Job Description

Job Title:

Quality Assurance (QA) Controller

Reporting To:

Quality Assurance/Regulatory Affairs (QA/RA) Manager

Accountable To:

Quality Assurance/Regulatory Affairs (QA/RA) Manager

Role (Summary)

The QA Controller is responsible for ensuring documents and records are created, approved and maintained in accordance with company procedures and available at point of use. The role will also play a key role in establishing an electronic document management system.

Key responsibilities

- Ensure documents are reviewed and approved for adequacy prior to use in accordance with defined processes.
- Support in maintaining and continuously improving the quality management system in compliance with regulatory requirements.
- Ensure that the current revision status of any changes to documents are identified.
- Ensure that relevant versions of applicable documents are available at points of use.
- Ensure documents remain legible and readily identifiable.
- Prevent deterioration or loss of documents.
- Prevent the unintended use of obsolete documents.
- Support systems integration and deployment of electronic document management system
- Manage training records.
- Support Audits, CAPA's, Change Control, Deviations/Concessions, Root-Cause Analysis, and Complaint handling.
- Maintain design change and equipment logs.
- Monitor quality related KPI's.
- Ensure documents are periodically reviewed in accordance with defined requirements.
- Monitor and control documents of external origin e.g. industry standards.
- Ensure proper organisation, retention, preservation and security of documents (paper and electronic).
- Make available, notify and distribute documents to relevant recipients.
- Keep abreast of new developments in QA/RA e.g. standards and regulations.
- Work closely with internal and external multi-disciplinary product development teams to ensure project success.
- Deliver relevant training on the QMS to existing and new staff within remit of responsibilities.
- Support the management team understand the QA/RA framework in which the business is expected to operate.
- Participation in company's H&S activities and support compliance.
- Any other duties to support company business activities and development as required.

Person Specification

Knowledge & Experience:

- Minimum two years Document Control experience in pharmaceutical, medical device or other related industries.
- Working within an ISO 13485 Quality Management System under the Medical Devices Directive (MDD)/Medical Devices Regulation (MDR) for product development and/or manufacturing in the UK/EU is desirable.
- Competent in MS Office Suite and Windows applications e.g. Word, Outlook, SharePoint, Excel, PowerPoint, Visio etc.
- Proficient in document formatting
- Experience of implementing an electronic documentation management system is desirable
- Excellent oral and written communication and interpersonal skills.
- Attention to detail, commitment to Quality, accuracy, efficiency, and consistency.
- Some exposure to regulatory agency inspections (e.g. FDA, notified bodies, etc.) is desirable.
- Ability to work under limited supervision, manage multiple tasks and prioritise assignments within established time constraints
- A strong team player who is motivated by the success of the business.
- A self-starter committed to making things happen.

Education:

- An HNC or degree in a related subject, or equivalent level of experience.