



## **Associate Director of Quality Management**

Responsible to lead the development, implementation and continuous improvement of Quality processes. Candidates should be flexible, motivated individuals, capable of working in a small company on a broad range of QA areas including GMP, GCP and regulatory compliance of commercial activities (including promotional activities). Candidates with experience at small companies preparing for commercialization or first launch of commercial pharmaceutical products and regulatory approval processes in the United States and the European Union are highly preferred. The candidate will report to the Vice President, Operations and will interact closely with the Corporate Management Team.

### **Specific responsibilities include:**

- Develop and direct company QA systems and documentation including document control systems
- Develop and implement risk based decision making throughout the organization
- Write and implement SOPs and appropriate guidelines
- Conduct GCP, GMP, and GLP auditing of vendors and internal processes
- QA release of commercial product to the US and EU markets
- Assess QA aspects of new business opportunities
- Teaching and coaching on issues of corporate quality

### **Key Skills:**

- A capacity to fully understand the business across development and commercialization
- Practical mindset
- Stellar team player
- Ability to influence others
- Continuous improvement mindset
- Budget management with a comfort in prioritizing activities in line with corporate objectives
- Comfortable working in a lean organization
- Knowledgeable in appropriate ICH, GMP, GCP guidelines