

## Job description: Chemist - Quality Control Testing and Method development

Bespoke Pharmaceutical LLC offers an exciting opportunity for passionate scientists and engineers to make a difference in the world while developing career paths for advancement.

Bespoke Pharmaceutical is seeking a Chemist to assist with Quality Control, Environmental monitoring, and stability testing.

The incumbent will be responsible for Analytical method development, method transfer, verification, Validation, and quality control testing. An ideal candidate should be able to improve the quality of products through testing specifications and support all quality unit activities.

### **Responsibilities include:**

- Develop test method and perform QC stability, in-process and finished product tests
- Review and approved Analytical methods and create product specifications.
- Review and approve analytical data and results.
- Train team members on USP analytical methods and techniques
- Assign and oversee QC operations (i.e., method validation, routine analysis of materials (raw, intermediates, and final products), retention library, etc.), independently.
- Ensure compliance with Quality Systems
- Provides technical support to team members (method development, validation, routine analysis)
- Assist in supporting day-to-day laboratory operations.
- Execute method development.
- Complete method transfers from R&D to QC (quality control) or to an external contract testing laboratory (CTL)
- Design stability plan and perform stability pull out testing of finish product
- Independently generate sound analytical data and produce the associated technical reports.
- Conduct verification and/or validation of methods execution.
- Writing and/or approval of qualification, validation, and stability protocols and/or reports
- Develop In-Process-Control test procedures.
- Perform QC testing and/or release of cgmp materials as needed.
- Write and approve QC and analytical documentation.

- Maintain Quality Control related documentation (QC sops and methods, test methods, analytical validation and/or qualification, reference standard qualification, and stability studies, specifications)
- Maintain data within company data integrity standards.
- Assist with other analytical services as needed.

### **Qualifications**

Minimum of a bachelor's degree in chemistry, pharmaceutical sciences, or related field; or training and equivalent work experience at a level that equates to M.S. degree. An ideal candidate will have a PhD in chemistry.

- At least 5-10 years of experience with analytical testing in a Pharmaceutical Quality Control Laboratory environment
- cGMP training including highly familiar with USP chapters, FDA, and ICH guidelines.
- Experience writing, reviewing, and approving QC documentation (protocols, SOPs, test methods, and investigations)
- Experience in modern analytical techniques including Karl Fisher titrator, UV-VIS, FTIR, TOC, BSC, Incubators, HPLC, GC, Mass Spectrometry etc.
- Demonstrate excellent attention to detail, ability to learn instrumental techniques, and maintain good record keeping.
- Experience in testing products to specifications and monitoring of stability testing of products
- Ability to interpret QC test results and provide trends and KPI for all the QC laboratory testing activities.
- Experience environmental monitoring of a clean room in sterile injectable.
- Sterile injectable, small molecule experience
- Ability to work collaboratively with multi-disciplinary cross-functional research teams.
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand Pharmaceuticals

### **Physical Demands/Work Environment:**

- Ability to safely manage hazardous materials.
- Ability to bend to reach floor level.
- Ability to wear respirator.

### **On Demand Pharmaceuticals is an equal opportunity employer.**

Bespoke Pharmaceutical LLC does not discriminate in employment with regard to race, color, religion, national origin, citizenship status, ancestry, age, sex(including pregnancy, gender identity, or related medical conditions), sexual orientation, marital status, physical or mental disability, past or present military service or any other characteristic protected by law.