

V&V Manager

Biomedical Startup company is looking for V&V Manager

Job Description:

Leading all the System verification and validation activities that are required to release the system for production. The role includes close work with R&D to specify and execute and report the required tests, working with QA / RA for medical QMS compliance.

In this role you will work closely with the project managers to:

- Review specifications and technical design documents to provide timely and meaningful feedback
- Define and lead the testing of a noble medical system
- Design and define testing methods
- Manage V&V contractors and labs that perform regulatory and environmental tests
- Generate comprehensive V&V test plans, protocols, and reports with the ability to maintain and cross-reference it with Risk Analysis Matrix and Design Control documentation.
- Identify and track defects during testing
- Deeply collaboration with Clinical, QA and RA team

Support QA aspects of technology transfer of developed manufacturing processes and new product development from R&D to manufacturing environment

Job Requirements:

BSc degree in System, Mechanical, Electrical or Biomedical engineering or related field

- Proven experience of leading and conducting V&V activities of Medical devices for at least 2 years, including writing, and executing test plans and protocols for medical devices with strong emphasis on QA and problem solving
- Experience from multi-disciplinary medical device companies
- Formal and practical knowledge of testing methodologies
- Excellent documentation skills
- Excellent written and verbal communication skills
- Fluent in English
- Familiar with Medical Device Quality Systems, ISO 13485 & CFR21 part 820, Design Control processes, Design and Development Usability procedures. Experience with the environment, safety, biocompatibility, and essential performance tests (e.g. IEC 60601)
- Experience with medical robotic system "Usability Testing" as an advance

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