Sandeep Yadav Chakka

csytpty@gmail.com | (872) 240-0693 | Wheeling, IL

Senior Manufacturing/Quality Engineer | Medical Devices | Validation, Prototyping, Product Launch, Process Optimization, CAPA, Risk Management

Quality-driven Manufacturing engineer with 5 years in medical device manufacturing, specializing in validation, process optimization, Root cause investigation and CAPA. Proven expertise in DOE, Automated mold qualification, CAPA management, and transitioning legacy systems. Strong background in driving compliance with ISO 13485, 21 CFR Part 820, ISO 14971and implementing digital workflows to enhance efficiency.

SKILLS

SolidWorks, VBA, R, Micro-Vu, CMM, Visio, Microsoft Automate, MiniTab, PFMEA, DOE, FAT/SAT/IQ/OQ/PQ, CAPA, ISO 13485, QMS 21 CFR Part 820, Lean Manufacturing, Six Sigma, Gage R&R, Control Plans, Capability studies, ISO 14971, ISO 594, ISO 80369-7, Design of experiments (DOE), Non-conformance Reports (NCR) Non-conformance Material Reports (NCMR), Standard operating procedures (SOP), Corrective Action and Preventive Action (CAPA), Statistical process control (SPC), Finite Element Analysis (FEA), Fault Tree Analysis (FTA), Test Method Validation (TMV), Supplier Audits, Product development.

PROFESSIONAL EXPERIENCE

Senior Manufacturing Engineer
Argon Medical Devices, Wheeling, IL *Jan 2023 – Jul 2025*

- Created and maintained process books, mold parameter verification systems, and quality documentation in response to CAPA findings.
- Transitioned to 3D-printed fixtures, saving machine time and material costs.
- Created 3D-printed fixtures for catheter assemblies (Centesis, Dipping Basket).
- Installed and validated custom-made index table molding machines, optimizing production efficiency.
- Conducted Cpk & Ppk capability studies to assess process stability and reduce variability.
- Developed and executed FAT,SAT, IQ, OQ, PQ, and DOE validation protocols, ensuring robust process control.
- Designed and implemented a process flow for Validation from Factory acceptance till the transition to production.
- Managed Material Change Requests (MCRs) and Design Change Requests (DCRs).
- Developed automation programs in R and VBA, streamlining process capability analysis and data visualization.
- Provided staff training on GMP, QMS documentation, and standard operating procedures (SOPs), ensuring regulatory compliance.
- Led supplier qualification and mold validation initiatives, ensuring conformance to quality standards.
- Implemented Microsoft Visio for process mapping and Microsoft Automate for workflow automation, increasing operational efficiency.
- Led a critical sustaining engineering project for a new IZI customer product facing post-launch failures including fit issues, mismatch, and part breakage. After multiple market complaints and halted production, redesigned mold components, updated engineering drawings, and commissioned new mold cores to resolve mismatch and structural failures, enabling successful product relaunch and complaint closure.
- Investigated and resolved label mix-up traced to warehouse issuance error; recommended labeling workflow improvements and spatial reorganization to prevent recurrence.
- Introduced Cognex Vision systems for defect detection such as burrs, flashes and mismatch for Grinded and molded parts.

Manufacturing Engineer
Phillips-Medisize, Hudson, WI *Dec 2020 – Dec 2022*

- Executed IQ/OQ/PQ validation for 4 production lines, including 2 new product introductions involving filling and MPAC packing machines. Conducted DOE to resolve flap-tearing defects on packing boxes, reducing scrap through design adjustment and vision system integration.
- Provided support on CAPA investigations and effectiveness assessments.
- Provided staff training on regulatory requirements, specializing in GMP/QSR.
- Monitored, maintained, and controlled the QMS for regulatory purposes under ISO 13485 standards.
- Supported initiatives in all product manufacturing aspects: Production floor support, Yield, Quality improvement, Process Improvement and Documentation.
- Developed and executed IQ, OQ, and PQs for manufacturing processes and supporting manufacturing equipment and instrumentation.
- Prepared standard work sheets and job instruction sheets with visual aids and operation description.
- Modified and created drawings, test procedures and bill of materials as part of manufacturing line support.
- Responsible for the creation, documentation, maintenance, and control of Quality System Plans and Risk Management Plans with the approval in accordance with applicable procedures.
- Supported investigations of non-conformance and CAPAs for operations and supply chain.
- Collaborated with Operations and Suppliers to close out audit findings or corrective actions.
- Gathered and analysed manufacturing metrics and worked closely with Quality organization to define and validate appropriate process changes.
- Support and/or perform internal audits of the quality system and Design History Files (DHFs).
- Supported design verification / validation activities including protocol and report writing.
- Collaborated on process characterization, experimentation, optimization and qualifications.

Initiated and lead the resolution of non-conformances / CAPAs.

- Analysed test data using statistical tools, perform in-depth interpretation of results, and generate detailed technical reports.

EDUCATION

Master of Science, Mechanical Engineering – University of Texas at Dallas
Bachelor of Science, Mechanical Engineering – Amrita University, India

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CERTIFICATIONS

- Lean Six Sigma Black Belt (CSSC)
- Certified SolidWorks Professional (CSWP)
- Certified SolidWorks Associate – Additive Manufacturing (CSWA-AM)
- Certified SolidWorks Associate (CSWA)
- Certified SolidWorks Electrical Design Associate (CSWA-E)