Hokanson
Passionate about Vascular Health

D. E. Hokanson, Incorporated
12840 NE 21st Place
Bellevue, Washington, 98005 USA

Phone 425 882 1689
Fax 425 881 1636
Web: hokansonvascular.com

Quality & Regulatory Manager

Hokanson Vascular, the Bellevue-based, world-renowned manufacturer of medical devices for peripheral vascular disease diagnosis is seeking candidates for the position of **Quality & Regulatory Manager**.

We are a small and impactful 2nd generation, women-owned business, currently with 17 on-site employees, and 50 years of successful manufacturing history and business stability. Our products are sold worldwide, and have an excellent reputation for durability, which we back with exceptional warranties and service levels.

We operate in the regulated field of medical device manufacturing, and take great pride in our ISO 13485 with MDSAP certified quality system, which simultaneously allows us to do business with customers around the world.

To find out more about our great company, check out our website: www.hokansonvascular.com.

Job Description

- Responsible for compliance of the company quality system, products and associated records to current domestic and international regulatory requirements including: FDA, EU, Canada, Australia, MDSAP, ISO 13485, IEC 60601-1 and subordinate standards.
- Responsible for assuring Medical Device Records and Device History Records are compliant with regulatory standards.
- Generates PMS plans and reports, summary reports for Health Canada.
- Responsible for quality system improvements based on internal and external audit results, quality driven data and management reviews.
- Assures that production work instructions, product test and checkout documentation and products released for shipment, comply with the quality system.
- Works with engineering to create engineering change letters, routes for approvals, and works with Production Planner to implement associated changes into production.
- Works with engineering on verification and validation of design and process changes.
- Assures that engineering designs and design changes are implemented in compliance with the quality system and regulatory standards.
- Drives risk management activities throughout the life cycle of products and relative to quality system processes. This includes DFMEA, PFMEA and Risk-Benefit Analyses.
- Responsible for training personnel about the quality system, and about changes to the quality system.
- Acts as the Quality System Management Representative and Person Responsible for Regulatory Compliance to regulatory agencies.
- Responsible for regulatory submissions, maintaining regulatory licenses, responding to regulatory audits and interacting with regulatory agencies on other regulatory topics.
- Establishes schedule of internal quality audits of production activities, products and the quality system.
- Assesses complaints, nonconformance issues and repair logs to identify quality trends of concern and mitigates associated risks.
- Responsible for assuring triggered failure analyses and CAPA investigations are conducted in compliance with procedures and regulatory standards. Implements resulting quality system changes and conducts follow-up reviews to ensure actions have been effective.

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- Supports the design transfer of new products to production, including ensuring training of personnel for new processes.
- Manages maintenance of production equipment. Schedules and maintains calibration of production instruments.
- Establishes program for supplier management, supplier/vendor approval, re-evaluation, audits, oversight and receiving inspection to assure compliance with regulatory standards and the internal quality system.
- Responsible for and facilitates quarterly and annual quality management review meetings, including all inputs and outputs.
- Attends Post Production Critique meetings and ensures all action items are closed in support of ongoing production activities.

More about this Job Opening

We are currently seeking a **Quality & Regulatory Manager** team member. While direct experience with medical device manufacturing is desired, we would consider the right individual who fits our core values AND has a proven track record of delivering high quality and high productivity in a regulated design, production or manufacturing environment.

Our company gets more stuff done with fewer people than most companies, so the impact of one person's work is large. We need you to have a keen sense of how your job relates to our goals, and to have ideas about how to improve our processes, quality and reliability. Your desire to drive quality activities - and your drive to improve yourself and the reputation of our company – will be hallmarks of your success in this role.

Requirements

- Bachelor's or master's degree in engineering, science, quality management, or related field.
- 5+ years experience working in a regulated design and production environment.
- 5+ years experience working with medical devices.
- Experience writing procedures, regulatory submissions and other similar documents is desired.
- Experience with regulatory audits, including direct interaction with auditors is desired.
- Excellent verbal and written communication skills are required.
- Ability to work independently and be a team player.

A little bit more about us and the open position:

Our work environment is fun and relaxed; our team is diverse, professional and committed to seeing Hokanson grow.

This position is on-site, full-time 40 hours per week, Monday – Friday. Starting salary: $95K - $120K depending on qualifications and experience. Company benefits include paid holidays, vacation and sick leave, 401(k) retirement plan with company match, health insurance, medical expense reimbursement, and profit sharing.