



ALEMBIC

Senior Quality Engineer

Reporting Manager

Director of RA/QA

Responsibilities

Includes the following:

- Work with other engineering functions for product design, development, verification, and validation.
- Lead in the completion and maintenance of risk management processes, such as the failure modes and effects analysis, hazard analysis, and other risk management tools/techniques.
- Support the application of quality engineering/compliance of various functions and levels with technical responsibility or strategic input.
- Build supplier relationships by working collaboratively with component and service suppliers. Monitor supplier performance, conduct non-conformance investigation, product testing, and perform occasional onsite audits/visits (occasional travel may be required).
- Identify and implement effective process controls to meet or exceed internal and external requirements, including the development of inspections and test methods.
- Identify and provide direction for statistical support in both design and routine manufacturing activities for achieving required levels of product reliability.
- Lead the investigation, resolution, and prevention of product and process non-conformances.
- Develop and conduct training when needed.
- Lead complaint investigations. Document findings, and provide reports and analysis
- Ensure compliance with all federal, state, local, and company regulations, policies, and procedures.
- Resolve quality-related issues in a timely and effective manner.
- Additional responsibilities, as required.

Skills/Requirements

Education and Experience:

- B.S. or M.S. degree in engineering or a scientific discipline is required.
- 10+ years of quality experience in the medical device industry following FDA regulations and ISO 13485 requirements; 3 years of decision-making responsibility.
- CQE certification preferred

Abilities/Skills:

- Strong technical writing and communication skills.
- Independent, team player, that leads 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 to supplier sites, as required.

Salary Range: \$85K - \$150K, based on experience.