

## QC Chemist

INCOG BioPharma is looking for a QC Chemist to join the QC team to identify analytical needs, solve complex problems, and deliver solutions for various routine and non-routine processes.

The QC Chemist will be working closely with the QC Chemistry Manager, and other members of the QC leadership team, and will be influential in supporting the QC operations.

### Key Responsibilities:

- Maintain a coaching/mentoring presence within the lab to allow for continuous personal and technical development of colleagues.
- Review and approve work of coworkers, whilst setting deadlines and work priorities.
- Collaborate with other departments and teams to resolve quality issues regarding facilities, and the products being manufactured and released.
- Support internal and external customers by ensuring timelines are met whilst maintaining the best quality service throughout the analytical method life cycle.
- Perform routine chemical and physical testing of drug products, excipients, raw materials, and process materials according to validated methods (HPLC, GC, UV-Vis, TOC, particulate matter, FTIR, wet chemistry). Testing is related to drug product lots, release testing, stability testing, analytical method transfer, and method validations.
- Partner with vendors to coordinate and perform routine preventative maintenance on QC Chemistry lab instrumentation as needed using written SOPs.
- Troubleshoot to support laboratory investigations with respect to methods, assays, and equipment errors, and exercise rapid decision making to implement CAPAs during OOS/OOT and other non-conformance events.
- Develop, execute, review, and approve protocols & SOPs for testing procedures, method transfers, method validations, stability studies, cleaning validations and any other non-routine testing required.
- Represent the QC department as a QC Chemistry SME (analytical and physical chemistry testing, validations, laboratory instruments, laboratory and testing compliance, cGLPs, and cGMPs, and investigations).
- Control and manage QC Chemistry laboratory waste streams in cooperation with relevant EH&S standards.
- Other aspects involved as instructed.

### Education and Experience Requirements:

- Bachelor's Degree in Science (Chemistry or Biochemistry).
- Minimum of 3+ years of industry experience, hands-on experience in a GMP environment/QC testing in a regulated environment..
- High proficiency level in operating UHPLC/HPLC, GC, titration, UV-VIS, TOC, particulate matter analysis, method validation/transfer, and relevant laboratory computer systems with associated data integrity requirements.
- Working knowledge, understanding and experience with practical implementation of FDA, EMA, and other regulatory authority expectations for QC.
- Exceptional computer skills evidenced by working with automated data management and/or data analysis systems (LIMS, JMP, Minitab, etc.)

**Preferred Qualifications (not essential):**

- Master's Degree in Science (Chemistry or Biochemistry) with 0-2 years biopharma industry experience and 1 year+ of hands-on experience within a GMP/ highly-regulated industry in a QC respect.
- PhD Degree in Science (Chemistry or Biochemistry) with 0-2 years biopharma industry experience. GMP environment/QC testing in a regulated environment preferred.
- 2+ years of working in a GMP/other highly regulated laboratory/ clean room environment.
- Experience with Continuous improvement, Six Sigma, and/or Lean principles.
- Experience with building processes and procedures.
- Experience in an isolator-based aseptic drug product manufacturing facility.
- Experience performing container closure integrity testing (CCIT).

*Don't meet all the requirements? Don't sweat! We're always looking for an excuse to discuss your next opportunity. You might just surprise yourself...*

*Lead Candidate wholeheartedly supports Equality and Diversity in employment and opposes all forms of unlawful or unfair discrimination on the grounds of age, disability, sex, gender reassignment, sexual orientation, pregnancy and maternity, race, religion or belief and marriage and civil partnerships.*