Ratan Lal Bunkar

SYSTEMS ENGINEER

Results-driven Systems Engineer with over 3 years of experience in the medical device industry, specializing in supplier transfer, systems integration, and risk-based verification & validation (V&V). Proven ability to translate design/user inputs into traceable system requirements using MBSE methodologies, and develop automated test systems with Python. Adept at ensuring compliance with ISO 13485, ISO 14971, and IEC 60601/11608 standards. Strong communicator with expertise in cross-functional collaboration and go/no-go reporting for stakeholder readiness.

CONTACT

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CORE SKILLS

- **Systems Engineering:** Requirements modeling (SysML/UML) | Architecture alignment | Traceability tools (Siemens Polarion) | MBSE in Enterprise Architect & Cameo Systems Modeler (CATIA Magic) | SRS/SDS/URS/EURS/EDS/ESDS | Requirements↔Tests traceability
- **Verification & Validation:** Risk-based test strategy | Python-based CATS & custom fixtures | Bench validation | IQ/OQ/PQ | TMV & GRR | Test plans/protocols/reports | Release readiness (go/no-go)
- **Risk & Reliability:** DFMEA | Risk control per ISO 14971 | RCA (firmware/electronics/mechanical) | Stress/component testing | Measurement system integrity
- **Regulatory Compliance:** ISO 13485 | ISO 14971 | IEC 60601 | ISO 11608 | IEC 62304 (familiarity) | QMS documentation | Awareness of FDA / EU MDR / NMPA / TGA / Health Canada / MHLW
- **Supplier Transfer & NPI:** Critical component specs | IQC & AQL setup | Incoming inspection criteria | Supplier readiness & accountability | Obsolescence/sustenance | Design Transfer to manufacturing | QMS/PLM workflow standardization
- **Interfaces & Protocols:** BLE | LTE Cat-M1 | RFID | Optical sensing | UART | RS-232/422/485 | SPI
- **Data & Analysis:** Python (NumPy, Pandas, Matplotlib) | Minitab (DOE/ANOVA/SPC/MSA) | Log analysis | Wireshark/pyshark
- **Tools & Platforms:** Siemens Polarion (requirements/ALM/traceability) | Siemens Teamcenter (PLM) | Confluence | JIRA | Git | Linux | PLC/SCADA (Siemens Step 7) | HMI configuration | SBCs (e.g., Raspberry Pi)

WORK EXPERIENCE

Systems Engineer
SHL Medicals
March 2023 to Present

- Led V&V planning and execution for multi-component self Injection SYstem platforms , ensuring traceability from user needs to test outcomes.
- Developed automated test systems and CATS using Python and sensors (BLE/LTE, RFID); decreased V&V cycle time by 30%.
- Spearheaded supplier transfer initiatives, including definition of IQC specs, AQL sampling, and critical part readiness.
- Executed IQ/OQ/PQ validations and Gage R&R for custom fixtures, ensuring accuracy and regulatory compliance.
- Authored and maintained SRS, SDS, URS, IQC, EDS, and traceability documents per ISO 13485 and ISO 14971.
- Supported DFMEA and led cross-functional RCAs to resolve complex integration and performance issues.
- Enhanced QMS/PLM workflows with standardized templates, improving documentation quality and design transfer.

Research Assistant – Control & Systems Lab
NTUT, Taipei | 2022 – 2023

- Designed and validated signal-processing algorithms for complex Signal Processing systems.
- Contributed to research papers and peer-review processes.

Control Systems Engineering Intern — DCM Engineering Products
Mar 2019 – Oct 2019

- Programmed PLCs (Siemens Step 7, Ladder Logic) and configured HMI dashboards for real-time machine monitoring and diagnostics.
- Supported system commissioning: signal mapping, sensor wiring, and logic validation for automated processes; produced control flow diagrams, system documentation, and troubleshooting guides.
- Collaborated with electrical and automation teams to improve process reliability and reduce machine downtime.

EDUCATION

Master Electrical Engineering
Institution: National Taipei Niversity Of Technology
Year of Graduation: 2023

Bachelor Electrical Engineering
Institution: Indian Institute of Technology
Year of Graduation: 2020