Title: Quality Assurance Manager

Eagle Labs, an Innovia Medical Company
Rancho Cucamonga, CA
March 2022

Innovia Medical combines the experience and expertise of Summit Medical, Network Medical, DTR and Eagle Labs to help our medical professional partners elevate the delivery of care to improve patient outcomes. We develop products not just for our customers, but with our customers. Our collaborative approach cultivates innovative medical solutions for the global health care industry. Through excellence in design, supply chain management, manufacturing and customer service we put quality at the forefront in all aspects of our business.

Job Summary

The Quality Assurance Manager (QA) will manage the Quality Assurance team to support a compliant Quality Management System. This includes document control, inspection, CAPA, complaints, training, supplier quality management, calibration, product/process monitoring, and design control.
Assists the Head of Regulatory with technical files, regulatory clearances/approval, annual regulatory registrations, notifications to regulatory agencies, and compliance to all medical device requirements and regulations domestically and internationally.

Essential Duties and Responsibilities

- Develop, Maintain and Responsible for a Quality Management System (QMS) that is complaint to FDA requirements, EU, Canada and ISO regulations
- Follow all regulations, standards, procedures, and work instructions defined in the Quality System Manual and insure the QMS is compliant to all current regulations
- Report the status of the QMS to top management
- Management Representative for FDA and ISO
- Manage Quality team including annual perform performance reviews
- Assign Quality job responsibilities and projects to appropriate employee to support compliance
- --This includes, but is not limited to: document control, complaints, CAPAs, training, NMR's, inspection, calibration, supplier approval, supplier audits, deviations, returned merchandise, certificates of compliance, sterilization, sterilization validations, sterile product release, internal audits, management review, product bioburden, dose audits, product monitoring, process monitoring, design activities, cleanroom certification, etc.

- Support Engineering and Manufacturing through the change activities
- Interface with all internal organizations
- Perform other duties as assigned by the GM.

Additional Regulatory support working closely with the Innovia Head of Regulatory Affairs and providing assistance with:

- Medical device reporting/vigilance, corrections, recalls, removals, safety notices to regulatory agencies (FDA, Notified Body, Authorized Representative, Canada, etc.)
- Product regulatory approvals as needed (FDA, EU, Canada, etc.) (510k, Technical File, CE Mark, Product License, etc.)
- FDA inspections, Notified Body audits and other audits performed at Summit
- Maintain FDA device listing and perform annual facility registrations
- change notifications (significant) to regulatory agencies (FDA, Notified Body, Authorized Representative, Canada, etc.)
- Maintenance of Certificate of Foreign Government
- Interface with customers in supporting their registration activities around the world

Desired Experience & Education

- Bachelor's degree or equivalent education and 5 years+ of Quality Management, Quality Assurance and Regulatory compliance to the FDA, ISO, & Health Canada regulations.
- Good understanding of the FDA GMP & ISO-13485 (FDA/ISO 13485 auditor training preferred).
- Good working knowledge of the international medical standards.
- Good working knowledge of sterilization validations.
- Possess good communication and interpersonal skills.
- Good working knowledge of the manufacturing and quality operations.
- Database management skills and report generation

We offer a full complement of benefits including health, dental, vision, life insurance, 401(k), vacation and sick time. Come work for a growing company that offers a fun, collaborative environment with work-family balance.

Please note: This position is based in the facility and not a remote position

Qualified applicants should send their resume and salary requirements to **careers@innoviamedical.com**.

Applicants for employment must have work authorization that does not now or in the future require sponsorship of a visa for employment authorization in the United States (i.e., H1-B visa, F-1 visa (OPT), TN visa or any other non-immigrant status).

EOE/Disabled/Veterans