

**Novast Laboratories, Ltd**  
**Nantong, China and Sterling, VA, USA**

*Sr. Manager or Associate Director*  
*Product Development (2 positions open)*

**DESCRIPTION**

Leading multiple project teams in development, scale-up, technology transfer and validation for solid products, supervising the daily activities of designated groups, assisting experimental design and data interpretation, writing and reviewing reports and CMC documents for regulatory filing. The individual will also act as the primary liaison between Novast and clients involved in product development and manufacturing.

**DUTIES AND RESPONSIBILITIES**

- Lead multiple project teams and responsible for all aspects of product development
- Plan, prioritize, and execute activities in accordance with company's objectives to ensure goals and timelines are met. Ensure resources, equipment and materials are adequate to achieve the goals.
- Provide training and guidance to staff for their performance and career development, monitor and appraise the performance of personnel reporting to this position
- Provide scientific and technical input to project teams for product/process designs and trouble shooting
- Collaborate and communicate with Novast internal cross functional departments to facilitate product development. Also work closely with external clients to ensure that customer's needs are met.
- Supervise the daily activities of the designated area in the department
- Review and approve batch records to ensure the compliance to cGMP and to evaluate the technical aspects of manufacturing process
- Write/review protocols, reports, and CMC documents for regulatory filing
- Responsible for preparing responses to FDA requests
- Promote science, publish research articles and develop intellectual property for Novast

**REQUIREMENTS**

- M.S./Ph.D. in Pharmaceutics or closely related sciences, 5-10 years of experience in solid oral product development and manufacturing; minimum 3 years experience managing product development or workgroups
- Thorough knowledge of current regulatory requirements for pharmaceutical industry, experience with successful track record in preparation of CMC documents for regulatory filing
- Proven ability to develop new products
- Excellent oral and written communication skills
- Exemplary professional skills and interpersonal skills
- Self motivated, and able to work independently
- Able to work with tight timelines, manage multiple projects simultaneously and maintain professionalism under pressure
- Goals and results oriented with ability to deliver on commitments
- Experience in the development of ANDA is preferred

***Manager or Senior Manager  
Regulatory Affairs***

**DESCRIPTION**

Reporting to the Senior Director of Regulatory Affairs, the Regulatory Affairs Manager will assume responsibility for assigned ANDA's to ensure that submission deadlines are met and that applicable laws, regulations and corporate standards are adhered to. The RA Manager will also assist in the review and compilation of submissions for other regulated markets where the company plans.

**DUTIES AND RESPONSIBILITIES**

- Responsible for collection, preparation and assembly of regulatory documents for ANDA submissions required by USFDA in e-CTD format.
- Maintains the regulatory compliance status of applications by ensuring that all required amendments/supplements are submitted in a timely fashion.
- Communicate with USFDA and other regulatory bodies for guidelines and directions.
- Assist in the preparation of draft labeling, meeting packages, submission responses, and similar summary documents.
- Review documents for adherence to ICH and territorial guidelines and expectations and provides recommendations for remediation of any deficiencies.
- Advises RA management of any potential compliance and or submission issues and assists in development of recommendations for remediation.
- Provide coverage to ensure annual reports are submitted within the required timeframe.
- Represent Regulatory Affairs in review of MBR and provide guidance for the scientists.
- Work closely with Regulatory operational staff to ensure efficiency of submission preparation, archival and document management.
- Expand oversight into Product Development, Production, Quality and other operation area where RA services are required

**REQUIREMENTS**

- BS/MS degree in a scientific discipline (e.g. Chemistry, Pharmacy, Biochemistry)
- A minimum of 5 years experience in filing ANDA applications, supplements and annual reports
- Must possess in-depth knowledge of appropriate Code of Federal Regulations, Regulatory Guidance Documents and ICH Regulations.
- Experience in the preparation and submission of regulatory applications, amendments, supplements and related submissions/reports.
- Strong communication and organizational skills and attention to detail.
- Ability to audit and edit written summaries of data.
- In depth knowledge of Acrobat and Microsoft Office and in particular Microsoft Word.
- The ability to work in a flexible, multi-functional, team environment.
- Experienced with e-CTD filings.

***Manager or Senior Manager  
Analytical Research***

**DESCRIPTION**

This individual will assist to lead multiple analytical project teams in method development, method validation, and to fulfill the NDA/ANDA submissions to USFDA. This analytical research manager supervises the daily analytical laboratory activities to ensure high quality and timely analytical results in a cGMP compliant environment.

**MAJOR RESPONSIBILITIES**

- Assist to lead multiple analytical project teams to fulfill the NDA/ANDA submissions to USFDA.
- Directly supervise staff to ensure that all group leaders and the persons directly reporting to him (her) are conducting their job properly, with all tasks properly completed before the deadlines and that all cGMP and corporate quality requirements are fully developed and maintained.
- Participate the SOP/STM writing, updating, filing and training. Participate method validation protocol/report writing and reviewing. And participate the writing and reviewing of CMC documentation in NDA/ANDA submissions.
- Participate and assist to build the working team, including hiring, training and supervising staff. Provide motivation, and creative energy while developing a team atmosphere
- Collaborate and communicate with Novast internal cross functional departments to facilitate product development. Also work closely with external clients to ensure that customer's needs are met.
- Actively participate the assessment, negotiation, and procurement of new analytical equipment.
- Provide leadership for FDA/SFDA audits as well as the regulatory awareness
- Assist in the preparation of appropriations, budgets, and reports for Director.
- Promote science, publish research articles and develop intellectual property of Novast.
- Ensure that all safety regulations are strictly followed.

**QUALIFICATIONS:**

- M.S./Ph.D. in chemistry, or in related sciences. At least 5 years of previous analytical laboratory experiences in pharmaceutical industry in a management role, at least group leader.
- Proven ability to develop new analytical method for pharmaceutical industry.
- Previous analytical instrumentation validation experience in the pharmaceutical industry.
- Exceptional cGMP and FDA compliance knowledge. Skills to write and review CMC documents for USPDA are preferable.
- Excellent oral and written English communication skills.
- Superior interpersonal and communication skills and organizational skills.
- Able to work with tight timelines, manage multiple projects simultaneously and maintain professionalism under pressure.

## **ABOUT NOVAST**

Novast Laboratories is a specialty pharmaceutical company based in both the United States and China, and focused on the development, manufacturing and commercialization of high quality products for global markets. It is led by a management team with extensive scientific and managerial experience, and successful track record of development of NDA and ANDA products at the U.S. -based global pharmaceutical companies. Novast has established, implemented, and maintained all its scientific and quality standards and systems according to the requirements of the US and EU. More importantly, it has built a diligent and dependable work culture with intellectual property protection, financial accounting, environmental, safety standards, and highest integrity and ethics.

Novast operates from its state-of-the-art cGMP complex located in Export Processing Zone of National Nantong Economy and Technology Development Area (EPZ-NETDA), Nantong, China, a city that is conveniently located on the northern bank of the Yangtze River and with about 80 and 100 minutes of driving distance from Hongqiao and Pudong International Airports, respectively.

Novast offers a competitive salary and a benefits package that includes medical insurance, life insurance, 401(K), and performance based bonus.

**Please send resume to:**

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