Job Title: Director/Sr Director, Quality Assurance

Reports to: Sr. Vice President, Regulatory Affairs & Quality Assurance

Responsibilities Overview:
Responsible for developing and maintaining the company's quality system to ensure compliance with applicable FDA and international regulatory requirements. Responsibilities include maintaining the company's electronic document management systems and archives.

Primary Duties and Responsibilities:

- Develops and maintains corporate quality policies, procedures and work instructions.
- Responsible for implementation of policies and procedures that are administered directly by Quality Department, such as document management, personnel training, CAPA system, etc. Provides guidance and assistance to other departments in developing and implementing policies and procedures governing their activities (e.g., for GLP/GMP/GCP compliance).
- Arranges for periodic, independent audits of the quality system to assure compliance and identify areas for potential improvement.
- Represents the organization to business partners and outside groups, including US and international regulatory agencies regarding quality related matters. Serves as a primary liaison with health regulatory authorities or applicable clients during any quality system audit.
- Provide department and executive management with process metrics and progress reports relating to all quality system activities. Conduct presentations and group briefings regarding quality activities.
- Assures all employees receive training appropriate to their job function.
- Maintain company infrastructure for paper and electronic document management systems (EDMS) and record retention. Update document management system requirements and specifications, evaluate system upgrades, and where necessary develop and execute tests scripts to maintain validation status. Monitor EDMS to assure timely processing and disposition of documents.
- Work with other departments to evaluate and qualify material and service suppliers, and, where necessary, arrange for independent audits of such providers. Monitor supplier performance to assure continued suitability. Execute the release and acceptance of input materials, clinical trial supplies, and approved commercial product on behalf of the company.
- Serves as alternate to VP RA/QA as signatory on documents regarding quality of drug substance or drug product such as material specifications, stability protocols, batch records, packaging and labeling records, etc. Participates in Material Review Board and other activities associated with investigation and disposition of issues associated with material quality. Disposition final drug product, including Release for human use.
- Establish annual and long term Quality goals, and lead efforts within Quality and other disciplines to achieve them. Proactively provide input and ideas to improve quality system and company business processes to maximize efficiency and effectiveness.
- Prepare annual functional area operation plan and budget, and ensure the Quality function delivers performance to plan.
- Perform quality checks of reports, data outputs etc. prior to release or submission to regulatory authorities.
- Position may supervise and direct the efforts of other staff member(s).
- Perform other tasks as assigned.

Background Requirements:

- Bachelor's or Master's degree in science or business discipline.
- Minimum 8 years experience in quality assurance in medical/pharmaceutical product development industry.
- Knowledgeable of regulations pertaining to quality system requirements and drug development. Possesses a thorough knowledge of cGLPs/cGMPs/cGCPs/QSRs and other relevant regulations in the US and EU. Experienced in conducting internal audits, and preparing for and hosting agency inspections and audits.
- Proficiency with office equipment, computer systems and software (including Microsoft Office and Outlook) required.
- Highly developed organizational skills and attention to detail are mandatory.