

## Job Description

Position: Training Manager, Quality

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**Posting Date:** 11/05/2021

### Company Overview:

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 Process Owner (PO) for Training to support the Quality Management Systems (QMS) programs at PBS. This role will be responsible for the implementation, deployment, and maintenance of the Training program as well as providing quality oversight of PBS's training program. The position requires experience supporting the deployment and maintenance of Training QMS in a GMP environment. This role requires effective leadership, collaboration, technical writing, and verbal communication skills. This position reports to the Director, Quality Management.

### Job Duties and Accountabilities:

- ❖ Support the company's efforts for CGMP qualification and ISO Certification.
- ❖ As the Training PO, be responsible for the implementation, deployment, maintenance, and continuous improvement of the Training program. Promotes on-going education of GMP Training, QMS, and regulatory requirements.
- ❖ Responsible for creating training materials and training staff on the Training program, leading training sessions, and ensuring proper execution of the Training program; including Quality orientation training for new GMP employees as part of the on-boarding process and annual GMP refresher training.
- ❖ Work collaboratively with process owners and management to facilitate the development of training activities specific to their individual department needs, to help drive staff skill improvement. Facilitate and support the creation of company training materials.
- ❖ Conduct tracking & reporting for the Training program, including development and monitoring metrics that support key performance indicators (KPIs) for the organization. Provides reports to management, as required. Provides and may execute suggested remediation activities.
- ❖ Support the deployment, maintenance, and continuous improvement of electronic Learning Management Systems (LMS).
- ❖ Identify opportunities for and participate in continuous improvement of the QMS program, which may include seeking feedback from stakeholders.
- ❖ Review and approve training materials, procedures, work instructions, etc., for adherence to applicable regulations regarding training.
- ❖ Provide assistance to internal and external customers in support of departmental functions related to Training and Quality Management Systems.
- ❖ Maintain a state of inspection readiness and participate in inspection preparation activities.
- ❖ Support internal and external audits and inspection activities through retrieval and provision of requested Quality Management Systems records and data in a timely manner. Serve as Subject Matter Expert.
- ❖ Support Document Control the department by performing tasks as assigned.
- ❖ May conduct other Quality related duties as assigned.

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### Education and Experience Requirements:

- ❖ Bachelor's degree or equivalent 10+ years of experience in Quality Management Systems, Training.
- ❖ Minimum 10 years in a Quality role.
- ❖ Minimum 10 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.
- ❖ Job Type: Full-time

### 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.