HEMOSONICS
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Quality Engineer

March 2017

The position is based in Durham, North Carolina. Relocation is not included.

Description

HemoSonics seeks a Quality Engineer as an addition to the Quality Systems team.

This is a dynamic career opportunity for an experienced quality professional to be responsible for ensuring the quality of all products in conformance to internal quality system policies, US regulations and ISO 13485 standards. This includes quality system documentation, manufacturing processes, quality customer problem resolution, and participation in product design, development, and vendor reviews/approvals.

Key attributes of the successful candidate:

Leadership:

- Recognized as a technical leader for quality systems within the company and ensures trust when working with staff, customers or suppliers.
- Capable of leading a CAPA team, or working with a customer or supplier to resolve product quality issues.
- Works effectively on cross functional teams to establish and maintain appropriate processes pertaining to quality.
- Strong organizational and time management skills

Communication:

- Excellent written and oral communication skills
- Ability to formulate responses to common quality inquiries from staff or complaints from customers and regulatory agencies
- Ability to review, analyze, summarize, and interpret data for Management Reviews; draw conclusions and make appropriate recommendations and decisions; write reports; and give oral presentations
- Ability to write and review SOPs, Forms, Work Instructions and review project team documentation

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Key Responsibilities:

The Quality Engineer is responsible for reviewing and analyzing complaint data, performing root-cause investigations to establish corrective action plans and implement corrective actions, writing and updating procedures as required to ensure the quality system is compliant with regulations including the FDA Quality System Requirements (QSR), ISO 13485, the In Vitro Devices Directive (IVDD), and Canadian Medical Device Regulations (CMDR). Perform product and process FEMA and write risk reports.

Product Acceptance & Investigations

- Plans and conducts incoming inspections to assure the quality of assigned products or components.
- Assist with maintenance of the Device History files, training records, and other quality system documents.
- Tracks and report quality metrics for HemoSonics Management Reviews.
- Advises on changes and their implementation and provides training, tools, and techniques to enable others to achieve quality
- Utilizes statistical analysis techniques to determine product acceptance and AQL sampling plans, evaluate process capabilities, and develop statistically sound tolerance limits
- Participates in the non-conformance reporting system, driving timely disposition and closure. Leads and/or participates in MRB meetings. Identify non-conformance trends and develop and administer technical investigation and CAPA programs to resolve recurring quality problems.

Product Development & Operations

- Contributes to the development and implementation of product test plans including Verification and Validation of products and processes
- Serves as liaison to design, procurement and manufacturing engineering
- Participates as a resource in validations applicable to processes and product
- Performs standard quality engineering reviews of design documentation for compliance with stated requirements, including supplier quality and company quality records
- Works with Manufacturing Engineering to address supplier quality issues
- Ensures quality management system and project documentation are maintained to ensure retrieval for audits.

Training and Document Control System

- Assist in managing the training tracking system. Sends out training update notices, files and maintains staff training binders.

Post Market Surveillance

- The Quality Engineer supports the Complaint Handling Unit and is responsible for investigating, determining root cause and ultimate resolution of product failures. Will work

closely with RA/QA, Engineering, Operations, Clinical and other functional areas to evaluate actual of potential product failures and update risk management files as needed
- Contributes to product safety, product quality, and customer satisfaction related decisions (both databased and risk-assessment-based decisions)
- Leads or participates and supports internal and external supplier audits and inspections
- Develops improvement plans and tracks customer Quality Ratings
- Monitors and advises on how the product quality is performing and publishes data and reports regarding the effectiveness of the quality management system in achieving the product performance goals.

Education and Experience Required:

- Minimum 3 - 5 years' experience as a Quality Engineer in the diagnostics or medical device industry.
- BA/BS degree in science, engineering or another technical field.
- Ability to demonstrate working knowledge of current and applicable GMP regulations e.g.: ISO13485 / 21 CFR Part 820.
- Experience participating in internal and external audits (e.g., FDA, Notified Body, Supplier)
- Knowledge of validation, statistical process controls, and regulatory compliance.
- Demonstrated skills in statistical analysis
- Experience with CAPA, non-conforming product investigations, deviations, change control, training and document control, complaint investigation, field action processes and risk management.
- Strong computer skills
- Individual must have a hands-on approach and be able to work with various staff and management.
- CQE, CQA preferred
- Knowledge with IEC 62304:2006 and IEC 61010-1:2010 a plus

To apply, please email your cover letter and resume to:

qualitycareers@hemosonics.com