SalubrisBio 45 West Watkins Mill Road, Gaithersburg, MD

Job Title: Scientist – Formulation Development

Salubris Biotherapeutics, Inc. (or SalubrisBio) is a science-driven biotechnology company dedicated to the discovery and global development of novel antibody therapeutics for the treatment of cancer, cardiovascular and metabolic diseases. We strive to develop novel therapeutic molecules which provide clinically meaningful improvements in disease burden and quality of life to patients with significant medical needs. SalubrisBio is seeking a highly motivated full-time scientist with exceptional ability in formulation development for biotherapeutic antibody drug product development. The candidates shall have strong ability in multi-tasking and are expected to work in a fast paced, dynamic and changing start-up environment with high degree of self-motivation.

The company offers competitive benefits including medical, dental, vision and life insurance, as well as 401(k) match and paid time leave. SalubrisBio is an equal opportunity employer. To apply for this job, please contact Jinhua Feng (Jenny) by cell # (240) 938-1469 or by email: jinhua.feng@salubrisbio.com

Job Responsibilities:

- Act as the key expert in the development of stable and robust formulation for biotherapeutic novel antibody drug candidates in preclinical/clinical stage
- Identify, design, execute, and evaluate formulation for drug substance (DS) and drug product (DP) through thermo, conformational, and photo stability and solubility studies
- Perform SEC, DLS, particle, viscosity, and other analytical testing as needed to assess aggregation, fragmentation, thermostability, conformational stability, & photostability
- Lead the evaluation and selection of DP container and packaging system, coordinate DP fill/finish with CMOs, manage clinical supplies including labelling, and conduct compatibility study with clinical administration components
- Effectively and closely work with coworkers in downstream purification and analytical groups
- Responsible for maintaining and ensuring adherence to GMP compliance
- Support regulatory filing and review technical documents
- Order and maintain laboratory reagents and supplies, perform tasks as assigned

Qualifications:

- MS or Ph.D. in Biochemistry, Biophysics, Chemical Engineering, Biology, other relevant scientific field. MS with 3-8 years or Ph.D. with 0-5 years biopharmaceutic industry or academic experience with focus on formulation development for biotherapeutic antibody drug products
- Knowledge and experience in current approaches for clinical phase appropriate formulation development is preferred.
- Experience in one or more techniques of DLS, SEC, IEC, RP-HPLC, UV/VIS, FT-IR, CD, etc
- Knowledge in Design of Experiments and statistical principles for early stage formulation development and experience in stability study coordination and report.
- Good understanding of cGMP regulation relevant to biotherapeutic drug product development
- Hands-on experience of protein lyophilization process development is preferred
- Experience in development of analytical methods, such as HIC and IEC is plus
- Strong verbal and written communication skills and ability to manage multiple tasks simultaneously and pay attention to details
- Ability to work independently in a small company setting with limited operational support