JOB DESCRIPTION

POSITION TITLE:
Scientist/Sr. Scientist, Preformulation-Formulation Development

REPORTS TO:
VP, 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 Scientist/Sr. Scientist, Preformulation-Formulation Development will play a pivotal role in assessing physical, chemical, and biological characteristics of Assembly's wide range of drug substance candidates in preparation for drug product development. In addition, the successful candidate will explore and characterize early drug product formulations with the intent to advance one or more into early phase clinical trials. It is expected that the individual will work closely with the drug substance and drug product development teams to facilitate selection of drug substance candidates for drug product development. This is a hands-on position in which the successful candidate will be expected to work with instruments and equipment in a laboratory environment.

RESPONSIBILITIES:

- Perform hands-on characterization studies on drug substance candidates, including, but not limited to, excipient compatibility, temperature sensitivity, O_2 sensitivity, light sensitivity, moisture uptake, particle size distribution, bulk density, tap density, solid state properties, powder/blend uniformity, thermal properties, etc.
- Perform hands-on unit operations for pharmaceutical formulation development of solid oral dosage forms.
- Develop the requirements for and build in-house preformulation/formulation capabilities at new Groton, CT laboratory location, including defining user requirements and procurement of equipment/instrumentation necessary to perform preformulation/formulation activities.
- Perform compatibility and stability studies to propose and assess early formulation candidates.
- Write procedures and execute qualifications for equipment and instrumentation.
- Understand and practice good documentation practices.
- Write and review SOPs and technical reports.
- Document all work in laboratory notebook(s) or other acceptable forms (*e.g.,* batch records).

- 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.
- 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 Substance, Drug Product, Analytical, and Quality.

PERSONAL ATTRIBUTES:

- Motivated self-starter who can work independently with minimal 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 work activities.

MINIMUM REQUIREMENTS

- Ph.D. in pharmaceutical sciences with 3-5 years or BS/MS with 5-15 years experience in pharmaceutical industry with hands-on preformulation/formulation laboratory experience to support solid oral dosage forms.
- Hands-on experience with all pharmaceutical equipment/instrumentation to support preformulation/formulation activities for solid oral dosage forms. Hands-on experience with small-scale processing equipment for solid oral dosage forms is a huge plus.
- Demonstrated ability to independently write SOPs and technical reports.
- Knowledge of pharmaceutical GLPs and GMPs, especially as related to solid oral dosage form manufacturing.

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