JOB DESCRIPTION

POSITION TITLE:
Associate Scientist/Scientist, Drug Product Development

REPORTS TO:
Director/Sr. Director, Drug Product 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 candidate for Associate Scientist/Scientist, Drug Product Development will play an instrumental role in the development of pharmaceutical formulations and processes, including hands-on operation of all equipment used to manufacture solid oral dosage forms.

RESPONSIBILITIES:

- Assist to develop the requirements for and build in-house drug product development and manufacturing capabilities at new Groton, CT location, including defining user requirements and procurement of equipment.
- Assist formulation scientists in the development of robust and stable pharmaceutical drug products.
- Perform hands-on operations for pharmaceutical manufacturing of solid oral dosage forms, including, but not limited to, dispensing, blending, milling/screening, encapsulation, tableting, banding, coating, weight sorting, packaging, and labeling.
- Manufacture drug product batches.
- Perform equipment set-up, break-down, and cleaning, including appropriate care and storage of all change parts.
- Procure supplies necessary to perform work, including excipients, components, laboratory supplies, etc.
- Assist and contribute to studies and/or activities necessary for process optimization and continuous improvement to assure robust and cost-effective manufacturing processes.
- Assist with troubleshooting, deviations, and investigations, as requested.

- Write and review SOPs.
- Write and review batch records.
- Understand and practice good documentation practices.
- Document all work in laboratory notebook(s) or other acceptable forms (*e.g.,* batch records).
- Build and maintain a strong cooperative working relationship with colleagues in Drug Substance, Analytical, and Quality.

PERSONAL ATTRIBUTES:

- Motivated self-starter who can work independently with minimal to moderate supervision.
- Excellent professional and interpersonal skills.
- Excellent oral and written communication skills.
- Ability to work efficiently and cooperatively in a small laboratory 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 for solid oral dosage forms.

MINIMUM REQUIREMENTS

- B.S/M.S. in chemistry, engineering, pharmacy, or related discipline with 5+ years experience in pharmaceutical industry with experience in formulations and processing of solid oral dosage forms.
- Hands-on experience with all pharmaceutical processing equipment for solid oral dosage forms, including the ability to set-up, operate, and troubleshoot equipment.
- Ability to use personal protective equipment, as required.
- Familiar with all aspects of drug product development for solid oral dosage forms.
- Familiar with pharmaceutical GLPs and GMPs, especially as related to solid oral dosage form manufacturing.

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