

Job Description

Position: Quality Assurance Specialist/ Senior Specialist

Posting Date: 4/14/21

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 Quality Assurance Specialist to support operations related to PBS bioreactor systems. This role performs Quality Assurance and/or Quality Control functions, including investigations (nonconformances), complaint analysis, CAPA, change control, product inspections, document approvals, product approval/release, and supplier management. The Quality Assurance role ensures compliance to applicable GMP and ISO requirements. This position will be assigned additional leadership and project management assignments based on the skills and experience of the individual.

Roles and Responsibilities:

- Quality Assurance approvals including manage and close nonconformance investigations, CAPA, complaints, change records, and internal audits.
- Quality reviewer/approver for various documents including standard operating procedures, manufacturing procedures, and material specifications
- Performs batch disposition/release (work order approvals) including QA batch record review, documentation, and approval
- Own and author quality assurance related procedures, forms, and checklists as assigned.
- May perform or support incoming material Quality Control receiving
- Support or manage suppliers including supplier qualification/approval, questionnaires, audits, supplier corrective action requests, and risk assessments.
- Lead or support improvement projects as assigned.
- Other duties as assigned.

Requirements:

- Bachelor's degree in Life Sciences, Engineering, other science based area, or equivalent skills and experience
- Minimum 3 years of experience performing quality assurance, quality control, supplier quality role, or 5 years of combined experience in a Quality and product related role such as manufacturing technician, 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

Salary and title will be commensurate with experience.