

Alembic, LLC

Job Description

FRM-0017.A

Job Title:	Principal Quality Engineer
Dept. Head/ Reporting Manager:	Head of RA/QA

Responsibilities:

- Includes the following and other duties may be assigned:**
- Lead design assurance activities in support of new product development or system and product continuous improvement projects.
 - Strong understanding and practical application of design and development standards such as IEC 60601, 62304, 62366 and ISO 13485.
 - Working knowledge of risk management processes such as the Failure Modes & Effects Analysis (FMEA) and other risk management tools/techniques.
 - Experience and working knowledge of FDA regulations/ISO standards for medical devices such as the ISO 13485/GMP.
 - Maintain supplier quality program by working collaboratively with product and service suppliers. Activities include supplier performance evaluation, quality investigation, product testing, and performing occasional onsite audits/ visits (occasional traveling may be required).
 - Lead or support the application of quality engineering/compliance of various functions and levels with technical responsibility or strategic input.
 - Follow Alembic QMS system, policies, and SOPs to ensure that FDA, EU, and other applicable regulatory body required standards and regulations are met.
 - Manage quality resources to meet the different needs of the organization.
 - Develops, modifies, applies, and maintains quality standards and protocols.
 - Lead complaint investigations. Document findings and provide reports and analysis

Skills/Requirements:

- Education & Experience:**
- B.S. degree in engineering or a scientific discipline is required.
 - 7+ years of medical device industry experience in engineering or Advanced degree in Engineering, Science or technical field with 5+ years of work experience in Engineering.
 - CQE certification preferred.

- Abilities/Skills:**
- Strong technical writing and communication skills.
 - Independent, team player and lead by example.
 - Ability to multitask and complete deliverables on time.
 - Ability to lead, represent or participate during quality system audits.
 - Ability to work in an office environment, CER, and travel as required.

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