GC Therapeutics

GC Therapeutics, Inc.
610 Main St., North
Cambridge, MA 02139
info@gc-tx.com

www.gc-tx.com

Scientist – Assay Development

Company Overview

GC Therapeutics is the first genome-wide cell landscape exploration company using an integrated synthetic biology and AI-driven platform for cell programming. Its patent-pending and proprietary pluripotent stem cell differentiation technology platform TFome™ was developed in Professor George Church's lab, a pioneer in synthetic biology, and allows for the development of unique cell therapies with significantly streamlined manufacturing, improved cell quality, efficiency, and speed. GC Therapeutics is based in Cambridge, MA. For additional information, please visit www.gc-tx.com.

Job Purpose

GC Therapeutics is seeking a talented and highly motivated Scientist to support the qualification and validation of assays for the testing, characterization, and release of novel Pluripotent Stem Cell (PSC) derived products. This individual will be expected to design and execute experiments that determine assay performance including the assessment of assay specificity, accuracy, precision, linearity, range, reproducibility, robustness, and ruggedness.

Duties and Responsibilities

- Design, develop and validate assays for testing the safety and efficacy of stem cell-derived drug substances, products, and critical starting material.
- Analyze data and contribute to complex technical reports and team meetings.
- Contribute and author module 3 documents including analytical procedure development and validation of analytical procedures necessary for IND submissions.
- Develop procedures and protocols for the genetic, transcriptomic, proteomic, and functional characterization of pluripotent stem cells and their derivatives.
- Qualify and validate product specific assays to determine identity, purity, and potency of PSC derived products including various cell based assays, flow cytometry, immunohistochemistry, ELISA, and ddPCR.
- Prepare complex technical reports including SOPs, test methods and method development reports.
- Lead the transfer of assays to quality control (QC) team and external contract manufacturing organizations as needed.
- Contribute to team and company presentations.

General Laboratory Roles:

- Responsible for experimental design, data generation, analysis, and communication of results to supervisor, and team members.
- Maintain well-organized and up-to-date records of all research activities, including writing detailed protocols, technical reports, and developing appropriate documentation for processes.
- Provide scientific and technical supervision to junior staff or contract manufacturing organizations for defined projects.
- Maintain a detailed laboratory journal, summarize results, and create presentations for internal group meetings.
- Exemplify scientific curiosity and deep expertise with relevant literature and cutting-edge technologies to advance research directions.
- Work with other members of the research team, process development team to accomplish company goals.
- Follow all safe laboratory practices and company policies.

Experimental Techniques:

Cellular Biology:

- Analyze differentiated cell products and establish QC assays.
- Qualify and validate cell based biological assays and other quantitative assays including flow cytometry and immunohistochemistry.

Molecular Biology:

- Utilize various molecular biology techniques such as PCR, qPCR and ddPCR.

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Qualifications

Essential Qualifications:

- PhD with 2 years of molecular and cellular assay development in the biotech industry, or MS in Biology, Molecular Biology or similar with 5+ years of related experience or BS with 10+ years of related experience.
- Experienced in the development and validation of cell based assays and flow cytometry assays to assess major cell population detected in several differentiated PSC derived products.
- Expert in designing and executing experiments that determine assay performance including the assessment of assay specificity, accuracy, precision, linearity, range, reproducibility, and robustness and ruggedness.
- Experience in developing assays that use methods such as flow cytometry, qPCR and ddPCR, immunoassays, and/or next generation sequencing.
- Experience writing technical documents for assays including SOPs, test methods and method development reports.
- Demonstrated ability to work in a dynamic environment as a team player and committed to completing projects within timelines.
- Experience in writing technical documents for assays including SOPs, test methods, and IND ready documentation for submission to FDA.
- Proficient in analysis, presentation and documentation of scientific data as well as preparation of scientific reports.
- Effective communicator with excellent interpersonal skills.
- Strong project management and organizational skills and ability to prioritize and multitask.

Additional Preferred Qualifications:

- Desired skills include stem cell culture experience and computational biology.
- Knowledge of PSC manufacturing principles, risk assessments, Chemistry, Manufacturing, and Controls (CMC) principles.
- Experience with PSC with practical familiarity with stem cell differentiation protocols.
- Knowledge of R, Python, Bionano instrument and FlowJo.
- Familiarity with techniques used to measure genome integrity and off target characterization.
- Familiarity with automation, high throughput (HTP) imaging and cell cloning.

Interested? Contact recruiting@gc-tx.com to apply!

Send your CV with the subject “Scientist - Assay Development”.

Equal Opportunity Workplace: GC Therapeutics is an equal opportunity employer. We provide equal employment opportunities to all applicants for employment and existing employees without regard to ancestry, national origin, place of birth, race, color, gender, sexual orientation, marital status, pregnancy, religion, age, disability, gender identity, results of genetic testing, service in the military or otherwise to the full extent of all federal, state and local laws. GC Therapeutics’ equal employment opportunity policy applies to all terms and conditions of recruiting, hiring, placement, training, compensation, transfer, leave of absence, employment, promotion, layoff and termination of employment.