

Alembic, LLC

Job Description

FRM-0017.A

Job Title:	QA Specialist
Dept. Head/ Reporting Manager:	Head of RA/QA

Responsibilities:

- Design, implement and manage the establishment of Alembic Quality System, procedures, work instructions and quality records. Act as Subject-Matter Experts and influence stakeholders and process owners to achieve all requirements of the quality system.
- Monitor the organization’s compliance with the laws and regulations governing product quality assurance.
- Monitor quality related operations for continuous quality improvement within the organization. Establishing systems for data collection & analysis on QMS process performance and present to management (i.e., training matrix).
- Oversees document management systems, including processing document change orders, document and record filing, archiving, retrieving, purging, and destroying.
- Establish and Maintain the External standard library.
- Lead by example and provide quality-based decisions to the team when needed.
- Conducting and ensuring company employees are trained on applicable GMP practices and internal quality management requirements.
- Host and supports internal and external regulatory audits.
- Manage continuous monitoring and measurement processes such as the CAPA system.
- Be responsible for local product complaint handling and quality related activities as well as medical device regulatory reporting. Maintain complaint files/database to ensure the regulatory requirements are met.
- Communicate and coordinate with complaint reporter, marketing, supply chain, RA and legal to address critical quality cases.
- Per business needs, assists in other business or complaint needs such as regulatory submission, filing, etc.

Skills/Requirements:

Education & Experience:

- B.S. degree is required.
- 3+ years of quality function experience in the medical device industry.

Abilities/Skills:

- Use Microsoft Office suites and other applications to manage databases for the company.
- Strong technical writing and communication skills are required.
- Act as an independent team player and lead by example.
- Consist the ability to multitask and complete deliverables on time.
- Ability to work in an office environment, CER, and travel to supplier sites as required.

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