislation and share potential impact these activities may have on the product development program
- Manage Regulatory Staff

Job Related Qualification/Skills

- Minimum B.S. degree in a scientific discipline is required
- Minimum of 4-6 years progressive experience within Pharmaceutical Regulatory Affairs
- Thorough knowledge of the ANDA drug development process
- Scientific knowledge to understand the drug development process
- Minimum 2 years hands on preparation and submission of ANDA applications, amendments and supplements in eCTD format
- Proven experience in interacting with various levels of the FDA
- Excellent verbal, written and communication skills
- Ability to manage people, materials and resources