RATAN LAL BUNKAR

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SUMMARY

R&D Product Development and Testing Engineer with **3+ years** of experience in **smart IoT** and **embedded medical devices**. Specialized in **Python-based test automation**, **UI-level system validation**, and **log and failure analysis**. Experienced in **bug triaging**, **test method validation (TMV)**, and **root cause analysis** across mechanical, electrical, and firmware domains. Strong background in cross-functional product development and testing in compliance with **QMS standards (ISO 13485, ISO 9001)**, **medical product development safety standards (IEC 60601)**, **software development lifecycle standards (IEC 62304)**, and **risk management standards (ISO 14971)**.

WORK EXPERIENCE

System Engineer SHL-Medical — **May 2023 - Present**

- Developed and maintained **Python-based automated test systems** for validating **embedded IoT medical devices** across **physical communication interfaces** including **RS-232, RS-422, UART, SPI and other serial protocols**, reducing manual testing effort and improving throughput.
- Designed custom **Computer-Aided Test Systems (CATS)** and **automated test jigs** to execute UI-level validations and simulate user interactions.
- Performed **log analysis** and **failure triaging** using Python, BLE/UART sniffers (e.g., **pyserial, pyshark, Wireshark**) to isolate and resolve system-level bugs across **firmware, mechanical, and electrical layers**.
- Authored detailed test protocols and validation reports **(IQ/OQ/PQ)** and contributed to **Test Method Validation (TMV)** documentation in line with **QMS** and **regulatory standards**.
- Collaborated closely with R&D, firmware, and quality teams for bug root cause analysis, design reviews, and issue resolution.
- Led system verification for **self-injection platforms (Elexy, Molly cCap)** and **smart medical data collectors** (SmartHub), validating real-time event capture, BLE and LTE Cat-M1 communication, and **cloud data transmission** across the device lifecycle.
- In the Elexy platform, conducted embedded PCBA-level validation, including **RFID module testing**, **optical sensor calibration, and LTE communication verification**, ensuring accurate signal processing, hardware integration, and compliance with design specifications.
- Conducted **manual testing** and behavior logging on prototypes under simulated **environmental and use-case conditions**.
- Supported risk control efforts by contributing to **DFMEA** sessions and aligning test design with **ISO 14971**.

ACCOMPLISMENTS

- Authored critical technical documentation for medical device platforms including electromechanical autoinjectors, BLE-enabled autoinjectors, and medical data collectors. Covered deliverables such as **System Requirements Specifications (SRS)**, **System Design Specifications (SDS)**, **Test Plans**, **Incoming Quality Control (IQC) protocols**, and **equipment specifications (EURS/ESDS)** to ensure full traceability, regulatory compliance (ISO 13485, ISO 14971), and alignment with certified **QMS processes**.
- Developed and deployed fully **automated test solutions** for platforms like Elexy and Molly cCap by designing custom test setups using cost-effective **SBCs** (e.g., Raspberry Pi) and **integrated sensors**. This significantly reduced **V&V cycle** time and project costs.
- Independently authored **Equipment User Requirement Specifications (EURS)** and **Equipment System Design Specifications (ESDS)**, built the hardware, programmed the automation logic, and executed complete equipment validation (IQ/OQ/PQ) and **Gage R&R (GRR)** in line with company QMS and regulatory guidelines.

WORK EXPERIENCE

Research Assistant **Control And Systems Lab** — **May 2023 - Present**

- Conducted research on noise reduction algorithms for singing voice separation using **NMF**, **RPCA**, and **REPet** techniques. Co-authored and presented findings at **ICSS&E 2022**. Supported peer review of academic submissions and received the **Taipei Tech International Student Scholarship** and **SVS Research Grant** for research excellence.

WORK EXPERIENCE

Control Systems Engineering Inten, DCM Engineering Products **Mar 2019 – Oct 2019**

- Gained hands-on experience in **PLC programming** (Siemens Step 7) using **Ladder Logic**, and configured **HMI dashboards** for real-time machine monitoring and diagnostics.
- Supported system commissioning, including **signal mapping**, **sensor wiring**, and **logic validation** for automated industrial processes.
- Assisted in creating **control flow diagrams**, system documentation, and troubleshooting guides to support equipment upgrades and fault visualization.
- Collaborated with electrical and automation teams to improve process reliability and reduce **machine downtime**.

SKILLS

Standards & Compliance

- Strong knowledge of **ISO 13485, ISO 14971, ISO 9001**, and **IEC 60601** for medical device quality, risk, and safety compliance.
- Familiar with **IEC 62304** (medical device software lifecycle), **ISO/IEC/IEEE 15288**, and **ISO/IEC/IEEE 29148** for structured systems engineering and traceability.

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 (e.g., oscilloscopes, multimeters) and developing Python-based automation scripts for test execution and data logging.
- 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, Linux, JIRA**, and **Polarion**.

Embedded & Control Systems

- Familiar with **PLC programming** (**Ladder Logic, HMI, SCADA**) – relevant to test equipment control or hardware diagnostics.
- Experienced in **BLE, UART, RS-232/RS-485, RFID, and LTE Cat-M1 communication interfaces** for embedded systems. Performed interface validation using tools like **pyserial, bleak, Wireshark,** and **pyshark.**

Communication & Documentation

- Authored System Requirements Specifications (**SRS**), System Design Specifications (**SDS**), Incoming Quality Control (**IQC**), Equipment User Requirements (**URS**), Equipment Design Specifications (**EDS**)
- Experienced in isolating interface-level failures through real-time data capture, signal timing analysis, and log diagnostics across communication protocols.

EDUCATION

Master's Degree (Electrical Engineering) **Feb 2021- Jan 2023**
National Taiwan University of Technology, Taipei, Taiwan

Bachelor's Degree (Electrical Engineering) **Apr 2016 - Aug 2020**
Indian Institute of Technology Ropar, Ropar, Punjab, India

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.