Quality Engineer

Summary:
The Quality Engineer is responsible for the development, application, validation and maintenance of manufacturing and quality management systems associated with compliance to internal procedures and applicable regulatory standards for products and components.

Responsibilities:
- Performs and documents Change Control Request (CCR) assessments.
- Performs and documents timely Corrective and Preventive Actions (CAPA) investigations.
- Performs and documents customer complaint investigations, performs root cause analysis and develops corrective and preventive actions. Works with customers to provide required technical support and information regarding the investigation.
- Acts as lead on assigned CAPAs to drive corrective actions and closure of CAPA within prescribed timelines.
- Completes Supplier Corrective Action Requests (SCARs) and communicates with suppliers in regards to non-conformances, supplier changes, etc.
- Performs product support for product development and commercial products (reviews/approves product specifications, customer drawings, product validations protocols).
- Performs statistical data analysis utilizing statistical software (Minitab and Excel).
- Develops and implements statistical methods and designs experiments to support process control and process/product improvement.
- Performs physical and visual Test Method Validation/Gage R & R activities by developing and executing protocols for new or existing processes.
- Performs Risk Management activities utilizing risk management tools (pFMEAs (Process Failure Mode and Effect Analysis), etc.).
- Supports development and implementation of methods for sampling, inspection, testing and evaluation of products.
- Interfaces with customers to provide technical support for our products/complaints/change control.
- Reviews/approves applicable validation and qualification documents for compliance with internal procedures (Installation Qualification (IQ), Operational Qualification (OQ), RQP, Internal Product Development Process (IPDP) phase transfer documents, Document Control Revisions (DCRs), etc.)
- Supports customer and/or third party audits as required.
- May be trained as an auditor and perform quality audits.
- Follows established safety requirements and adheres to Fenner Framework HSE Management System.
- Performs other job related responsibilities as assigned

Qualifications:
- 3 - 5year's experience regulated industry in one or more of the following functions: Quality Assurance, Quality Engineering, Validation, Product Development, Process Engineering or Manufacturing Engineering.
- Bachelor's degree in Engineering.
- Familiarity with ISO 9001 and/or ISO 13485 Standards.
- Demonstrated experience in Process Improvement and deviation reduction.
- Able to read, analyze and interpret common legal, financial, scientific and technical documents, to respond to common inquiries, customer complaints and regulatory agencies.
- Strong problem solving & analytical skills, with concentration on risk analysis & driving to root cause.
- Experienced in developing project plans, SOPs, work instructions, etc. that are well-organized, clear and concise; with varying degrees of technical content.
- Prior Quality Auditing, preferred
- Knowledge of statistics, design of experiments, sampling, gauge R&R, FMEA/risk management and process control.
- Demonstrated ability to participate in and/or lead cross functional teams, ability to independently prioritize and execute projects and responsibilities.

Visit our Careers page to send in your resume and cover letter to apply for the above position.