GOWTHAM RAMAMOORTHY

Senior Verification and Validation Engineer

Mail: rgowtham134@gmail.com

Phone: 7397345175
Location: Pune

Profile Summary:
Versatile Verification & Validation Testing Engineer with [9] years of experience specializing in environmental testing, stability testing, and traceability matrix. Expertise in labeling update, US FDA regulations, ISO 13485 quality activities, and technical documentation. Adept in managing drawing updates, BOM updates, and change Management requests. Leading team and ensuring to deliver change request implementation on time.

Work Experience:

Cyient –Philips, Pune (June- Present)

- Supported for EOL components implementation, ROHS Exemptions for the electrical and mechanical components.
- MLD change implementations, ensuring smooth integration into the production process and reducing downtime.
- Coordinated with 5+ suppliers DFM activities, Ensuring tolerance alignment for Philips MRI coils and electromechanical components.
- Remediating the PRS,URS,Verification plans and technical documentation.
- Performing Gap assessment for DFMEA,RMM to ensure 100% regulatory compliance.
- Technical Investigation for the customer complaints by using trackwise and ClearQuest defect management.

Caliber Assurance Services Pvt Ltd –Philips, Pune (Apr'2023 – May 2025)

- Supported MLD change implementations, ensuring smooth integration into the production process and reducing downtime.
- Conducted gap assessments for forward production and S&R, identifying areas for improvement and resolving related issues Performed Gap assessment and created DFMEA,PFMEA to compile the regulatory .
- Performed bench tests and SPT tests by using Phantoms, interpreting verification data to ensure compliance with product specifications and identify areas for performance improvement.
- Analyzed and investigated non-conforming material reports (NCMRs) and defects of arrival (DEFOA), identifying root causes and recommending corrective actions and technical investigation for the customer complaints
- Implemented solutions through Change Requests (CRs) and Engineering Change Notices (ECNs) to address product defects and improve engineering processes.
- Led label corrections and modifications, ensuring labels reflected accurate and up-to-date product specifications.
- Updated and maintained BOMs and drawings, ensuring that engineering changes were accurately reflected in production documentation.
- Created engineering parts in the system to ensure proper classification .Collaborated with vendors to manage material supply, ensuring timely delivery of components while adhering to cost and quality requirements.
- Utilized PLM tools to implement and manage the Design Change Plan (DCP), ensuring design changes were efficiently integrated into the production process.
- Prepare and review FDA audit documents, as well as Dekra audit documents, with various internal and external cross-functional teams.

Triad Square InfoSec Pvt Ltd – (Aug'22 to Feb'23)

- Developed comprehensive project plans, ensuring timely completion within budget constraints.
- Served as a DHF Remediation engineer, involved in developing requirements, design verification and Validation plans, protocols, test execution, and test reports to ensure compliance with EU MDR 2017/745.

- Designed experiments, categorized studies based on requirements, developed test methods, and validated Test methods (TMV).
- Classified verification methods including functional, regulatory/industries, packaging, shelf-life studies, visual Inspection and product performance.
- Conducted Product functional testing's (leakage test, Leakage under pressure test, visual Inspection test ,drop test and stability testing
- Expertise in Independently determining and developing technical solutions to complex problems using Engineering principles and design of experiments (DOE) while utilizing experimental, computational and/or Analytical methods.
- Coordinated ECN, BOM updates, and drawing updates to support product development and manufacturing.
- Experience on the PLM tools (TcU/windchill) and Analytical tool (Minitab).

Medsource Ozone Biomedicals Pvt Ltd,Chennai (Jul'21 to Jul'22)

- Conduct equipment demos, installations, and services, ensuring efficient and effective operation.
- Perform system software installation, programming tailored to specific client requirements and LIS Configuration support.
- Execute process validation (IQ, OQ, PQ) to ensure compliance with industry standards.
- Provide comprehensive training for technicians and doctors to ensure proper use and maintenance of equipment.
- Deliver application support, troubleshooting issues and optimizing system performance.
- Monitor instrument health status through the ECON system, performing necessary calibrations and preventive maintenance.
- Manage materials management.

Suyog Diagnostics Pvt Ltd,Chennai (Sep 16 to Jun'21)

- Conduct equipment demos, installations, and services, ensuring efficient and effective operation.
- Perform system software installation, programming tailored to specific client requirements and LIS Configuration support.
- Execute process validation (IQ, OQ, PQ) to ensure compliance with industry standards.
- Provide comprehensive training for technicians and doctors to ensure proper use and maintenance of equipment.
- Deliver application support, troubleshooting issues and optimizing system performance.
- performing necessary calibrations and preventive maintenance and Material Management.

Skills:

DHF Remediation / Product Testing / Environmental testing / Stability Testing / Treacematrix / Defect management / EU MDR/ US FDA / Complaint Investigation / Process validation (IQ,OQ,PQ), / ISO 13485 / Verification and Validation / Technical Documentation / Change control and ECN activities / Labelling / FDA Mock audit / Dekra audit / Factory CAPA / Deviation / Windchill PLM tool / SAP/ TcU/basic knowledge in ISO14971/Verification and Validation

Education:

B.E – Electronics and Communication Engineering.

Certifications:

- Biomedical Quality assurance from IBSC
- EUMDR Awareness training from Greenlight solution.
- Biochemistry and immunology analyzer training from ortho clinical diagnostics.
- RT-PCR training from ELitech.

Declaration:

All details furnished above are true to the best of my knowledge. I will be solely responsible for any discrepancy in the given details.