Job Description

Position: **Sr. Quality Engineer/Quality Engineer (Validation)**

Posting Date: Feb. 25, 2021 (revised 3/31/21)

PBS Biotech, Inc. is a private company in Camarillo, CA that produces technologically advanced, single-use bioreactor products for the rapidly growing cell therapy industry. PBS also provides world-class process development services to help our customers solve complex cell culture challenges. This is a great opportunity to join a dynamic and high growth company in the biopharmaceutical equipment and service industry.

Job Description:

PBS Biotech is seeking a Quality Engineer to oversee the program for qualification and validation of PBS's Bioreactor systems. This role supports product development, product transfer, manufacturing, and commercialization of bioreactor products. The position requires experience with developing and validating medical devices, GMP bioprocessing equipment, or single use medical products and requires the application of Quality Engineering methods and tools to define requirements for testing, verification, qualification, and validation. This role requires effective leadership, collaboration, technical writing, and verbal communication skills. This position reports to the Head of Quality.

Job Duties and Accountabilities:

- Provides Quality leadership to product development teams in the areas of testing, verification/validation, design transfer, product quality/risk, and specification development.
- Owns and implements validation program, validation master plan, product qualification, and related documents and training.
- Quality contact/approver for requirements and documents which support design control, testing, verification, validation, and transfer of products including bioreactor control units (electromechanical), single use bioreactor vessels, and controller software.
- Manage or support qualification/validation studies for gamma sterilization, shipping/transport, packaging, and shelf life.
- Organize and manage product test samples and lab results for testing of particulates, endotoxin, biocompatibility, and extractables.
- Quality contact for validation of manufacturing process, facility, and equipment.
- Generate written assessments for impact to validation due to changes or nonconformances.

Job Description

Position: Quality Engineer (Validation Specialist)

Education and Experience Requirements:

- Bachelor's degree or higher in an Engineering field is preferred, a Bachelor's degree in a Science field is acceptable with 3+ years of relevant industry experience
- Minimum 2 years in a Quality Engineering or Validation role, or 3 years in a related role such as Product Development Engineering, Manufacturing Engineering, or industrial engineering.
- Minimum 2 years of experience working with products regulated by GMP/Biopharma (21 CFR 210/211, ICH Q7/10), medical device (21 CFR 820, ISO 13485/14971), or medical products field (ISO 9001, ISO13485)
- Minimum 2 years using one or more engineering tools and methods such as CAD, statistical analysis (MiniTab, JMP, SigmaXL, or equivalent), statistical sampling/acceptance methods (ANSI, MIL-STD, AQL), design of experiment, design control, DFM, etc.
- Advanced skills with MS Office applications Word, Excel, Visio, as well as Adobe Acrobat.
- Candidates must be authorized to work in the U.S.

Compensation:

Compensation and job level will be commensurate with skills and experience of the individual candidate.

PBS provides equal employment opportunity to all applicants and employees.