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Scientist/Senior Scientist - Process Development

Company Overview

GC Therapeutics is the first genome-wide cell landscape exploration company using an integrated synthetic biology and Al-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 for our Process Development (PD) team. The candidate will have strong expertise in process optimization with focus in human pluripotent stem cell (PSC) biology. This individual will be expected to generate PD lots consisting of engineered PSCs based on the technology developed by the research team. This role will involve bringing a new class of cellular therapies to patients using GCTx's Human TFome[™] platform, a synthetic biology-driven technology to differentiate stem cells. The scientist will be responsible for daily tasks involving optimization of critical process parameters using Quality by Design (QbD) approach and Design of Experiments (DOE).

Duties and Responsibilities

- Active hands-on involvement in developing an optimized process for manufacturing of PD lots.
- Design and execute detailed experiments using QbD principles, DOE, and process characterization/modeling techniques to develop and understand drug product processes.
- Participate in tech transfer of processes from a non-GMP environment to a GMP-compliant manufacturing facility (e.g. contract development and manufacturing organizations (CDMOs) will be essential to this position.
- Interface with key functions such as R&D, manufacturing, quality control, clinical development, and regulatory teams to develop and execute on multiple programs.
- Support authoring and reviewing regulatory submissions as necessary.

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 research organizations (CROs) 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 and within GCTx to accomplish company goals.
- Follow all safe laboratory practices and company policies.

Experimental Techniques:

Cellular Biology:

- Design and execute synthetic biology-based differentiation experiments of PSCs.
- Optimize, refine and scale differentiation protocols for candidate cell therapeutic products.
- Analyze differentiated cell products and establish quality control (QC) metrics.
- Selection and culture PSC lines including maintenance and analysis (e.g. cell culture, transfection, preparation of media, passaging, cryopreservation).
- Perform cell type differentiation, characterization and experimental endpoint analysis including flow cytometry, ELISA and microscopy.
- Perform DOE studies to optimize parameters affecting engineered cell line differentiation and stability.



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Molecular Biology:

- Utilize techniques such as PCR, qPCR, ddPCR, molecular cloning and plasmid isolation.
- Characterize target cell types using next-generation sequencing methods (e.g. library preparation for bulk and single cell RNA-seq) and other gene expression analysis techniques.

Qualifications

Essential Qualifications:

- Ph.D. degree in stem cell biology, cell biology, bioengineering, biochemistry, or related discipline and 5+ years of laboratory work experience in industry.
- Required experience with mammalian cell culture.
- Proven experience in basic molecular biology laboratory techniques.
- Strong work ethic with the ability to perform tasks independently and lead junior staff effectively.
- 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.
- Strong knowledge of PSC manufacturing principles, risk assessments (FMEA), Chemistry, Manufacturing, and Controls (CMC) principles.
- Ability to work in a laboratory environment approximately 75% of the time including some weekends.

Additional Preferred Qualifications:

- Experience with PSC with practical familiarity with stem cell differentiation protocols.
- Experience in genome editing.
- Proven track record and strong publications in stem cell or developmental biology.
- Ability to analyze next generation sequencing or other genome-scale datasets.
- 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 - Stem Cell Biology Process Development and 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.