Job Description

Job Title: Quality Control Analyst
Department: Quality Control
Reports to: Senior Manager, Quality Control
Work Hours: Full-time
FSLA Status: Exempt

Job Summary:

The QC Analyst will support the establishment and growth of BioFactura's QC department. Responsibilities include, but are not limited to, performing QC testing of DS/DP release and stability samples in support of BioFactura programs; ensuring compliance with established regulatory practices and standards; working with Analytical Development (AD) on the transfer of qualified assays to QC; assisting with assay validation activities; and authoring and review of SOPs, protocols, and reports.

Responsibilities:

- Execute Drug Substance and Drug Product release and stability testing in support of Phase I, II, III and commercial manufacturing of biotechnology products
- Draft and execute Method Qualification/ Validation Protocols and Reports
- Complete documentation needed to support testing procedures; including data capture forms, equipment logbooks, inventory forms, etc.
- Interpret test results against established specifications and control limits to assist in the disposition batches for release or identify trends in stability
- Write or revise Standard Operating Procedures, Work Instructions, Standard Test Methods, Qualification/Validation Protocols, and Data Forms
- Generate various compliance records- Deviations, Out of Specifications, Change Controls, CAPAs, etc.
- Monitor testing procedures to ensure that all tests are performed according to established item specifications, standard test methods, or protocols
- Verification of Compendial Methods for new product lines
- Train other analysts to perform laboratory procedures and assays
- Serve as a technical liaison between quality control and other departments, vendors, or contractors.
- Participate in functional teams with various experience levels and provide Quality input as needed
- Assist in the organization and management of GMP release and stability data
- Evaluate new technologies and methods to make recommendations regarding their use
- Ensure that lab cleanliness and safety standards are maintained
- Identify and troubleshoot equipment problems
- Evaluate analytical methods and procedures for continuous improvement

- Support QC laboratory inspection readiness strategy and activities
- Facilitate the tech transfer of methods from Analytical Development to Quality Control

Required Skills/Abilities:

- Hands on experience on a wide variety of analytical methods: Compendial assays (pH, A280, Sub-Visible Particles, Appearance, Endotoxin), ELISAs, PCR, SEC, CE-SDS, and CEX
- Experience working with, and testing, large molecule biologics
- Hands on experience in housekeeping of GMP QC Laboratories
- Excellent verbal and written communication skills, including technical writing.
- Excellent organizational skills and attention to detail.
- Strong level of initiative and quest for knowledge
- Ability to prioritize and manage tasks and operational flexibility.
- Ability to work well in a team and as an individual contributor
- Ability to function well in a high-paced and at times stressful environment.
- Proficiency with Microsoft Office Suite.
- Quest for knowledge and growth

Physical Requirements:

- Prolonged periods of sitting at a desk, working on a computer and scientific lab bench.
- Must be able to lift up to 20 pounds at times.

Education:

Bachelor's degree required.

About BioFactura:

BioFactura develops and commercializes biodefense drugs, novel drugs, and high-value biosimilars (i.e., follow-on biologics or generic biopharmaceuticals) using its patented StableFast™ Biomanufacturing Platform, the optimal choice for bringing these products to market with faster, lower cost, superior-quality manufacture. For over 10 years, BioFactura has been advancing life-saving medicines from the research bench to the patient using its innovative drug development and manufacturing technologies. Current and past programs include biodefense drugs against smallpox and Ebola, novel medicines for cancer, and low-cost/high-quality biosimilars for autoimmune and infectious diseases.

To Apply:

Complete online application at:
https://app.smartsheet.com/b/form/608870e585e145b9a1e3821a25370f7b
www.biofactura.com

BioFactura is a participant of E-verify.

BioFactura provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation, and training.