Lead Equipment, Systems Validation Engineer

Company Overview

NextCure is a clinical-stage biopharmaceutical company located in Beltsville, MD, focused on the discovery and development of first-in-class immunomedicines for the treatment of cancer and other diseases We are committed to professional development in the context of learning, managing, and developing our employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development.

Role Summary

We are seeking a highly motivated Lead Equipment, Systems Validation Engineer. The Lead Equipment, Systems Validation Engineer is responsible for the validation of new and existing equipment, systems, and facility including new computerized systems, new or revised Manufacturing processes and Facility systems to support the manufacture of NextCure biotech / pharmaceutical products and to ensure each product is produced safely and with the identity, strength, quality, and purity that it purports to possess. This position is an individual contributor role which, under the guidance of the Quality Management, is also responsible for the validation lifecycle of laboratory instruments and systems moderate or higher complexity within the Quality Laboratories at NextCure, Inc., Beltsville, MD.
As a dynamic, growing company, a successful candidate must be able to adapt and thrive in a fast-paced, innovative, and changing work environment.

Responsibilities

- Serves as validation representative for equipment, systems, facility, and laboratory instruments and partners with the laboratories, Quality System Administrators, Manufacturing, Quality Control (QC), Process Development, Facility, Metrology, and Quality Engineering on validating new instruments and upgrading existing instruments/equipment at the site.
- Performs periodic review of instrumentation and associated computer systems as needed and collaborates with Quality Computer System Validation Associate(s) for compliance alignment.
- Initiates and leads equipment assessment, risk assessment, gap analysis and deviation management for commissioning, changes to or decommissioning of laboratory equipment, systems/instruments, facility, and associated instrument control software where applicable.
- Initiates draft protocol, User Requirements, Traceability matrix, and other identified SDLC (System Delivery Lifecycle) deliverables.
- Executes protocol testing and debugging automated / embedded systems software and scripting automated tests and data analysis.

- Conducts software integration testing and validation strategies, including black-box and white-box approaches.
- Evaluate various equipment/instrument/ system processes prior validating via system risk assessment.
- Lead the requalification of existing systems and assist with installation, commissioning and startup, system upgrades, new facilities, and continued process improvement.
- Implement control methodology in DCS, PLC or HMI platforms with a high level of understanding of various system programming languages
- Oversee and assist in the development and review of System Integration Design Specifications for the integration of third-party equipment.
- Authors GxP and Computer System Risk Assessments, User Requirements & Functional specifications, validation plans, protocols (i.e. IQ, OQ, PQ), traceability matrices, reports, addendums, decommissioning plans and other validation deliverables as required by the site validation SOPs and Site Validation Master Plan.
- Ensures lab instrument's adherence to national and international regulatory guidelines on Electronic Records and Electronic Signatures and Data Integrity, cGMP, FDA 21 CFR Part 11/210/211, 58, EU Annex 11, MHRA guidelines.
- Authors protocol to challenge the main aspects of these requirements listed above during validation to demonstrate and meet regulatory and compliance requirements.
- For systems found unable to fully comply, formulate workarounds/strategies with core stake holders to mitigate the gaps by enhancing / upgrading systems or establishing ALCOA principles for remediation to the system/equipment or processes.
- Assists the system owner with evaluating and recommending the appropriate user roles and privileges for data integrity (where applicable), writing instrument operation instructions, and setting up preventive maintenance program/plans in conjunction with Metrology Representative(s).
- For continuous improvement, completes periodic reviews of laboratory instruments, equipment, systems, and associated instrument control software with focus on change control, deviation investigations and CAPA to ensure compliance and validated state of the instrument/systems.
- Reviews validation SDLC (system delivery lifecycle) deliverables created by others for adherence to site validation SOPs and acts as validation approver as needed.
- Supports client and regulatory audits.
- All other duties as assigned.

Required education and experience

- Bachelor's degree in science, automation, engineering, manufacturing technology or closely related field.
- 5 years HMI systems programming and testing experiences
- Proficient understanding of analog advanced control and batch control

- Proficient knowledge of P&IDs (piping and instrumentation diagram) and instrumentation/control equipment in an industrial environment
- 8+ years of experience in the validation of equipment, facility, and laboratory instruments including those with computerized systems (e.g. Bioreactor, Agilent HPLC, Micro-osmometer, Analyzer, Micro Plate Reader, Autoclave, Incubator, Unifuge, Endosafe, Endoscan, FT-IR, LIMS, Empower, Bioanalyzer, Particle Counter, TOC, UV_Vis) in a biotechnology or pharmaceutical cGMP manufacturing environment.
- 5+ years of experience in performing periodic review of laboratory instruments including those with computerized systems.
- 5-8 years' experience in validation of instruments including those with computerized systems (ie. FT-IR, HPLC, UV Vis, SCADA, Wonderware, Particle Counter, TOC, Conductivity, LIMS, MES/EBR, ERP, etc..) in a cGMP environment.
- Experience with SFOL/MES, AssurX, InstantGMP, Change Management, CAPA systems.

Qualifications

- Excellent attention to detail and working knowledge of FDA Regulations/Guidance, and Good Manufacturing Practices
- Demonstrated understanding of global regulations on data integrity, FDA 21 CFR Part 11 and validation/qualification requirements.
- Understanding of the control methods, analog and discrete and the critical components to developing sustainable control algorithms
- Ability to manage multiple activities and constantly change priorities.
- Exposure to lab operations, automation and scientific processes associated as well as familiarity with a variety of laboratory instruments within various areas (Biological, Chemical, Environmental Monitoring, Quality Control, Micro, Manufacturing, Lab, etc.).
- Ability to work both independently and in partnership with others; proven ability to use initiative and drive to achieve results.
- Proven ability to follow a variety of instructions furnished in written, oral, diagram, or schedule form.
- Excellent communication skills, oral and written, and attention to detail.
- Mastery of core computer software/systems (Word, Excel, Microsoft Project, Visio, SharePoint, Teams, etc.).
- Able to act in a leadership role.
- Demonstrated expertise in identifying as well as formulating procedural controls to compensate for shortcomings in the system's data integrity and FDA 21 CFR Part 11 controls.
- Demonstrate leadership in loop checking, startup, troubleshooting and commissioning support in a biotech/pharma environment
- Lean Sigma Greenbelt Certification.
- Strong critical thinking and problem-solving skills.
- Project Management experience.

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.