

Job Description

Position: Quality Assurance Specialist / Sr. Quality Assurance Specialist

Company Background:

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 Assurance Specialist to support the Quality Management Systems (QMS) programs at PBS. This role will support the implementation, deployment, and maintenance of the QMS program. The position requires experience supporting the deployment and maintenance of QMS in a GMP environment. This role requires effective leadership, collaboration, technical writing, and verbal communication skills. This position reports to the Director of Quality Management.

Job Duties and Accountabilities:

- ❖ Support the company's efforts for CGMP qualification and ISO Certification.
- ❖ Supports the deployment of QMS processes and promotes on-going education of the QMS and regulatory requirements.
- ❖ Facilitate quality management systems operational mechanisms which may include Change Review Board, CAPA Triage, etc.
- ❖ Develop and monitor metrics that support key performance indicators (KPIs) for the organization. Provides reports to management, as required. Provides and may execute suggested remediation activities.
- ❖ Identify opportunities for and participate in continuous improvement of the QMS, which may include seeking feedback from stakeholders.
- ❖ Support development of procedures, work instructions, etc., for QMS.
- ❖ Provide assistance to internal and external customers in support of departmental functions related to quality management systems.
- ❖ Support the implementation of electronic quality management systems.
- ❖ Maintain a state of inspection readiness and participate in inspection preparation activities.
- ❖ Support internal and external audit and inspection activities through retrieval and provision of requested quality management systems documents and data in a timely manner.
- ❖ May conduct other Quality related duties, as assigned.

Education and Experience Requirements:

- ❖ Bachelor's degree or equivalent 7+ years of experience in Quality Management Systems.
- ❖ Minimum 5 years in a Quality role.
- ❖ Minimum 5 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).
- ❖ 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.