# Manager, Quality Systems and Records

**Remote**

## Summary

Reporting to the Director of Quality, the Manager of Quality Systems and Records is responsible for operating and overseeing the company's GXP records and quality management activities.

## Responsibilities

- **Document Control/Records Management**
  - Maintain Controlled Document Database, or EDMS as applicable
  - Create/Update/Archive the Controlled Document Index
  - Support the Draft/Review/Format Standard Operating Procedures, Work Instructions, Specifications
  - Oversee naming, numbering, version control and updating the Controlled Document Assignment Spreadsheet
  - Oversee the implementation/succeeding/retiring of controlled documents.
  - Generate reports from databases/EDMS upon request
  - Manage SOP periodic review calendar and send out notices to functional areas
  - Oversee off-site record storage, track locations of GXP documents across projects and facilitate the shipment of these documents from vendors to Vancouver Office for indexing and archival at Iron Mountain as needed
  - Develop and manage record retention schedule, archiving and destruction procedures

- **Quality Systems**
  - **Change Control**
    - Manage change control process, checking for completeness and routing to functional area assessors
    - Maintain Change Control database/EQMS
    - Conduct Change Control meetings as necessary
    - Follow up with outstanding change control assessments
    - Manage *pre* and *post* implementation requirements for active change controls
    - Develop and produce Change Control metrics for management review
  - **Deviations and CAPAs**
    - Manage Deviation and CAPA processes and drive associated investigations with SME input
    - Maintain Deviation and CAPA databases/EQMS
    - Assign and track action items associated with Deviations and CAPAs
    - Develop and produce Deviation and CAPA metrics for tracking/trending and management review
  - **Training**
    - Manage training program and procedures
    - Maintain training curricula and matrix

    - Oversee administration and archive of GXP training records
    - Follow-up on overdue training
    - Develop and produce training metrics for tracking/trending and management review
- **Product Complaints**
    - Administer Product Complaint system, working with SMEs for investigations, as needed
    - Maintain Product Complaint database/EQMS
    - Develop and produce Product Complaint metrics for tracking/trending and management review

- **Other related duties as assigned**

## Qualifications and Requirements

- Bachelor of Science in a Life Sciences related discipline with a minimum of 5 to 7 years directly related Quality experience in a biopharmaceutical environment, or the equivalent combination of education and experience.
- Expert user of MS Word, Excel, Access with the capability of effectively working with large complex documents.
- Working knowledge of drug development and commercialization processes, FDA/ICH/EMA guidelines and cGMPs.
- Experience writing SOPs, Work Instructions, Policies.
- Experience with MS Access and electronic document management systems (EDMS) preferred.
- Strong technical/analytical skills to identify and solve problems.
- Ability to exercise independent judgment in making decisions to assure quality
- Demonstrated project management experience and skills, with the ability to coordinate multiple projects in a demanding fast-paced environment.
- Excellent oral and written communication skills for effectively interfacing with all levels of management and departments within the company, vendors and contract sites.