IceCure Medical, an innovative and fast-growing medical device company in the field of cryoablation, is looking for a V&V Engineer

Reports to: Director of Engineering
Department: R&D and Engineering

Job description and responsibilities

➢ Review specifications and technical design documents to provide timely and meaningful feedback for Engineering Verification & Validation activities.
➢ Ownership & Maintain the company Verification, Validation & Process Validation infrastructure (SOP, Forms, SW tools, Jigs, Simulators).
➢ Create detailed, comprehensive and well-structured V&V test protocols and reports, with the ability to maintain and cross-reference it with Risk Analysis Matrix & Design Control documentation.
➢ Define & Execute the Usability & Ergonomic Verification Test protocols
➢ Develop, apply & maintain test methods, equipment and instruments for medical device throughout all development and production stages of the product to meet user needs & product requirements.
➢ Being involved in reliability and integration tests for prototypes and products.
➢ Developed manufacturing processes validation activities for sustain & NPI projects (IQ\OQ\PQ, Validation Plans, Sample size, ATP, Testing forms and Documentation)
➢ Maintain relevant chapters of DHF & DMR
➢ Development and implementation of methodologies for collecting and analyzing field failure data and determining root cause of field failures (FTA, LOG’s investigation, SPR, service Failure analysis, etc’)
➢ Leading company efforts to eliminate life field failures in products.
➢ Coordinating failure analysis with other disciplines as necessary to lead to determination of root cause
Ensuring corrective actions are implemented in manufacturing to prevent recurrence of failure

Incorporating automation and improvement of failure analysis process.

**Education and Experience**

- BA/BSc. Degree in Mechanical \ Biomedical or equivalent
- Experience in similar positions
- Excellent human relations, independence, authority, readiness for strenuous work, proven ability to work across multiple tasks and interfaces, Strong teamwork ability.
- Fluent in Hebrew and English. Additional languages are preferred

IceCure Medical, an innovative and fast-growing medical device company in the field of cryoablation, is looking for an **R&D System Engineer**.

**Roles & Responsibilities**

- Develop Mechanical & Multidisciplinary modules from the initial concept to release as a part of the R&D department, with reference to medical device standards.
- Create system and modules design specifications and requirements, translating user needs to technical requirements.
- Create design and transfer to production documentation (DHF/DMR) following procedural development of medical products (Design Control).
- Responsible for creating and maintaining RMF (Risk Management File).
- Point of contact for R&D subcontractor’s activities: DR’s, Integration & Implementation in company products.
- Responsible for creating and maintaining RMF (Risk Management File).
- System aspects design in products portfolio: top-level architecture, new technologies implementation, define performance goals and tests, serviceability, interfaces specs, design to assembly and cost, human factors design.
- Responsible for product integration, reliability, qualification, environmental and safety tests in external LAB and in-house.
- Perform RCA (Root Cause Analysis) and drive outcoming system technical solutions to implementation through tests and data.
- Technical Leadership across project scope and the various company functions and resources.
- Support and cooperate with company departments (Regulatory, Service, Manufacturing, Engineering, Quality, and Marketing), being responsible for their early involvement during
system design processes. Preparation of Risk Analysis and FMEA for system elements according to QMS.

- Lead system process validation activities.
- Availability to travel abroad and domestically.

**Education and Experience**

- B.Sc. or M.Sc. degree in Mechanical\System Engineering.
- At least 4 years of proven experience in Engineering environments of multidisciplinary products in medical devices - **must**
- Excellent design and development skills, from parts and sub-modules to final product and production support, proficient in the full life cycle of a product, including requirements generation, conceptual design, DR's, Experiments, Design Transfer Plans, etc.
- Excellent troubleshooting skills and drive to bring best-in-class solutions
- Experience with Machining, designing hydraulic & pneumatic elements, Sheetmetal.
- SolidWorks & PDM - High-level expertise
- Knowledge of standards and regulations: DIN, ASTM, ISO 13485, IEC 60601 CFR21, IEC 60601, UL, CE, etc.'
- Knowledge in Cryogenics – Preferred.
- Knowledge in DFx (A\M\C\T\S) methodology implementation – Preferred.
- Knowledge in PMP & INCOSE methodology – Preferred.
- Familiarity with other ERP, PLM, and PDM tools – Preferred

Please send CV to : Meravnd@icecure-medical.com