NextCure

Manager, Bioanalytical Sciences

Company Overview

NextCure is a growing clinical-stage biopharmaceutical company located in Beltsville focused on discovering and developing first-in-class immunomedicines for the treatment of cancer and other diseases. NextCure is committed to professional development in the context of learning, managing, and developing its employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development. We are excited about the ongoing work at NextCure and invite you to come join us in the culture and build your career in an environment that nurtures professional growth and development.

Role Summary

We are seeking a highly motivated Manager to join our Bioanalytical Sciences Team. The candidate will be part of an innovative team focusing on bioanalytical and biomarker assay development, validation, and sample testing.

Responsibilities

- Regulatory and scientific oversight of regulated and non-regulated bioanalytical studies.
- Analysis, interpretation, and approval of study data
- Manage and supervise staff.
- Preparation and/or review of validation plans, validation reports, and sample analysis plans.
- Ensure studies are conducted according to approved plans and applicable SOPs.
- Initiate new projects
- Preparation and creation of analytical runs, data review, and final reports that are written according to SOPs and ready for QA review.
- Ensure all study personnel are trained on applicable SOPs, equipment, protocols, and amendments.
- Maintain metrics to track workflows using business management software.
- Assist in the development and maintenance of review schedules and functional area metrics as applicable.
- Preparation and review of SOPs, documents, or protocol deviation documentation associated corrective actions and prompt notification of the Study Director and/or Management.
- In coordination with management, method development/validation, QA, and Reagent Groups to ensure that adequate resources are available for proper execution of the study.
- Scheduling and coordination with study review team, addressing findings promptly, with corrective actions.
- Scheduling and coordination with QA of audit events, including in-process audits. Address and correct issues arising from quality assurance audits promptly.
- Coordinate with Management, method development and validation staff to troubleshoot methods as needed including conduct and reporting of laboratory investigations.

- Responsible for updating report and project tracking to ensure timelines are being met.
- May fulfill other jobs/responsibilities as directed by management consistent with skill level and training.

Required education and experience

- Bachelor's in a related field with 4-6 years of relevant laboratory and/or project management experience, 2-4 years' experience with a master's degree, and 0-2 years with a PhD.
- Experience with MSD, Gyrolab, ELISA, and Luminex assays are highly desirable
- Pharmaceutical, biotechnology company or CRO experience is highly desirable.
- Working knowledge of GLP regulations and regulatory guidelines as they pertain to large-molecule bioanalysis.

Qualifications

- Excellent communication skills, both oral and written.
- Track record of leadership.
- Excellent organizational skills.
- Ability to multi-task and produce quality analysis while working under the pressure of strict deadlines.
- Proficient in time management and resource planning.
- Ability to initiate and implement self-development efforts.
- Ability to make decisions and complete assignments with minimal supervision.
- Ability to self-direct work priorities.
- Proven problem-solving ability.
- Ability to draft technical reports.
- Proficiency with computers and data analysis software (e.g. Watson LIMS, Workbench….etc).
- Outstanding project management and organizational skills and ability to multitask and perform in a fast-paced entrepreneurial and growing environment
- Ability to work in matrix team environment
- Demonstrated understanding of the biotech/pharma industry and therapeutic product development
- 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 teamwork environment.

Qualified candidates should email their resume to info@nextcure.com.