

## Regulatory Affairs Manager/Senior Associate



### Job Description:

The Regulatory Affairs Manager will actively participate in the development and implementation of regulatory strategies with project team members for submissions and will manage document deliverables to ensure that submission targets are met. The RA manager is responsible for coordinating and supporting all aspects of regulatory submissions relevant to assigned projects for the U.S. and Europe, including coordinating regulatory workflow, leading regulatory submission teams when necessary, and tracking submission timelines. The RA manager will play a major role in reviewing and performing data quality checks on technical (clinical, CMC, and nonclinical information), and regulatory submission documents, as well as internal documents to ensure the proper implementation of regulatory strategies and adherence to appropriate statutes, regulations, and guidances. The RA manager will provide clear and valid regulatory guidance and direction to other departments and project teams. The RA manager will interact with regulatory agencies as appropriate and perform other duties as assigned.

### Qualifications:

- BA/BS/University degree required; Life/Health Sciences preferred
- Minimum 5+ years pharmaceutical/biotechnology industry experience, at least 3 years in Regulatory Affairs
- Experience with U.S. and European (UK and Germany) regulatory requirements; experience with post approval activities desired
- Ability to work independently with minimal direction and within project teams, committees, etc. to attain group goals
- Excellent communication skills
- Ability to represent the department on project teams
- Strong organizational skills, including ability to prioritize personal workload
- Strong interpersonal skills and the ability to deal effectively with a variety of personnel including medical, scientific, and manufacturing staff
- Experience and knowledge in the preparation of major regulatory submissions (INDs, NDAs, MAAs) and supportive amendments or supplements
- Knowledge and understanding of applicable regulations