Job Description

Job Title: Scientist - Levels I, II, Senior, Principal
Department: Bimolecular Analytics
Reports to: Associate Director, Octet & Biomolecular Analytics
Work Hours: Full-time
FSLA Status: Exempt

Job Summary:

The Scientist will participate in and/or lead (1) the development of Octet assays to measure kinetic binding constants of protein-protein interaction and (2) development / qualification of a variety of assays for ensuring product quality. Title and salary are commensurate with education, experience, and responsibilities.

Responsibilities:

- Participate and/or lead the development, optimization, qualification, and troubleshooting of analytical methods.
- Perform analyses of complex data sets.
- Support implementation of new instrument and evaluation of new instruments/technology.
- Execute analytical assay methods for routine sample testing to support lot release/stability testing for monoclonal antibody products.
- Apply technical knowledge and abilities to ensure all testing is performed in a regulatory compliant manner.
- Participate and/or lead in transfer of methods to Quality Control Group.
- Author and review STMs, Protocols, and Reports.
- Mentor junior staff.
- Performs other related duties as assigned .

Required Skills/Abilities:

- Subject Matter Expert for Octet methods to determine kinetics of protein binding interactions.
    - Experience developing novel kinetic methods a plus.
- Experience in ELISA, qPCR cell-based assays, and/or compendial methods (A280, pH, etc.).
- Hands on experience in protein analytics including assessment of potency and/or residuals .
- Strong understanding with method development guidance (ICH, FDA, EMA, USP).
- Experience with current Good Laboratory Practices (cGLP) and Good Documentation Practices (cGDP).
- Organized and self-motivated.
- Experienced in method development and/or qualification.
- Excellent time management and proven ability to meet deadlines.

- Excellent communication, presentation, and writing skills.
- Excellent organizational skills and attention to detail.
- Excellent time management skills with a proven ability to meet deadlines.
- Ability to function well in a high-paced and at times stressful environment.
- Familiarity with Microsoft Office Suite.

Physical Requirements:

- Prolonged periods of sitting at a desk, working on a computer and scientific lab bench.
- Must be able to lift up to 15 pounds at times.

Education:

- Bachelors, Masters, or PhD diploma in life sciences.
- At least 7+ years (BS), 5+ years (MS), or 0 years (PhD) of industry, hands-on-experience with development and qualification of characterization/release assays for protein/DNA biological products.

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.

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