Associate Director/Director, GMP Quality Assurance

POSITION SUMMARY

The Associate Director/Director of GMP QA is responsible for developing strategy and managing activities involving GMP quality assurance and compliance with applicable regulatory requirements; development and implementation of Quality Assurance policies and procedures to ensure quality standards in compliance with relevant regulatory and quality guidelines for Good Manufacturing Practices. The Associate Director/Director, GMP Quality Assurance will support the vision and drive the implementation of the quality systems required to ensure GMP compliance and inspection readiness.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Work with and provide compliance guidance to cross-functional teams including Chemical Development, Pharmaceutical Development, Analytical Development, Quality Control, and Clinical Supply Management.
- Support Quality System implementation initiative by creating and/or revising SOPs related to the Quality and CMC functions.
- Update and oversee clinical and commercial batch review/disposition process
- Review of executed batch records for all phases of manufacturing and packaging including resolution of quality system events in conjunction with technical leads and CMOs such as deviations, CAPA, OOS and Change Control.
- Review of manufacturing documentation including master batch records, protocols and reports associated with manufacture and testing of materials.
- Review of analytical release and stability data.
- Update/establish Quality Agreements with CMOs
- Support Denovo's GMP vendor management/audit program
- Perform audits of Contract Manufacturing Organizations (CMOs), documents and internal systems and processes to ensure compliance with regulatory requirements and company policies and procedures
- Prepare written audit reports and communicate findings and recommendations and evaluate the adequacy and completeness of corrective and preventative action plans.
- Support the development and delivery of GMP training
- Support GMP system and process improvement initiatives; Lead continuous process improvements within Quality
- Lead GMP global inspection readiness activities of CMOs
- Maintain required knowledge of applicable regulations, guidelines and company standards and procedures

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor's Degree or advanced degree in a scientific discipline; Quality assurance professional certification is a plus.
- 10+ years' experience in GMP QA in pharmaceutical development, hands-on GMP experience in both big pharma and small biotech environment preferred.

Knowledge, Skills, and Abilities

- Knowledge and demonstrated experience in the applicable GMP regulations, FDA Regulations and Good Manufacturing Practices, EMA EudraLex Regulations, and ICH Guidelines for all phases of pharmaceutical development and good manufacturing practices.
- Excellent communication and interpersonal skills to build key networks and business relationships across all levels of the business
- Proven experience in working with CMC teams; working in a multidisciplinary environment
- Ability to analyze complex issues, problem solve and take appropriate decisions and actions
- Excellent computer skills (MS office: word; excel; Visio)

SPECIAL WORKING CONDITIONS

- Physical Activities: On a continuous basis, sit at desk for a long period of time; intermittently answer telephone and write or use a keyboard to communicate through written means. Some walking and lifting up to 25 Ibs may be required. The physical demands described above are representative of those that must be met by an employee to successfully perform the essential functions of this job.
- Ability to travel up to 25% both domestic and internationally is required.

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.