

P MOHAN REDDY

Senior Systems Engineer

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PROFESSIONAL SUMMARY

Senior Systems Engineer with **7+ years** of cross-domain experience in **medical devices**, **automotive systems**, and **electrical switching equipment**.

Proven track record in **requirements engineering**, **functional architecture**, **MBSE (SysML)**, and **risk management** across regulated environments. Delivered outcomes such as **30% faster design cycles**, **100% requirement traceability**, and **audit-ready compliance** to **ISO 13485**, **ISO 14971**, and **IEC 60601-1**.

Adept at translating stakeholder needs into robust architectures using **Cameo**, **System Composer**, **Rhapsody**, **DOORS**, **Jama Connect**, and **Polarion**; mentor teams to adopt systems engineering best practices.

Skilled at **leading cross-functional teams** across engineering, regulatory, and business units to deliver compliant products on time

CORE COMPETENCIES

Systems Engineering

Requirements Engineering; Functional Architecture; MBSE (SysML); Traceability; V&V Planning; Change Impact Analysis; Stakeholder Management; Configuration Management

Tools & Software

Cameo Systems Modeler; IBM Rhapsody; IBM DOORS; Jama Connect; Polarion; ConfigIT; Windchill; MasterControl; Creo; SolidWorks; CATIA; AutoCAD; ANSYS; Minitab

Design & Analysis

GD&T; Tolerance Analysis; Thermal/Structural Simulation; Enclosure/Packaging Design; Variability Modeling (OVM)

STANDARDS & REGULATORY EXPERTISE

Medical Devices

ISO 13485; ISO 14971; IEC 60601-1; IEC 62304; ISO 62366; ISO 10993; ISO 11607; ISTA; FDA 21 CFR Part 820; EU MDR 2017/745

Automotive

ISO 26262 (Functional Safety); ASPICE

Electrical Systems

IEC 60947 (incl. 60947-2); IEC 60898; IEC 61439; UL 489

PROFESSIONAL EXPERIENCE

Senior Systems Engineer — Onward Technologies Ltd

Pune, India | Oct 2024 – Present

- Led requirements management for MCCB, achieving **100% traceability** from stakeholder inputs through verification in Jama; maintained requirement traceability matrix (RTM), V&V Planning.
- Developed system architecture for circuit breakers using MBSE best practices to align customer, regulatory, and design constraints.
- Trained **15+ engineers** on Jama Connect; reduced review/rework cycles by **30%**.
- Elicited and negotiated requirements across marketing, regulatory, and design teams, reducing clarification iterations.

Key Achievement: Operationalized a requirements model for variant-specific configurations that shortened alignment time with customers by **25%**.

Systems Engineer — Blue-Kei Solutions Pvt Ltd

Pune, India | Sep 2022 – Sep 2024

- Managed **ISO 14971**-compliant risk processes (risk analysis, RMP) for a Class II medical device; ensured audit-ready documentation.
- Introduced **RRFLP** (Risk–Requirement–Functional–Logical–Physical) approach to system architecture; improved cross-functional alignment.
- Built a **System Impact Analysis (SIA)** framework improving change assessment efficiency by **25%**; maintained structures aligned to **ISO 13485** processes.
- Implemented **digital thread** and end-to-end **system integration** in an automotive company; demonstrated complete concept using **SysML** and other tools.
- Drove change control and EC closures; facilitated cross-functional FMEA sessions.

Key Achievement: Spearheaded a cross-domain modeling initiative that reduced architecture definition time by **15%** and improved review quality.

- Designed chiller components using **top-down Creo** methodology; ensured manufacturability and cost targets.
- Performed **tolerance stack-up** and applied **GD&T** to critical drawings; reduced late-stage defects.
- Performed **structural analysis** for chiller frames for early verification of load distribution using Creo 4.0.
- Contributed carbon-footprint reduction concepts shortlisted for implementation.

Key Achievement: Early structural analysis reduced redesign iterations by **20%** across design and simulation teams.

- Designed enclosures and performed **thermal/structural** analyses for electro-mechanical systems.
- Developed pneumatic & heater systems; prepared test plans, transfer functions, and verification methods.
- Selected materials per **ISO 11607/ISTA** for medical device packaging; collaborated with suppliers on DFM.

Key Achievement: Improved thermal management via optimized heat sink and airflow design, enhancing reliability under load conditions.

KEY PROJECTS & ACHIEVEMENTS

Precision Heating System for Medical Device

2020

- Designed and validated a precision heating subsystem capable of maintaining $\pm 0.2^{\circ}\text{C}$ stability for clinical solutions.
- Authored system-level specifications, control logic, and verification protocols; ensured alignment with **IEC 60601-1** performance and **ISO 14971** risk controls.
- Conducted thermal simulations (**ANSYS**); used **Minitab** for statistical validation and **Creo** for mechanical integration.
- **Outcome:** Improved temperature control accuracy vs. legacy design and reduced calibration effort by **15%**.

Optimized Fin Design for Automobile Engine Cooling

2016–2017

- Performed numerical studies and CFD-style analysis in **ANSYS** and **MATLAB** to evaluate fin geometries for heat dissipation.
- Assessed manufacturability and cost trade-offs; prepared recommendations for prototype iteration.
- **Outcome:** Achieved predicted **thermal dissipation improvement** without increasing manufacturing cost; reduced overheating risk in simulation.

EDUCATION

B.Tech, Mechanical Engineering — *National Institute of Science & Technology, Berhampur*

Aug 2013 – May 2017

CGPA: 8.0/10

CERTIFICATIONS & TRAINING

- **INCOSE CSEP** (*exam passed, certification pending*)
- ISO 14971 Risk Management (self-training)
- ASPICE & ISO 26262 awareness (self training)