Senior Facilities Engineer, Validation, Calibration and Equipment Management
Job Code 578SB

Description:
Fate Therapeutics is seeking a talented and highly motivated facilities engineer to work with our Facilities, Manufacturing, Process Sciences, and R&D teams to provide hands-on Calibration and Metrology support, equipment management services and validation support. The successful candidate will schedule and perform maintenance of equipment utilized by R&D and GMP end-users, in conjunction with third party resources. The successful candidate will support the Facilities Department complying with cGMP, SOPs and applying GDP (Good Documentation Practices). This individual will oversee that contractors are trained on our SOPs and complete the tasks in a compliant manner, ensuring that the necessary documentation is completed accurately. This is a full-time position reporting to the Senior Manager, Facilities and is located at our corporate headquarters in San Diego, California.

Primary Responsibilities:
- Complete calibrations and maintenance activities with accurate and timely GMP documentation following Company SOPs.
- Develop, implement and deploy validation policies, procedures, and protocols. Work alongside Technical functions including Manufacturing and Quality to create and execute validation protocols, and equipment, systems and process validation studies.
- Read quality control manuals and testing specifications to obtain data to test and / or calibrate specific devices.
- Ensure validation follows a lifecycle approach from URS development through equipment/facility retirement. Ensure the validated state of equipment, systems, and processes are maintained through periodic review and revalidation programs.
- Support the maintenance of all facilities working standards (manufacturing, utilities and labs).
- Use of hand tools and precision measuring and calibrating instruments and equipment.
- Interact with other departments and personnel to resolve any calibration or equipment issues.
- Provide guidance and recommendations on selection of instruments and operational parameters.
- Maintain a safe work environment; work in a safe manner following all safety SOPs and wear Personal Protective Equipment as required.
- Maintain accurate record keeping of equipment and systems while being cGMP compliant.
- Work independently and make sound judgments regarding work methods and tools.
- Work with third party Vendors while performing services on the equipment to ensure that all are following Company and GMP policies.
- Review, investigate, and report on the identification of Out of Tolerance (OOT) conditions. Assist with investigations and corrective actions to preclude the recurrence of similar issues.
- Keep inventory of equipment critical spare parts.
- Support investigations, change controls, RCAs, or new projects.
- Execute and/or ensure that assigned Calibrations and Work Orders (WO) are completed per schedule.
- Maintain equipment lists and enroll new equipment into calibration and maintenance schedules; Generate weekly and monthly system reports.

Qualifications:

- A minimum of 7 years of equipment maintenance and calibration/metrology related experience in the biotech or pharmaceutical industry.
- Bachelor's degree preferred.
- Must have an excellent understanding of GMP, lab operations, and a working knowledge of validation protocols: IQ, OQ, and PQ.
- Mechanical knowledge of equipment and tools, including their designs, uses, repair, and maintenance such as Biosafety Cabinets, incubators, centrifuges, refrigerators, freezers, and other general laboratory equipment.
- Broad knowledge of GMP principles, concepts, practices and standards in the US and internationally.
- Broad knowledge of 21CFR Part 210 and 211.
- Specific calibration and metrology training preferred.
- Requires the use of basic math skills and the ability to use technical calibration equipment.
- Ability to troubleshoot basic electrical, programmable logic controllers (PLC), plumbing systems and issues.
- Proficient problem-solving abilities along with being detail-oriented.
- Ability to work and communicate cross-functionally.
- Good written and verbal communication and interpersonal skills.
- Self-motivated, flexible, able to prioritize, multi-task, and work in a fast-paced & dynamic environment.

Working Conditions and Physical Requirements:

- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work will be required

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference job code 578SB.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.