Quality Engineer II

About this role

Develops, establishes and maintains quality engineering methodologies, systems, and practices which meet Boston Scientific customer and regulatory requirements in support of product development. Serves as a Quality representative to improve awareness, visibility, and communication on quality initiatives to support departmental, functional, site, divisional and corporate quality goals and priorities. Provides focused quality engineering support within new product development, operational, or system/services support.

Your Responsibilities

Leads and/or participates in project teams coordinating the quality efforts of engineers, technicians and other professionals of various disciplines/departments to design, develop, and continuously improve medical device products. Plans, schedules, conducts or coordinates detailed phases of the engineering work in a part of a major project or in a total project of moderate scope.

- Performs work which involves conventional engineering practice but may include a variety of complex features such as conflicting design requirements, unsuitability of standard materials, and complex data analysis.
- Facilitating and performing internal QA audits.
- Performing statistical analysis to assess cost of, and determine the responsibility for products or materials that do not meet required standards and specifications;
- Create, maintain and update PFMEAs, Test method validations, Visual Standards, Quality Control Inspections.
- Participate in MRB as appropriate and partner and assist manufacturing with the implementation and maintenance of SPC.
- May specialize in one of the areas of in-process inspection, design of product evaluation, and/or research and development as they apply to quality control.
- Performs responsibilities required by the Quality System and other duties as assigned or requested.
- Identify non-conformance trends and develop and administer technical investigation and corrective action programs to resolve recurring quality problems, as required.
- Demonstrates and actively promotes highest levels of professional QA engineering discipline and rigor.
- May complete Design Assurance Quality Engineering tasks, typically one or more of the following:
- Participate, as required, in the development and qualification activities related to the platforms and breakthrough.
- Participate, as required, in the development and qualification activities related to initial product design and subsequent design changes.
- Perform complaint handling, including root cause analysis, investigations, corrective action determinations, and as appropriate, adverse event determinations and reporting
- Designing and implementing methods and procedures for inspecting, testing and evaluating the precision and accuracy of products.
- Determination of user needs for the design & subsequent translation into engineering requirements.
- Test methodologies to verify/validate the design performance, procedural use and design related risks.
- Verification & validation planning & execution.

What we are looking for

Basic Qualifications:

- Bachelor in Scientific Discipline
- Minimum 2 years of experience in an FDA regulated business, preferably medical device
- Experience in CAPA/Non-Conformance investigations
- Experience with PFEMA, DFMEA, Test Method Validation
- Excellent Writing and Communication skills

Preferred Qualifications:

- 3-5 Years of experience with BS in Biomedical, Engineering, Quality or related discipline OR 1-4 years with Master's degree.
- Experience in Process Validation, Test Method Validation, Statistical Analysis, Statistical Process Control
- Experience in Non-Conformance/CAPA investigations
- Six Sigma Certification, ASQ SQE certification
- SPC, Tableau or other business intelligence tools