



Job Title	Quality System Associate
Department:	Quality
Reports to:	Director of Quality
Date Approved:	1/15/2026

Summary:

Aulea Medical is seeking a self-driven, ambitious and highly motivated Quality Management System (QMS) Associate, to effectively execute the organization's quality management system, ensure regulatory compliance, and help oversee quality management systems compliance. The organization QMS is developed following the requirements outlined in ISO13485 and compliant to CFR part 820 of FDA QSR (Quality System Regulation). This position reports to the Director of Quality.

Responsibilities:

- Maintain and support the company's Quality Management System (QMS) in compliance with FDA, ISO 13485, and other applicable regulations
- Manage and update quality system documentation, including SOPs, work instructions, forms, and records
- Support document control activities, including creation, revision, approval, and archival of controlled documents. Ensures GDP (Good Documentation Practices) is followed in all controlled documents.
- Support internal audits, supplier audits, and other applicable regulatory inspections (FDA, notified bodies, ISO).
- Track and support corrective and preventive actions (CAPA), including root cause analysis and effectiveness checks
- Perform nonconformance management, deviation investigations, and change control processes
- Assist with complaint handling, including documentation, trending, and regulatory reporting support
- Support training program administration, including training matrix maintenance and effectiveness tracking
- Analyze quality metrics and prepare reports for management review
- Responsible for overall document coordination and records retention of controlled documentation within the organization (document control)
- Promote a culture of quality, compliance, and continuous improvement throughout the organization

Qualifications:

- Bachelor's degree in engineering, Life Sciences, or other science field
- 2+ years of experience working within a medical device or other health care related field
- Knowledge of FDA 21 CFR Part 820, ISO 13485, and applicable quality system requirements
- Strong attention to detail and excellent organizational skills
- Effective written and verbal communication skills

At Aulea Medical, we provide equal employment opportunities to all employees and job applicants, as required by federal, state, and local laws. We are committed to creating an inclusive and diverse workplace where everyone is respected and supported, and we believe that diversity enhances our ability to serve customers and strengthens our organization. We welcome individuals from all backgrounds to apply for employment opportunities with us. We are an Equal Opportunity Employer.