Job Description

Position: **Quality Engineer (Validation Specialist)**

Posting Date: Feb. 25, 2021

PBS Biotech, Inc. is a private company in Camarillo, CA that produces the most technologically advanced, single-use bioreactor products for the rapidly growing cell therapy industry. We also provide 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 with a skill set that can apply to validation activities related to product development and commercialization of PBS's single use bioreactor systems. This role requires experience related to validating medical devices, GMP bioprocessing equipment, or single-use medical products. A qualified candidate will be suited to operating in the dynamic environment of a growing startup company. It is preferred that the candidate has additional capability and experience leading process improvement projects which utilize Quality Engineering methods such as Six Sigma, Lean, Kaizen, and/or have experience performing Quality Assurance functions such as Investigations, CAPA, Root Cause Analysis, and Change Control. This role requires effective cross functional collaboration, strong oral communication skills, and proven technical writing ability. This position reports to the Head of Quality.

Job Duties and Accountabilities:

- Collaborate with product development Engineers to define Quality requirements
- Develop, approve, and execute protocols for testing, design verification, and validation of various components and functions of bioreactor systems
- Act as Project Team member (representing Quality Dept.) for development, testing, and verification/validation of electromechanical bioreactor control units, single-use bioreactor vessels, bioreactor system controls, and related software
- Author and own procedures which govern validation programs and master plans, as well as related forms, templates, and trainings
- Provide Quality requirements, procedures, and oversight for validation of manufacturing process, facility, and equipment
- Perform change assessments and write reports for impact of changes to validated state; may be assigned as Quality contact for Change Control records

- May be assigned to lead process or product improvement projects which require Quality Engineering methods or support Quality Assurance
- May lead or support development and implementation of manufacturing process controls or process monitoring
- May support or lead investigations, root cause analysis, and troubleshooting related to product or validated process
- The mix of assignments for this role will be modified based on company strategic priorities and capability of the individual

Education and Experience Requirements:

- Bachelor's degree in an Engineering field is preferred; a Bachelor's degree in a Science field is acceptable if there is 3+ years of relevant industry experience
- Minimum 2 years in a Quality Engineering and/or Validation, or related role, preferably 3-5 years of experience
- Minimum 2 years of experience working with regulated product and within a structure Quality Management System preferably in GMP/Biopharma, medical device, or medical products field
- 2 years of using Six Sigma/DMAIC methodology (or equivalent) such as value stream mapping, FMEA, Kaizen, SIPOC analysis, root cause analysis, fault tree analysis, risk analysis and pareto charting OR 3 years of experience in a Quality Assurance related role performing Investigations, CAPA, Change Control, or product quality evaluations in a regulated environment
- Advanced skills with MS Office applications Word, Excel, Visio, as well as Adobe Acrobat
- Ability to work in a dynamic start up environment and manage multiple assignments
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines
- Strong interpersonal skills including verbal and written communication are essential in this collaborative work environment
- Candidates must be authorized to work in the U.S.

Compensation:

Compensation will be based on skills and experience of the individual candidate.

PBS provides equal employment opportunity to all applicants and employees