Quality Engineer

Company Overview:

PBS Biotech, Inc. is a private company based in Camarillo, CA. that manufactures and sells the most advanced single-use bioreactors for the biopharmaceutical market. Our fully scalable bioreactors enable process development and commercial manufacturing of cell-based products, particularly for the rapidly emerging cell therapy market. We also provide world-class contract research and development services with leading expertise in various cell therapy product types.

Job Description:

We are seeking a **full-time**, highly motivated, and experienced Quality Engineer who will apply engineering methods to processes and products to identify and drive improvements to quality, compliance, and efficiency. The ideal candidate should be able to work and thrive in a fast-paced, collaborative environment while tasked with a wide variety of responsibilities related to quality engineering.

Responsibilities and Tasks:

- Provide quality engineering support to product development, production, supply chain, quality control, and quality assurance functions
- Manage product qualification activities for bioreactor systems, accessories, and components, including oversight of project management, testing, and documentation
- Provide support to engineering function for the design control process including product development, product introduction, and change management
- Support and/or manage nonconformance investigations, complaint analysis, and CAPA
- Support and/or manage supplier management process and program including supplier selection, qualification, and ongoing management
- Identify and implement improvements to processes, products, and materials, using quality engineering methods and tools
- Perform data gathering and apply statistics and root cause analysis to measure process performance and identify improvement opportunities in support of management review, improvement projects, and investigations

Required Qualifications and Skills:

- Bachelor's degree in an Engineering-based discipline or related technical field
- Minimum 3-5 years of experience performing quality engineering, industrial engineering, or a directly related function
- Experience supporting a complex regulated product such as medical devices, biotech/pharma drug products, biotech/pharma equipment, products requiring ISO 9001 certification, or similar manufacturing field
- Experience owning and applying one or more process improvement methodologies such as Kaizen, Six Sigma, LEAN, TQM, root cause analysis, statistical process control, etc.
- Knowledge of and experience with one or more regulatory standards and quality system approaches including ICHQ10 (GMP), ISO 13485, ISO 9001, ANSI, ASTM
- Ability to work individually with minimal supervision, and also collaboratively within a multifunctional team, or as a team leader

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