Job Description

Quality Assurance

The Company:

Yapan Bio is a Biotechnology Company established to serve the rapidly expanding Custom Development and Manufacturing (CDMO) market for Vaccines and Biologics/Bio-therapeutics. Yapan Bio has established state-of-the-art facilities for process development and GMP manufacturing for human clinical studies, including both Drug Substance (DS) and Drug Product (DP - Liquid Vials), at Genome Valley in Hyderabad. The facility is built as per the quality and regulatory expectation of the global regulatory authorities. The current facility includes two manufacturing suites, including one Bio Safety Level 2+ (BSL-2+) suite to develop and manufacture high containment product classes.

As we expand our team, we are looking for talented and experienced individuals, with can- do attitude, who are self-starters with excellent communications & leadership skills, who enjoy working on the details without losing site of the larger organizational goals, and are adaptable to a dynamic "startup" environment, to join our team.

At Yapan Bio, you will get a supportive, collaborative, and empowering work environment to make a significant impact along with ownership as we drive the growth of the company together. This is an excellent opportunity to be a part of the team to establish a new biotechnology company in India, with global impact.

The Role:

This individual will be responsible for deliverables for the Quality function for Yapan Bio.
This position requires demonstrated ability to manage tasks, resolve problems and issues and drive implementation/action plans to meet objectives along with excellent interpersonal and presentation skills to present effectively in various interactions, meetings, and reports. The candidate should be self- sufficient in planning and executing along with applying innovative

thinking to improve effectiveness and efficiency of the function.

Duties and Responsibilities:

- Support establishment and management of all aspects of compliant Quality function, Development of SOPs/Batch Records, document management system etc.
- Overall responsible for Document Management System and ensure process control documents adhere with set requirements.
- Support development of company training programs for GxP-related procedures, practices, and system requirements
- Ensure appropriate implementation of the quality systems by all relevant teams/functions
- Ensure on time processing of non-conforming components.
- Assist disposition process by involving in failure analysis and suggest corrective actions
- Coordinate with suppliers and customers relating to quality trends, performance, and corrective action.
- Verify conformance and productivity of quality system through Internal/ Supplier audits and surveys.
- Support in Microbiology activities like Environmental Monitoring Program, Water Sampling, and review of Analysis reports.
- Interact with product development committees to inspect and review product releases.
- Review all product quality aspects like planning, manufacturing methods and process specifications.
- Perform other duties as required.

Education and Experience Required:

- Bachelor's degree in Science; advanced degree is preferred.
- **4-6 years** of Quality function experience in the vaccines and/or biologics industry.
- Proven track record of establishing/working-in/managing development and manufacturing GxP Quality infrastructure and systems compliant with global requirements.
- Thorough understanding and knowledge of global GLP and GMP regulations and requirements to support vaccines and biologics development from early stages of development to manufacturing for human use.
- Professional certification, such as Six Sigma, Quality Engineer, or Quality Auditor is preferred.

Skills:

- Superb computer competence, including database management.

- Knowledge of quality assurance terminology, methods, and tools.
- Analytical, problem-solving, and decision-making skills.
- Demonstrated knowledge of testing best practices, version control practices and defect management practice.
- Strong communication and interpersonal skills.

The Next Steps:

If the above role fits your experience and expertise and you would like to build and grow your career with a dynamic start-up, working on the next generation products and technologies, please share your CV at hr@yapanbio.com.