

## Position Title: Sustain System Engineer (SSE)

**Reports to:** Director of Engineering

**Department:** R&D and Engineering

### **Job description and responsibilities**

- Responsible for product integration, reliability, qualification, environmental and safety tests in external LAB and in-house. Perform FTA and detecting preferred system technical solutions.
- Lead and maintain products configuration following procedural development of medical products (Design Control): Design History Files (DHF), Device Master Record (DMR), (RTM) Requirements Traceability Matrix and their change approval.
- Creating \ reviewing & maintenance wide range of Engineering documentation (Assy WI, IQ\OQ\PQ,V&V protocols, Acceptance Criteria, Procedures, Templates and Forms) with QA & Operations Departments deep cooperation.
- Lead System aspects in products portfolio: top-level architecture, modern technologies implementation, define performance goals and tests, serviceability, interfaces specs, design to assembly and cost, human factors design, with reference to medical device standards, and focus on customers and business specifications.
- Execution of engineering investigations and LOG analysis as part of NCRs, CAPAs, Customer complaints.
- Support and cooperate with company departments (Regulatory, Service, Manufacturing, Engineering, Quality, and Marketing), being responsible for their early involvement during system design processes.
- Lead and maintain of Risk management file, Risk assessment, FMEA for system elements according to QMS.

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- Responsible for assessing risks arise for complaints, ECOs, CAPAs etc. Vs. risk management file.
- Initiate and lead the design reviews at required stages of the project development process.
- Involved in cost reduction \ improvement design & process activities.
- Availability to travel abroad and domestically.

### **Education and Experience**

- B.Sc. or M.Sc. degree in Medical\Mechanical\System Engineering.
- Knowledge in Cryogenics – Preferred.
- 2-5 years of proven experience in Engineering environments of multidisciplinary products or medical devices.
- Interpersonal skills and excellent teamwork - the ability to meet technical as well as human challenges.
- Experience in medical device quality systems, specifically Risk management file and Design Inputs.
- Experience resolving complex system issues and being “hands on” when needed.
- Good documentation skills.
- Experience in MS-Office, MS-Project, MS Planner – Must.
- Experience in Solid works, LabView, ERP, PLM, PDM tools – Advantage.
- Fluent in Hebrew and English.

Please send your CV to “[Meravnd@icecure-medical.com](mailto:Meravnd@icecure-medical.com)”

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