



## **JOB DESCRIPTION**

### **POSITION TITLE(s):**

Senior Scientist/Senior Manager – Analytical Development

### **REPORTS TO:**

Senior Director, Analytical Development and Quality Control

### **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 Senior Research Scientist/Senior Manager – Analytical Development will be expected to perform a hands-on functional leadership role in the development and execution of analytical methodologies in support of process development and characterization activities. The successful candidate will be tasked with establishing and operating a functional analytical development laboratory, including equipment procurement and qualification as well as leadership in identifying, evaluating, and qualifying new technologies. It is expected that the individual will work closely with Process Development teams to coordinate testing activities, as well as authorship of technical protocols and reports, as well as contributing to the content of regulatory filings. Expertise in method development, execution and troubleshooting of existing methods are key requirements for this role. Specific proficiency with Karl Fischer, water activity, dissolution/disintegration and experience with other microbiological testing such as microscopy, viability, and general spectrophotometric techniques is highly desired. A proven track record of successful leadership and demonstrated abilities for out of the box thinking, and motivation to seek answers in troubleshooting activities are key competencies of this role. Additionally, the successful candidate will be expected to function independently with minimal supervision. Knowledge of good documentation practices and an attention to detail are also expected of the incumbent.

### **RESPONSIBILITIES:**

- Develop, build, and oversee operations for in-house analytical development and testing capabilities, including participation in the hiring process
- Identify, evaluate, and qualify new technologies related to microbiological agents
- Serve as analytical liaison to process development teams
- Transfer and develop robust and reproducible analytical methodologies for evaluation of product quality attributes and characterization studies

- Support OOS, root cause, and CAPA investigations, including management and execution of troubleshooting activities, as necessary
- Execute analytical testing and author technical documents
- 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, 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 CMOs
- 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 analytical development activities

**MINIMUM REQUIREMENTS**

- Education in Microbiology, Chemistry or a related discipline, experience in Biotech/Pharma industry with hands-on background and directly relevant experience with microbiological/biologic testing. Position level and compensation for Senior Scientist or Senior Manager will depend on education and experience; Ph.D. preferred, relevant experience may substitute for education level
- Specific experience with anaerobic cultures is highly desirable
- Hands-on experience with applicable analytical instrumentation, including the ability to set-up, operate, and troubleshoot equipment
- Demonstrated ability to independently write technical reports
- Knowledge of cGMPs, regulatory expectations

Please respond directly to the hiring manager at [scockrill@assemblybio.com](mailto:scockrill@assemblybio.com)