

Recruiter : Steven Karski

Email : skarski@alchemyscientific.com, Phone : 786-347-6300

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

**Manager/Senior Manager - Regulatory, CMC 12/7/09**

The incumbent is responsible for maintaining competent knowledge of current / emerging regulations, guidance documents and corporate/industry standards, with an ability to evaluate same for impact on tactical operations. Good technical knowledge, provides committed, value-added effort in support of development projects and approved products. Must be detail-oriented with good oral and written communications skills; able to prepare accurate, clear and concise regulatory documents and manage the quality review process. Excellent time management skills essential; must be able to multi-task and drive timelines for deliverables. The position is primarily tactical however strategic insight is required. The Senior Manager is expected to work with minimal supervision.

**ESSENTIAL DUTIES AND RESPONSIBILITIES:**

1. Will have an in-depth understanding of regulatory CMC requirements, including FDA, EMEA, ICH guidelines and relevant government regulations (21 CFR, EU Directive).
2. Reviews websites and develops initial impact assessment of draft regulatory guidance, communicating changes in regulatory requirements to senior regulatory management.
3. Provides regulatory guidance to ensure development activities are compliant with relevant regulations and in line with current global guidance.
4. Communicates regulatory strategy and guides manufacturing in developing data for approval of post-marketing changes.
5. Works with development teams and Regulatory Operations to outline submission requirements and negotiate timelines for regulatory CMC submissions.
6. Prepares the CMC section of INDs, BLAs, CTAs, CTDs, amendments, supplements and annual reports, including the compilation and review of the required data, scientific reports, and written submission contributions.
7. Reviews and assesses the regulatory impact of all change controls/requests for the manufacture, testing and release of development and marketed products.
8. Assists in the implementation of processes and applications to support regulatory activities

**ESSENTIAL KNOWLEDGE, SKILLS, EXPERIENCE:**

1. Must have 3 – 7 years of pharmaceutical industry experience including 2 – 3 years of regulatory experience.
2. Demonstrated knowledge of the drug development process and government regulations/guidelines, including US and international product registration.
3. Good oral and written communication skills with a focus on accuracy (vigilant attention to detail) and clarity are essential.
4. The Senior Manager will have the ability to supervise and mentor junior staff members.
5. BA/BS degree or equivalent experience.

If you know of anyone who might be interested, any suggestions are greatly appreciated. Also,

all interested candidates are welcome to contact us and send their resume as a Word file.

All inquiries are kept strictly confidential.