



Innovating cryotherapy solutions

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

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IceCure Medical Ltd. | 7 Ha'Eshel St., Southern Industrial Park P.O.B. 3163, Caesarea, 3079504, Israel
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- 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

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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.
- Experience with Injection molding, Extrusion, Electronic packaging, and Sterilization processes – Preferred.
- 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 DF'x (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

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