System Engineer

Job description:

• Elicit stakeholders' needs, translate into requirements specifications and lead/escort requirements' materialization
• Develop and maintain Design Inputs documentation, including system-level requirements, product specifications, etc.
• Develop and maintain technical documentation related to the Design History File following procedural development of medical products
• Lead Risk Management activities
• Support and verify system integration, system testing, and validation and verification covers design inputs and outputs correctly
• Serve as R&D focal point to other functional departments including Quality Assurance, Regulatory Affairs, Clinical and Manufacturing
• Support regulatory submissions and audits
• Actively participate in the Design Change process to ensure the proposed changes to the products are systemically and thoroughly analyzed and assessed
• Proposes algorithmic solutions and trade-off analysis to problems presented by vendor, other engineers, customers, etc. - from problem definition to pertinent concepts and solutions to facilitate project outcomes and goals
• Support Engineering with customer complaint investigations

Education, Experience and Skills:
• BSc. Or higher in Mechanical, Biomedical Engineering (or equivalent)
• Minimum of 5 years' experience in class II (or higher) medical device R&D
• Minimum of 3 years' experience as a System Engineer
• Demonstrated experience with working under relevant regulations and standards: FDA QSR, ISO-13485, MDD (MDR) - with a focus on Design Controls and Risk Analysis
• Experience with leading Risk Analysis activities (FMEA, ISO-14971)
• Deep understanding of Medical Device development standards such as: ISO-10933, ISO-14971, ISO-11607, ISO-11737, ISO-11135
• Knowledge in DF'x (A\ M \C \ T \S) methodology implementation
• Ability to communicate in written and verbal English

Advantage Qualifications:
• MSc. in System Engineering
• Experience as a design engineer in the Cardiovascular
• INCOSE applicable education
• Experience with R&D of class III medical device
• Experience with Usability requirements and testing (ISO-62366)

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