NextCure

Associate Director of Quality Assurance

Job Description

NextCure is a start-up biopharmaceutical company located in Beltsville, MD, and focuses on the discovery and development of novel immunomedicines for the treatment of cancer and other diseases. We are seeking a highly motivated Associate Director of Quality Assurance to oversee our Quality Assurance (QA), Quality Control (QC), Quality Systems groups. As an Associate Director of Quality Assurance, you will develop and oversee robust and sustainable quality systems that ensure that manufacturing and quality control activities are conducted in compliance with current good manufacturing practices (cGMP), GCP, GLP, cGPT, GxP, FDA requirements, EU Annex 1 and 11 preferrable, and various pharmacopeia and internal institutional requirements. The candidate must thrive and adapt to a fast-paced, innovative, and changing environment.

Responsibilities

- Continue advancement of Quality Systems
- Fully support a pipeline development
- Implementing and supporting new cutting-edge technologies including automation systems
- Provide leadership and mentorship of the Quality group
- Lead the Quality department in all GXP functional areas (GMP, GLP, GCP, GxP document control, GXP training) as we are transitioning from discovery through product development
- Manage the vendor qualification program, including vendor audits
- Oversee the document control and enforces compliance of all the company's SOPs, GMP and FDA guidelines and applicable regulations
- Oversee root cause analysis of non-conformance events and deviations
- Maintain an efficient workflow to facilitate the operational excellence
- Establish and maintain an efficient and complaint validation program including process validation, cleaning validation, computer software validation, and instrument qualification
- Keep current on changes in industry and regulatory standards for GXP requirements and advise on business impact
- Ensuring employees and consultants are appropriately qualified and trained
- Provide compliance guidance to Product Development and Operations teams
- Ensure manufacturing and testing, clinical studies, and clinical trials are compliant with applicable

Required education and experience

- M.S. degree in Chemical Engineering, Biochemistry, Chemistry, Cell Biology, or a related field with relevant thesis work and or appropriate experience required
- PhD in biochemistry, chemistry, bioassays, molecular biology, or microbiology preferred

- At least fifteen (15) years of experience in the biotech/pharmaceutical industry, with at least five (5) of those years being experience in Quality and five (5) in a supervisory role
- Knowledge and experience in principles and practice of current Good Manufacturing Practices (cGMPs), CMC, Clinical Operations, and Pharmacology/Toxicology is beneficial
- Knowledge in Good Laboratory Practices (GLPs) for FDA expectations preferred
- Solid knowledge in FDA regulations, especially the GMP
- Experience with writing and reviewing regulatory submissions (IND, IMPD) and inspections

Qualifications

- Proven experience in developing, qualifying, and validating analytical methods to support product development and regulatory filings
- Sound understanding of regulatory and compendial requirements for early stage through commercialization of products
- Good understanding of requirements outlined in ICH Guidelines and FDA guidance documents
- Substantial experience in a regulated biotech/pharmaceutical industry including manufacturing, quality assurance, quality control, R&D, and drug regulatory affairs
- Experience of sterile manufacturing
- Superior influential and negotiation skills
- Details-oriented, strong analytical and problem-solving skills
- Ability to rapidly learn new skills and accept new ideas
- Flexible and able to adapt to changing circumstances while maintaining a focus on quality.
- Passionate about scientific innovation, self-starter, goal-driven, and strive to continuously build knowledge and skills for personal, professional, and organizational growth

NextCure is an Equal Opportunity Employer and offers a competitive salary and benefits package in a scientifically engaged team work environment. Qualified candidates should email their resume to info@nextCure.com