Senior Computerized Systems Validation (CSV) Engineer
Job Code 601SM

General Description

Fate Therapeutics Information Technology group is seeking an experienced Senior Computerized Systems Validation (CSV) Engineer to oversee and perform computer systems validation activities enterprise-wide, ensuring that business processes required to operate are qualified and maintained in a validated state according to company directives and procedures. The successful candidate will have advanced knowledge and experience developing and leading CSV and Life-cycle management activities to support GxP conforming systems, facilities, manufacturing and laboratory systems. The Senior CSV Engineer understands industry-wide and Regulatory expectations for computer system validation and works with members of IT, QA, and Site organizations to ensure that Computerized System Validation (CSV) packages are consistent with validation plans and standard operating procedures and utilizes industry experience to identify continuous improvement opportunities for IT CSV practices. This position reports to the Director, Information Technology and is located at our corporate headquarters and research facilities in San Diego, California.

Responsibilities

- Conception, planning and performing of Computer Systems Validation (CSV) in the regulated environment.
- Advisory and support of application owners to build and maintain GxP conforming systems and ensure compliance with applicable regulations and industry standards.
- Implementation of qualification/validation requirements for new and existing computer systems.
- Development and implementation of IT procedures that adhere to Data Integrity requirements as defined in applicable regulation for Raw-Data-Handling systems and solutions.
- Oversee and perform computer system validation activities and ensures the approach and execution aligns to applicable regulations, GAMP 5, and Fate's directives and procedures.
- Develop/enhance and implement Computer Systems Validation documentation such as VPs, Test Scripts, Assessments, Reports, SOPs, Policies.
- Support the implementation and adoption of the global CSV program and remediation.
- Support data integrity implementation and remediation for systems within CSV program.
- Participate in audits and continuous improvement efforts related to CSV program.
- Support Fate to achieve all CSV site and corporate goals.
- Manage CSV staff and contractors.

Qualifications

- Bachelor's Degree (BS) with an emphasis in Engineering/Sciences or equivalent.
- A minimum of 7 years relevant CSV experience, preferably in the biotech / pharma industry. Direct experience with IT and MFG automation systems supporting GMP manufacturing.
- Direct experience implementing CSV activities to support GxP systems.
- Strong knowledge of FDA and cGMP regulations and documentation practices.
- Strong knowledge of GAMP 5.
- Strong knowledge of 21 CFR Part 11 and Annex 11.
- Strong knowledge of computer system validation methodologies.
- Understanding of modern and risk-based validation executions.

- Background in Lifesciences and/or Pharma/Biotech industries (or understanding of bioprocessing and support processes).
- Ability to work both independently and cross-functionally with IT, QA, and Site organizations in a dynamic, ever-changing environment.
- Experience managing direct reports and external vendors.

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 curriculum vitae to: careers@fatetherapeutics.com and reference job 601SM.

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.