JOB DESCRIPTION

Position Title: Manager, Document Control

Job Summary

The Document Control Manager reports to Director of Quality Assurance. The position will be responsible for management of document control quality system, include document control, SOP Management and training.

Responsibilities

- Management of document change control system, which includes process all Document Control Requests (DCR's), route and track the document review, approval and distribution.
- Track assigned batch numbers, deviation, non-conformance, corrective actions (CAPA) and material specification numbers and maintain a log of each for completion within a specified time frame.
- Maintain material lot files, databases, and spreadsheets.
- Assisting QA Director with metrics trending for compliance reports to Sr. Management
- Management of SOP system, which includes initiation, managing review and approval of departmental policies, procedures, and specification.
- Review document drafts for grammar, spelling and formatting and making corrections as needed for making documents effective for use.
- Issue hardcopies of effective documents as distribute to Dept. Document Control personnel and update QA binders with current versions
- Maintain electronic folders of drafts, edits and approved/effective documents.
- Ensure adequate filing systems, storage, tracking and archival of quality controlled documents
- Maintain electronic folders of drafts, edits and effective documents.
- Maintain and update company shared drive with effective/approved QA controlled documents.
- Organize and maintain a filing system(s) for paper-based GMP controlled documents such as SOPs (Standard Operating Procedures), Master batch records, QC test data, weekly monitoring charts, memos, policies, and training records.
- Support scanning, file creation and maintenance to upload controlled documents in the QA database.
- Working with regulatory affairs, implementing, managing and control clinical trial labelling to assure GMP/GCP compliance with applicable regulatory agency requirements
- Lead and/or coordinate the development or update of QA processes (SOP, Work Instructions, and internal guidelines)
- Assist in identification of potential future systems and tools within QA to support evolution of the quality systems.
- Managing and updating company GXP training system, which includes initiation of new hire training records, assuring effective SOP training across GXP departments, and ensuring annual GXP training for applicable employees, and training records are entered into the database.

- Send out documents for periodic review requests to department heads
- Assist with planning of internal audits, supplier audits and regulatory audits to ensure compliance current practices.
- Remain current on relevant health agency requirements. Assess impact of regulatory changes to current quality system practices.

Qualifications

- Bachelor's degree (or equivalent)
- Minimum of 5+ years of direct experience either supervising a Quality Assurance department
- Working knowledge of QA records and procedures
- Thorough knowledge of cGMP, QA/QC and regulatory compliance, and FDA/EMA regulations and guidelines relating to CMC-related areas
- Experience in the conduct global clinical trial programs including phase 3, and management of clinical labeling.
- Experience in change control, deviation, and batch record content review, is a plus
- 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
- Possesses excellent teamwork skills, able to work in a matrix project team setting and a proven track record establishing and achieving clear and consistent goals and objectives.
- Excellent verbal and written communication skills.

Compensation

An appropriate financial package will be developed for the successful candidate to include a competitive base salary and equity, with a performance related bonus opportunity.

Work Environment

This is a high growth, fast paced small organization. The ability to be productive and successful in an intense work environment is critical. Willingness and ability to travel domestically and internationally on occasion is required, it is anticipated that this will be 10-15% of work time.