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QA Manager

At least 5-7 years of experience in medical device industry

Responsibility:

management of on-going quality activities
support of company manufacturing/operation activities
managing of inspection processes
management of NCR's/deviations
monitoring of controlled environment, packaging areas, storage areas.
monitoring of calibration and maintenance activities.
managing a team of three quality engineers and QC department.
Review and approval of all relative documentation
High level English
Knowledge of applicable standards related to the scope of work.

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V&V Engineer

Responsible for verification and validation tests plans with the ability to maintain and cross-reference it with risk analysis matrix, design requirements and applicable standards.
Responsible for verification and validation aspects submissions, throughout the different stages of the process in conformance with CE and FDA regulatory.

- Review and analysis of requirements for development of V&V test protocols which provide sufficient coverage
- Develop and maintain test methods, equipment and instruments for medical device throughout all development stages of the product.
- Design, selection and documentation of test equipment (HW).
- Formulates test guidelines, protocols, and tests reports.
- Perform verification and validation testing of hardware (mechanical, electronic implantable devices) and SW for prototypes and products.
- Participate in design reviews and risk assessment sessions as needed.
- Overview and manage standard testing process performed in certified labs
- Maintain V&V traceability matrix

Position Requirements:
- University graduate in Biomedical Engineering
- 2-3 years experience in design, execution and reporting of verification and validation tests for medical device companies
- Knowledge and experience with relevant standards (ISO14708, EN60601, etc.) – an advantage
- Proven experience in working with digital testing lab equipment
- Very Good English skills
- Hands on approach

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Design Assurance Engineer

• Bachelor's Degree in Engineering required
• 5 years' related experience – design experience and knowledge in medical devices
• ASQ/CQE Certification – An advantage
• Certified IPC and knowledge in J-STD – An advantage
• Knowledge of Design Validation and Design Verification tools and techniques
• Experience or knowledge with injection molded components (mold qualification, FAI, validation and process controls)
• Excellent English verbal communication and technical writing skills
• Ability to interface with multiple groups in the organization Exposure to FDA Quality System Regulation
21 CFR Part 820 and ISO13485 required, in particular Design Control requirements
• Knowledge of risk management tools and techniques. FMEAs, FTAs, ISO 14971 risk management standard
Hands on experience with the following standards: Biocompatibility (10993 series) ,Sterilization standards, Electrical Safety (IEC 60601), Software (IEC 62304) and Usability (IEC 62366).
• Demonstrated ability to act as Subject Matter Expert related to Design Controls, DHF, Master Validation
Plans and FMEAs

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R&D Engineer/Project Manager

Scope & Responsibilities:
- Lead R&D projects from concept through regulatory submission, transfer to production, clinical evaluation, and commercialization.
- Design machinery and tools.
- Design and perform verification testing.
- Work collaboratively with other team members and positions from other departments in the company (manufacturing, quality, regulation, clinical, marketing and sales).

Requirements:
- Mechanical or Biomedical Engineer with a strong mechanical background.
- Minimum 2-5 years of experience in development of invasive medical devices.
- Excellent teamwork ability.
- Hands-on approach
- Proficient in SolidWorks.
- Good technical English
- Ready to travel if needed (up to 20%)

Advantages:
- Developing mechanisms with fine/micro-mechanics.
- Development of products for intervention procedures.
- Experience in braiding technologies.
- Experience in transfer from development to commercial production.
- Familiar with intervention suite environment.

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