Crown Laboratories, along with our affiliated companies, has a long-standing heritage in skin care, and we are passionate about providing consumers and clinicians with innovative solutions for the skin. As our mission states, we are committed to developing and providing a diverse portfolio of pharmaceutical and consumer products that improve the quality of life for our customers.

With consumer brands like Blue Lizard Australian Sunscreen, Vita Liberata, and more, we offer best-in-class sunscreens, self-tanning lotions, moisturizers, cleansers and oral care products. Our prescription products provide healthcare professionals with solutions for managing a variety of skin conditions. We are excited about our future, as we grow to become an innovative leader in the dermatology, skin care, and aesthetics industries while enriching the lives we touch.

We are currently recruiting for an experienced **Regulatory Affairs Associate**, based at our Johnson City, TN facility which will be responsible for preparation of Annual Product Reviews for all manufactured products and compiling, organizing and tracking all documentation from contributing departments to be included in ANDA product submissions throughout post-approval products life cycle.

Main Accountabilities

- Prepare Annual Product Review reports for all products manufactured and trending data
- Responsible for compiling, organizing and tracking of documentation throughout post-approval products life cycle
- Assist the Regulatory Affairs Manager to deliver quality regulatory submissions to agreed project targets
- Assist the Regulatory Affairs Manager for filing necessary post-approval applications through FDA electronic gateway or with consultant
- 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

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Qualification/Skills

- Minimum degree in a scientific discipline is preferred; 2-5 years progressive experience in Pharmaceutical Regulatory Affairs in lieu of degree will be considered
- Minimum of 1-3 years progressive experience within Pharmaceutical Regulatory Affairs
- Minimum 1 year hands on preparation and compilation of APRs, ANDA applications, amendments and/or supplements
- Entry level knowledge of the post-approval ANDA reports
- Some understanding of FDA and ICH regulatory guidelines, processes and best practice. Some understanding of regulatory guidelines in other regions of the world would be an advantage.
- Scientific knowledge to understand the drug development process
- Experience with Cross-functional teams
- High attention to detail, tenacity and diplomacy.
- Excellent interpersonal, communication (written and verbal), organizational skills and computer skills, including Microsoft Office Suite
- Demonstrated ability to operate with a considerable degree of initiative and independence (i.e., a thinking writer).
- Proven ability to work in a focused environment, often to tight timelines.

To apply click HERE.

NOTE: This job profile is intended to provide an overview of expected job duties and requirements. It is not intended to be a contract of employment, explicit or implicit. All contents are subject to change at the sole discretion of the company. Cooperation is expected of all employees. Other duties may be assigned as needed.

We offer a competitive benefits package including vacation, medical, dental, vision, short/long term disability and 401(k) w/match.

an Equal Opportunity Employer

For other career opportunities, please visit our careers page:

https://www.crownlaboratories.com/employment-opportunities

To learn more about our company and our brands, please visit our websites:

www.crownlaboratories.com

www.bluelizard.net

www.vitaliberata.com

www.nkdskn.com

www.bellusmedical.com