Job Opportunity

Position: **Quality Systems Specialist**

Posting Date: July 2020

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 Systems Specialist trained in Process Improvement to establish processes and procedures for improvements and advancement of the Quality Management System. Must be able to work independently and function as the company subject matter expert in relation to the Quality Management System and cross-functional improvement initiatives. This position reports to the Senior Director of Quality.

Job Duties and Accountabilities:

- Work with management to identify new process improvement opportunities in the areas of quality, cost, performance, and preventive/predictive maintenance.
- Evaluate and analyze current process metrics and performance to identify areas requiring improvements.
- Analyze and identify opportunities to reduce process variation, improve process capabilities, and optimize process performance.
- Develop process improvement initiatives to increase operational efficiency and productivity, as well as decrease overall business and/or quality risks.
- Facilitate the deployment of new and changed processes to provide improved results. Develop standard procedures and policies to be followed by staff members.
- Work with various team members to reduce process and business variations. Assist department manager with the management of key strategic projects.
- Prepare project presentations for management when needed.
- Review and update business procedures and documents based on project requirements.
- Train and guide staff as needed.
- Other duties as assigned.

Education and Experience Requirements:

- Bachelor's degree preferred, or at least 5 years of experience in a GMP or Quality System Review-related field within a biotechnology, medical device, or pharmaceutical manufacturing facility.
- Strong knowledge of GMP, SOPs, quality systems and regulatory requirements (e.g., 21 CRF 210/211 & 820, ISO 9001).
- Minimum 2 years of six sigma or equivalent training with demonstratable application of skills.
- Knowledge of value stream mapping, FMEA, Kaizen, SIPOC analysis, root cause analysis, fault tree analysis, risk analysis and pareto charting.
- Advanced skills with MS Office applications Word, Excel, Visio, as well as Adobe Acrobat.
- Strong attention to detail with the ability to multi-task and handle multiple responsibilities simultaneously in a fast-paced environment.
- Excellent organizational skills and an ability to prioritize effectively to deliver results within established timelines.
- Ability to work independently or as part of a cross-functional team.
- Strong interpersonal skills including verbal and written communication.
- Candidates must be authorized to work in the U.S.

Compensation:

A qualified candidate will be offered a competitive compensation/benefits package including stock options and a bonus plan based on performance and company growth.

PBS provides equal employment opportunity to all applicants and employees.