Job Description

Position: **Senior Quality Specialist**

Posting Date: Nov. 29, 2021

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:

PBS is seeking a Sr. Quality Specialist to support operations related to PBS bioreactor systems. This role performs product related Quality Assurance functions, including investigations related to nonconformances, complaints, and supplier quality management. This position will be involved in performing and developing the Process Owner role for these areas and will support the development requirements and training for the QMS program to deploy the Process Owner function. Additional leadership and project assignments will be assigned based on evolving needs of the business.

Roles and Responsibilities:

- Support the company's efforts for CGMP qualification and ISO Certification.
- Define and perform role of Process Owner for assigned processes including owning procedures, procedure creation/updates, training, and data trending/reporting.
- Own and lead product complaint and nonconformance investigations and reports.
- Support and/or perform Supplier qualification and management by assisting with supplier questionnaires, audits, supplier corrective action requests, and risk assessments.
- Own CAPAs, perform or support Root Cause Analysis related to investigations and other improvement initiatives and projects as assigned.
- Conduct tracking & reporting for the quality programs, including development and monitoring metrics that support key performance indicators (KPIs) for the organization. Provides reports to management, as required. Provides and may execute suggested remediation activities.
- Responsible for continuous improvements of assigned processes. Identify opportunities for and lead or participate in continuous improvement of the QMS program, which may include seeking feedback from stakeholders.
- Provide Quality Assurance support as back up approver for various quality processes including CAPA, change management, and supplier management.
- Other duties as the business needs evolve and as assigned.

Education and Experience Requirements:

- Bachelor's degree in Life Sciences, Engineering, other science-based area, or equivalent skills and experience
- Minimum 5 years of experience performing quality assurance investigations or related role, and/or 5 years of combined experience in a Quality and product related role such as manufacturing operations, product testing, validation, or investigations.
- Excellent verbal and written communication skills including excellent technical writing skills
- Ability to work in teams, as well as work individually with minimal supervision, or in a lead role
- Job Type: Full-time

Compensation:

Salary and title will be commensurate with experience.