September 26, 2024

Lyophilization Technology, Inc. (LTI), established in 1992, is a unique Contract Development and Manufacturing Organization enjoying a leadership position in the health care and related industries. The company conducts applied research, provides scientific services and technical support, and manufactures clinical supplies for freeze dried pharmaceuticals, biologics, diagnostics, biopharmaceuticals and fine chemicals. LTI is located in Ivyland, Bucks County, Pennsylvania.

We have a position opening for a **Quality Assurance Associate**. As a member of the team, the Quality Assurance Associate is responsible for administering the Quality Management Systems using basic skills and knowledge of appropriate procedures, methods, and techniques, as well as, applicable regulations, current Good Manufacturing Practice, compendial, and client requirements for the manufacture of aseptically produced drug products. This position requires working with and providing assistance to other staff and clients.

Quality Assurance Associate

- Provide support and oversight of environmental sampling/testing /reports, manufacturing, packaging, labels, material approval, and review of investigations.
- Review and update SOP's, policies and processes regularly to ensure all quality standards are in compliance with cGMP standards, applicable regulatory compliance, and industry standards.
- Review and approve documents supporting manufacturing and development operations, such as batch processing records, SOPs, deviation reports, corrective and preventative actions, and change controls.
- Perform limited quality control testing for in-house purified water and clean steam systems, and environmental monitoring.
- Perform Independent Quality Inspection of finished product.
- Assist with client and regulatory audits.
- Perform internal audits in either a lead or team auditor role.
- Perform external audits is support of vendor qualification.
- Participate/write/review/approve investigations, deviations, discrepancies, technical problems, complaints and non-conformances.
- Perform basic utility assessments.
- Develop measures to monitor effectiveness of Quality Systems, including appropriate metrics, and prepare reports for management.
- Provide QA support and guidance to personnel across the site.
- Assist in Document Control activities as needed.
- Other activities as assigned by the group manager, Quality Assurance or requested by Quality Assurance staff.

Applying your background, knowledge, and experience in a unique technology with an internationally recognized organization will afford you an excellent salary and comprehensive benefits that include tuition reimbursement, as well as opportunities for professional development and career growth.

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

- Bachelor's degree in Science (BS/BA) preferred; or three (3) to five (5) years pharmaceutical quality experience and training; or equivalent combination of education and experience.
- Thorough understanding of aseptic processing and sterile product science and technology, including US and EU compliance requirements.
- Knowledge with implementing cGMPs, DEA, and US and EU regulations.
- Demonstrate ability to work independently, handle multiple tasks simultaneously, negotiate and meet critical timelines, thorough attention to detail and strong organizational skills.
- Strong working knowledge of Microsoft Office 365 Products, Adobe Acrobat; and ZenQMS document management software.

Environment and Physical Requirements:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

While performing the duties of this job, the employee is frequently required to stand, walk and sit and regularly required to effectively communicate with scientific and technical staff. Employee is occasionally required to walk, use hands to finger, handle or feel and reach with hands and arms. The employee must occasionally lift and/or move up to 25 pounds. Ability to routinely don scrubs and sterile gowning as appropriate for clean room access.

- Specific visual acuity required by this job include color vision.
- Office activities, and occasional work in a laboratory and manufacturing environment, including an aseptic environment requiring good aseptic technique.
- Wearing proper attire for a laboratory or manufacturing environment, as necessary.
- Occasional exposure to potentially hazardous chemical and biological materials such as anti-cancer drugs and human or naturally derived biologics, use of personal protection devices such as goggles, gloves and respiratory protection.

Equal Opportunity Employer

We are NOT using search firms to fill this position.

Interested candidates, please submit your résumé along with a cover letter and three (3) professional references to Nichelle at Nsharper@lyo-t.com. For additional information about Lyophilization Technology, Inc., visit https://www.lyotechnology.com/.