Quality Systems Manager

Reports to: VP of Quality

Classification: Exempt

Summary:
Responsible for and participates in the design, development, management and maintenance of the GxP quality systems and activities, including document control and training.

Essential Functions and Job Responsibilities:

- Management, control and maintenance of the QA document control function, including initiation, revision, review, approval, distribution and archiving of internal GxP documents
- Review and approve within the document controls system for adherence to quality standards for formatting and publication
- Participate in the evaluation of the organization's Quality Systems and processes for optimization
- Organize and maintain a filing system(s) for paper-based internal GxP and CMO documents
- Track and maintain logs for internal (document change controls, deviations, investigations, CAPAs, specifications, etc.) and external CMO (batch records, protocols, reports, analytical methods, deviations/investigations, etc.) documents
- Maintain repository for CymaBay GxP documents and CMO documents
- Manage and maintain the GxP training program including the creation and maintenance of training files for GxP personnel
- Assist in the development and maintenance of training content, training curricula and metrics in compliance with internal policies and procedures. Coordinate annual GxP training.
- Ability to lead, collaborate and work independently in a team environment
- Assist in the identification of potential future systems and tools within QA to support evolution of the quality systems
- Lead QA efforts to implement and maintain electronic document management system (EDMS)
- Assist QA Management with metrics trending for compliance reports to Senior Management
- Assist with and complete other responsibilities as assigned by Quality Management
- Complete other responsibilities as assigned and agreed upon

Minimum Qualifications:

- Bachelor's degree or equivalent
- ASQ Certification a plus
- Minimum of 6- 8 years' experience in biopharmaceutical/pharmaceutical or related industry. Preferably performing within a Quality Assurance role with at least 4 years direct experience in Document Control and GxP Training Program
- Thorough knowledge of cGMP regulations, quality systems and regulatory requirements
- Possesses excellent teamwork skills, able to work in a matrixed project team setting and a proven track record establishing and achieving clear and consistent goals and objectives
- Experience in change control, deviation management, and batch record content review, is a plus
- Experience in validation and implementation of electronic document management systems (EDMS) and/or quality management systems (QMS)

- Strong organizational skills, communication and interpersonal skills, and attention to detail
- Demonstrated ability to manage priorities, multi-task and follow projects through to completion
- Must be comfortable working with changing timelines, scopes and priorities
- Excellent verbal and written communication skills