

RATAN LAL BUNKAR

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SUMMARY

Result driven R&D Engineer with over 3+ years experience in product development and test systems for embedded electromechanical and smart IoT medical devices aligned with International regulatory standards such as ISO 13485, ISO 14971, ISO 11608, IEC 60601. Proven success leading cross-functional teams to execute end to end complex medical device platforms.

WORK EXPERIENCE

System Engineer SHL-Medical

May 2023 - Present

- **Engage** with end users, product managers, and cross-functional stakeholders from the earliest stages of product development to elicit **user needs, usability expectations, and functional constraints**, translating these often ambiguous or conceptual inputs into **structured, measurable, testable, and, traceable system-level requirements**. Additionally, **define the entire product lifecycle**, encompassing **design, manufacturing, labeling, usability, maintenance, and eventual disposal or end-of-use scenarios**, to ensure **holistic system engineering and regulatory alignment** across all phases of development.
- **Lead requirements engineering and system definition (MBSE and SyML)** across domains such as **user interaction, mechanical and electronic design, manufacturing, labeling, and packaging**, while ensuring full traceability and compliance with **ISO 13485, ISO 14971, ISO 11608, and IEC 60601** throughout the development lifecycle.
- **Drive risk management activities**, supporting **DFMEA sessions** to identify potential failure modes early in the design process, and **lead design transfer** to ensure **production-ready, regulatory-compliant deliverables** that align with business and manufacturability goals.
- **Design and implement custom test jigs and automated fixtures** using **Python-based scripting** and **Computer-Aided Test Systems (CATS)** to validate system functionality and performance under realistic use-case scenarios; **lead equipment validation** processes including **IQ/OQ/PQ** and **Gage R&R (GRR)** to ensure **accuracy and compliance** in test systems.
- **Define critical components** from both design and manufacturing perspectives, ensuring alignment with **performance, safety, and compliance requirements**. Establish **Incoming Quality Control (IQC)** processes, including **specification setting, inspection criteria, and sampling plans** based on **Acceptable Quality Limits (AQL)** to guarantee **consistent quality and supplier accountability** throughout the production lifecycle.
- **Champion continuous improvement initiatives** by identifying gaps in **design control practices** and enhancing system documentation through the development of **process templates, checklists, and design guidelines** while also strengthening the company's **Quality Management System (QMS)** and **Product Lifecycle Management (PLM)** processes through **workflow optimization, documentation standardization, and improved cross-functional integration** throughout the product development lifecycle.

ACCOMPLISMENTS

- **Authored critical technical documentation** for medical device platforms including **Electromechanical Auto-injector, BLE Connected Mechanical Autoinjector, Medical Data Collector**, covering **System Requirements Specifications (SRS), System Design Specifications (SDS), Test Plans, Incoming Quality Control (IQC) protocols, and EURS/ESDS** for test equipment, ensuring **full traceability, regulatory alignment (ISO 13485, ISO 14971)**, and adherence to Company's certified **Quality Management System (QMS)** processes.
- **Developed fully automated test solutions** for key medical device platforms including **Elexy (electromechanical autoinjector) and Molly cCap (BLE-enabled mechanical autoinjector)**, by **designing and building in-house test systems** using **cost-effective single-board computers (SBCs) and sensors**, significantly reducing project verification and validation costs. Independently **authored Equipment User Requirement Specifications (EURS)** and **Equipment System Design Specifications (ESDS)**, built the test equipment, and executed full **equipment validation (IQ/OQ/PQ)** and **Gage R&R (GRR)** in compliance with the company's QMS.

WORK EXPERIENCE

Research Assistant Control And Systems Lab

May 2023 - Present

- Supported academic research and peer review at the Systems and Control Lab by evaluating journal and conference submissions for technical quality, clarity, and relevance. Provided structured feedback under faculty supervision, contributing to academic editing and review workflows.
- Co-developed and validated a novel NMF-based noise reduction algorithm for singing voice separation, integrating RPCA and REPet techniques. Co-authored and presented findings at ICSS&E 2022; received the Taipei Tech International Student Scholarship and SVS Research Grant in recognition of research excellence.

SKILLS

Standards & Compliance

- Strong knowledge of **ISO 13485, ISO 14971, IEC 60601** for medical device quality and safety.
- Familiar with **ISO/IEC/IEEE 15288, 29148** supporting structured systems engineering and traceability.
- Experienced in writing and executing test protocols and equipment validations (**IQ/OQ/PQ**) aligned with QMS.

Hardware Validation & Testing

- Proficient in **Test Method Development & Validation (TMV)** including fixture qualification and custom protocol writing.
- Built and validated **custom test jigs and CATS (Computer-Aided Test Systems)** using **low-cost SBCs** and sensors.
- Conducted **stress testing**, component evaluations, and bench-level verifications under various conditions.
- Skilled in using lab instruments like **oscilloscopes**, and scripting **Python-based automation** for validation tasks.
- Defined and implemented **IQC protocols** and **AQL-based sampling criteria** for incoming component inspection.

Failure Analysis & Reliability Engineering

- Led **root cause analysis** across mechanical, electrical, and firmware domains.
- Supported **DFMEA** and interdisciplinary troubleshooting to improve system reliability.
- Applied signal analysis and noise-reduction methods in system evaluations.

Data Processing, Analysis & Automation

- Proficient in **Python**, with experience using **NumPy, Pandas, Matplotlib, scikit-learn** for data analysis and automation.
- Skilled in **signal processing**, algorithm validation, and test data visualization.
- Experienced in **Minitab** for **DOE, ANOVA**, and **capability analysis**.

Software & Scripting

- Strong in **Python scripting** for test automation and validation.
- Working knowledge of **JavaScript, C++, HTML, CSS** in multidisciplinary environments.
- Experienced with tools like **Git, Docker, Linux, JIRA, and Polarion**.

Embedded & Control Systems

- Familiar with **PLC programming** (Ladder Logic, HMI, SCADA) – relevant to test equipment control or hardware diagnostics.
- Comfortable with **BLE/UART/serial communications** for embedded system interface testing.

Communication & Documentation

- Authored **System Requirements Specifications (SRS), System Design Specs (SDS), IQC, URS, EDS, and test reports** ensuring regulatory alignment.
- Experienced in coordinating with **third-party labs** for certification and compliance validation.

EDUCATION

Master's Degree (Electrical Engineering)

National Taiwan University of Technology, Taipei, Taiwan

Feb 2021- Jan 2023

Bachelor's Degree (Electrical Engineering)

Indian Institute of Technology Ropar, Ropar, Punjab, India

Apr 2016 - Aug 2020

LANGUAGES KNOWN

- English (Professional)
- Hindi (Professional)

HOBBIES & INTERESTS

- Passionate about emerging technologies such as quantum computing, Industry 4.0, and Artificial General Intelligence (AGI), with a strong focus on modern machine learning techniques including reinforcement learning and large language models.
- Enthusiast in Model-Based Systems Engineering (MBSE) and SysML, actively exploring simulation, Design of Experiments (DOE), and system modeling techniques for solving complex engineering challenges in biomedical and R&D domains.
- Enjoys solving advanced mathematical problems, engaging with algorithmic thinking, and continuously learning new technologies that push the boundaries of innovation in smart medical systems and intelligent automation.