Contract Senior QC Analyst

To apply please send your resume to **jobs@sqzbiotech.com**

Our Purpose: Empower Cells to Change Lives

At SQZ Biotechnologies (NYSE: SQZ) we believe that our cell therapies will revolutionize the way we treat diseases. Our unique capabilities enable us to engineer almost any function into any cell type, breaking down the barriers in the field, and creating the possibility for cell therapies that could not have been previously envisioned.

The Role

SQZ is a dynamic, fast-paced, and people-centric biotechnology company located in Watertown, MA. With an ambitious mission in the field of personalized medicine and continued growth, we are seeking a **Contract Senior QC Analyst** to join our Quality Control (QC) team group in Q2 2023.

Reporting to the Director of Analytical Development & Quality Control, the successful candidate will support release and characterization testing on autologous cell therapy final drug product, FIO raw materials and process media testing, and stability studies on final drug product and process media.

The ideal candidate communicates effectively, drives results, motivates, and is team oriented.

Responsibilities Include, But Are Not Limited To

- Execution of cGMP routine in-process and final release testing of autologous cell therapy products (multicolor flow cytometry, qPCR, cell-based assays, compendial methods)
- Compilation of CoA packets
- Peer review and evaluation of raw data
- Timely submission of testing documentation to support rapid turnaround time for product release.
- Maintain familiarity with cGMP guidance documents (USP, EP, CFR, ICH)
- Initiate and review laboratory deviations (invalid assays, OOSs/OOTs), continuous improvement initiatives, and CAPA or other investigations, as required.
- Manage QC operational systems (logbooks entry and review, data integrity, cGMP documentation, LIMS, and laboratory audit)
- Work with cross functional departments including but not limited to Analytical Development, Process Development, Supply Chain, and Quality Assurance
- Adhere to analytical test methods, standard operating procedures, and good documentation practices to ensure data integrity and traceability.
- Support execution and review of phase-appropriate test method validation protocols, as needed.
- Support regulatory filings and inspections, as needed.
- Train new hires, or cross-train existing QC team members

- Author and review quality records (Deviations, CAPA, change controls), analytical test methods, SOPs, protocols, and reports.

Candidate Must

- Work independently and support multiple projects simultaneously in a fast-paced and collaborative environment.
- Demonstrate critical thinking, strong problem solving, and attention to detail
- Possess excellent oral communication, technical writing, and time management skills.

Minimum Qualifications

- Degree in scientific field required (Chemistry, Biotechnology, Biochemistry, Biological sciences, or relevant field) with a **required minimum of 4+ years (BS.) or 1-2 years (MS.) of industry Quality Control experience.**
- Experience working in a drug development or GCLP environment.
- Experience with cell-based assays, multi-color flow cytometry, and other analytical methods such as ELISA, Western blot, qPCR, and compendial methods.
- Knowledge and experience in CMC and regulatory strategy, cGMP, ICH guidelines, USP and EP compendial methods.
- Experience with Good Documentation Practices.

Preferred Qualifications

- Experience with cell therapies or vaccines
- Experience with analytical method validations and/or transfers.

SQZ Biotechnologies is proud to be an equal opportunity employer and to provide equal opportunities to all employees and applicants for employment without regard to race, color, religion, sex or gender identity, national origin, age, disability, sexual orientation, or genetics. In addition to federal law requirements, SQZ complies with applicable state and local laws governing nondiscrimination in employment.

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