Quality Assurance (QA) Specialist

Job Description

Job Title: Quality Assurance (QA) Specialist

Field: Product Development

Company: Salubris Biotherapeutics, Inc.

Location: Gaithersburg, MD

Salubris Biotherapeutics, Inc. (hereafter referred to as SalubrisBio) is a science-driven biotechnology company dedicated to the discovery and development of novel antibody therapeutics for the treatment of cancer and cardiovascular diseases. Our mission is to use innovative concept and technology to make a meaningful and impactful improvement in the health and lives of the patients. SalubrisBio is seeking highly motivated full-time scientists with exceptional ability to develop and transfer upstream process from development laboratory to clinical manufacturing facilities for antibody drug product production. 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.

Responsibilities and Duties

- Establish and improve Quality Assurance (QA) system and provide quality expertise
- Conduct quality review, audit, and tracking for processes, procedures, and data from CMO and CRO with GMP compliance
- Review and approve Standard Operating Procedures (SOPs), batch record, CofA, etc.
- Draft and review audits, quality plans, quality agreement and other quality related reports
- Manage quality systems including change control, deviation, training, document control
- Participate in or lead quality related investigations for process or product or testing
- Analyze and write deviations and reports and further recommend corrective actions
- Serve as a resource for staff at Gaithersburg site on issues pertaining to product quality
- Responsible for ensuring compliance to applicable quality regulations and standards
- Play an individual role in a multifunction project team

Qualifications and Skills

- Education: BS or MS in Chemistry, Biochemistry, Chemical Engineering
- BS with 9+ or MS with 7+ years of FDA regulated industry experience in quality assurance for biotherapeutic drug product development
- Strong background in US FDA regulations with cGMP compliance in support of biopharmaceutical manufacturing operation
- Ability to independently conduct quality audit and review of processes, procedures and data
- Hands-on experience in analytical development and/or process development is preferable
- Knowledge of quality assurance concepts and practices and managing basic quality systems, such as change control, deviation reporting, training, and document control
- Knowledge of Quality Control for biotherapeutic drug product development
- Strong verbal and written communication skills
- Self-motivated, well organized, and highly effective in team-oriented environment

Benefits

The company offers competitive benefits including medical, dental, vision, short/long term disability 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 send your resume to hiringqa@salubrisbio.com