imara

SENIOR MANAGER, QUALITY ASSURANCE

POSITION SUMMARY

This position provides Quality Assurance oversight of current good manufacturing practice (GMP) regulated activities for Imara, including those performed at contract manufacturing organizations (CMOs).

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Provides QA support for Imara's GMP-regulated activities and products to ensure they comply with applicable regulatory requirements and internal standards
- Represents Imara QA on project teams and serves as the main Quality point of contact with CMOs on assigned projects
- Reviews and approves GMP quality system records including change controls, deviations and investigations, corrective and preventive actions (CAPA) and complaints. Ensures appropriate root cause investigations are performed, when required
- Reviews and approves specifications, master manufacturing records, analytical methods, labeling, protocols, reports and other GMP documentation for Imara products
- Reviews completed batch production records and determines the final Imara disposition of drug substance, drug product and clinical trial materials
- Establishes and maintains quality agreements with CMOs
- Develops effective partnerships with cross-functional staff (e.g., regulatory affairs, technical staff and qualified persons (QPs)) to facilitate the identification and resolution of quality matters and other opportunities for quality process improvement
- Manages the supplier qualification program and performs audits, as required
- Tracks, evaluates and generates written reports of quality data for management review
- Supports the development, implementation, and maintenance of Imara's quality management system
- Organizes and files quality records to ensure their ready access and retrieval throughout the retention period
- Assists management with inspection readiness activities for Imara and CMOs

JOB REQUIREMENTS

Education

- Bachelor's degree, preferably in a scientific discipline
- Quality auditor certification (CQA) is desired

Experience, Knowledge, Skills and Abilities

- A minimum of 10 years related QA experience in the pharmaceutical or related industry
- Experience working with contract manufacturing organizations (CMOs)
- Broad knowledge of GMP regulatory requirements and guidance (ICH, FDA, EMA and other regulatory authorities) related to pharmaceutical research and development activities
- Thorough understanding of manufacturing, packaging and laboratory operations, particularly for solid oral dosage forms
- Proficient in the development and utilization of quality systems (e.g., deviations and investigations, change control, CAPA, training)

- Comfortable in a fast-paced environment with minimal direction and able to adjust workload based upon changing priorities
- Demonstrated ability to collaborate and communicate well with others
- Experience conducting GMP vendor audits is highly desired
- Excellent attention to detail and observation skills
- Computer skills competency including Microsoft Word, Excel and PowerPoint

Occasional air and ground travel is required (up to 15%), including international travel.