PBS BIOTECH®

Job Opportunity

Position Title: Quality Engineer (or Senior Quality Engineer)

Company and Job Description:

PBS Biotech, Inc. is a fast-growing private company based in Camarillo, CA that manufactures the most advanced single-use bioreactors for the global biopharmaceutical market. We also offer industry-leading contract research and development services to create large-scale cell therapy manufacturing processes for clients. We are seeking a highly motivated and experienced Quality Engineer (or Senior Quality Engineer) who will be responsible for improving the company's products and processes in regard to quality, compliance, and efficiency. The qualified candidate will also participate in the Quality team's efforts to secure the supply chain of products while ensuring the highest quality and robustness of our products and services.

Roles and Responsibilities:

- Apply quality engineering methodology to various business areas including product development, production, product monitoring, and QA/quality system functions
- Gather data, apply statistics, and perform root cause analysis to measure process/product performance and identify improvement opportunities
- Investigate and analyze customer complaints and nonconformances, and perform root cause analysis to recommend corrective and preventative actions
- Manage and/or support the product validation program, including GMP qualification testing, for single use bioreactor vessels, bioreactor systems, and accessories
- Secure the product supply chain by qualifying critical suppliers for technical and quality aspects, as well as managing risk of single-source suppliers
- Support the Engineering department for design control processes including product development, design verification/validation, product transfer, and change management

Requirements:

- Bachelor's degree in Quality Engineering, Industrial Engineering, or related Engineering discipline
- Minimum 3-5 years of experience performing quality engineering, industrial engineering, QA, and validation functions in the biotech, pharma, or similar highly regulated industry
- Experience with biotech/pharma products and equipment such as medical devices, as well as ISO 9001 certified processes
- Experience applying process improvement methodologies such as root cause analysis, statistical process control, Kaizen, Six Sigma, LEAN, TQM, or other similar methods
- Experience with one or more quality system approaches and standards including GMP, ISO 13485, ISO 9001, GEP, ANSI, ASTM, etc.
- Strong problem solving, verbal, and written communication skill
- Proven ability to thrive in a fast-paced, multifunctional, team-based environment

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