

Recruiter : Steven Karski

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Alchemy Scientific, Inc., 51 JFK Parkway, First Floor West, Short Hills, NJ 07078

Director – Manufacturing Technology CMC, Regulatory Support 12/7/09

Individual will lead a team that will provide support to the Regulatory Affairs (CMC) Organization. This team's primary responsibility will be to provide the technical content for the Chemistry, Manufacturing and Controls (CMC) sections of all investigational drug applications (INDs, CTAs) and any required amendments, initial marketing applications along with any required supplements and amendments. Additional responsibilities include assisting the RA(CMC) group with the compilation of responses to the respective health authorities resulting from the noted filings, coordinating and synthesizing input from the required technical experts. This individual will represent this function on multi-disciplinary project teams. Must be detail-oriented with good oral and written communication skills. Must be able to multi-task and keep to the timelines established for the respective filings.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

1. Responsible for generating the technical content for the Chemistry, Manufacturing and Controls (CMC) documentation required for investigation new drug applications and their respective amendments as well as initial marketing applications along with the required supplements and amendments.
2. Work with the Regulatory Affairs (CMC) Organization to develop a series of standard templates for routine filings.
3. Coordinate the completion of the CMC templates with the Regulatory Affairs (CMC) Organization for all noted filings.
4. Summarize technical reports and documents to meet the needs of a given template section.
5. Prepare and maintain an up to date project plan for each molecule to ensure CMC sections are delivered on time. The project plans will be based on the deliverables established by the product core teams and the filing schedule established by the Regulatory (CMC) Affairs organization.
6. Work collaboratively with the Biopharmaceutical Manufacturing and Development technical experts and the Regulatory (CMC) Affairs organization to implement an agreed upon regulatory strategy.
7. Participate as a member of multi-disciplinary teams organized to ensure project timelines are met and clinical and commercial supplies are available when needed.
8. Build and supervise a multi-disciplinary team.
9. Develop an optimized work flow for document creation, review and completion.
10. Assist manager with the development and maintenance of department budget.

ESSENTIAL KNOWLEDGE, SKILLS, EXPERIENCE:

1. A minimum of 15 years Biopharmaceutical or Pharmaceutical Industry experience which should include a minimum of 5 years of regulatory including handling/authoring regulatory documentation or related experience. Credit given toward years of industry experience to those with advanced degrees.
2. A working knowledge of the regulatory requirements for the US, Europe and Japan.
3. A working technical knowledge of the biopharmaceutical manufacturing process preferably in the area of antibody manufacturing. Expertise in a technical discipline a plus.

4. BS//BA degree in Biochemistry, Chemistry, Microbiology, Pharmaceuticals, Chemical Engineering or related field. An advanced degree a plus.
5. Working knowledge of cGMPs as they apply to the Regulatory environment.
6. Strong organizational and project management skills.
7. Excellent communication skills, both oral and written with demonstrated skills in the preparation of complex regulatory filings.
8. Demonstrated supervisory skills.