JOB DESCRIPTION

POSITION TITLE(s):
Research Scientist/Associate Scientist – Drug Substance Process Development
Two (2) positions are available

REPORTS TO:
Senior Director, Process Development

LOCATION:
Groton, CT.

GENERAL DESCRIPTION:

Assembly Biosciences, Inc. is a clinical-stage biotechnology company advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and novel oral biotherapeutics for disorders associated with the microbiome. The selected candidates for Drug Substance Process Development will play a pivotal and leadership role in the development of processes for the production of human commensal bacteria suitable for formulation as Drug Product. The Scientist will have responsibilities for building in-house GMP-ready drug substance manufacturing capabilities and associated analytical support and also identify, evaluate, and qualify new technologies. The Scientist will also play a critical role in the Technology Transfer of developed processes to CMOs contracted to perform GMP Manufacturing of Drug Substance. It is expected that the individual will also work closely with the Drug Product formulations team to coordinate the transfer of formulations and processes, facilitate phase-appropriate scale-up, provide analytical support and lead troubleshooting activities.

RESPONSIBILITIES:

- Develop the requirements for and build in-house GMP-ready drug substance manufacturing capabilities
- Identify, evaluate, and qualify new technologies related to fermentation, harvest, and lyophilization
- Contribute to studies and/or activities necessary for process optimization and continuous improvement to assure robust and cost-effective manufacturing processes
- Assure consistent and reproducible manufacturing processes and final drug substances
- Support OOS, root cause, and CAPA investigations, as necessary
- Manage and execute troubleshooting activities, as necessary

- Transfer manufacturing operations to alternate sites, as appropriate, to assure continuity of supply
- Support the Drug Product Process Development group with material supply and some analytical support
- Write technical reports
- Contribute to preparation and review of regulatory documents for submission to FDA and other regulatory authorities
- Identify and utilize expert consultants, when necessary
- Build and maintain a strong cooperative working relationship with colleagues in Drug Product, Analytical, Quality, Regulatory, Clinical Development, Project Management, and Legal
- Must have ability to travel on a limited basis (10%).

PERSONAL ATTRIBUTES:

- Motivated self-starter who can work independently with minimal supervision
- Excellent professional and interpersonal skills, especially for developing and maintaining relationships with CMO's
- Excellent oral and written communication skills
- Ability to work efficiently and cooperatively in a virtual company environment
- Goal oriented and ability to deliver on timelines and commitments
- Exhibits a proactive, transparent, and rigorously objective confidence in all aspects of manufacturing operations

MINIMUM REQUIREMENTS

- Ph.D. in Microbiology, Biology or a related discipline, or BS/MS with 6+ years' experience in Biotech/Pharma industry with hands-on background and experience with fermentation and/or lyophilization
- Specific experience with processing and fermentation of anaerobic cultures is highly desirable
- Hands-on experience with all pharmaceutical processing equipment, including the ability to set-up, operate, and troubleshoot equipment
- Demonstrated ability to independently write technical reports
- Understanding of the drug development process outside an academic setting
- Knowledge of cGMPs, especially as related to a virtual environment where manufacturing is currently outsourced to third party vendors

Please respond directly to the hiring manager at chartnett@assemblybio.com