

Venkata Kanaparthi

SENIOR MEDICAL DEVICE QUALITY ENGINEER (ASQ CQE | LSSGB)

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PROFESSIONAL SUMMARY

Results-driven Senior Medical Device Quality Engineer with 7+ years of experience leading design controls, risk management, and regulatory compliance for Class I, II, and III medical devices. ASQ Certified Quality Engineer (CQE) and Lean Six Sigma Green Belt with dual Master's degrees in Industrial and Mechanical Engineering. Demonstrated expertise in FDA Quality System Regulation (QSR), ISO 13485:2016, ISO 14971:2019 risk management, design assurance, and process validation. Proven track record managing design history files, requirements traceability matrices, and regulatory submissions (510(k), EU MDR) for cardiac, orthopedic, and catheter-based devices. Strong collaborative leader who aligns R&D, manufacturing, quality, and regulatory teams to drive data-driven improvements and ensure patient safety.

AREAS OF EXPERTISE

✓ ISO 13485/ 9001/14971	✓ NEW PRODUCT DEVELOPMENT	✓ IEC 62366/62304/60601/60601-2	✓ EU 2017/745 (MDR)
✓ DESIGN CONTROL	✓ RISK MANAGEMENT	✓ VERIFICATION & VALIDATION	✓ DESIGN TRANSFER
✓ DFMEA/UFMEA/PFMEA	✓ HAZARD ANALYSIS	✓ SAMPLING PLANS	✓ SPC
✓ CHANGE CONTROL	✓ DEVIATIONS	✓ ROOT CAUSE/NC/CAPA	✓ SUPPLIER QUALITY
✓ PROCESS VALIDATION	✓ TMV/ATMV/VTMV	✓ COMPLAINT HANDLING	✓ STERILIZATION
✓ SAP/ SMART SOLVE	✓ MASTER CONTROL/ WINDCHILL	✓ REGULATORY AUDITS (FDA)	✓ PMS

CAREER HIGHLIGHTS

- Demonstrated expertise in Quality Engineering, Design Assurance, and Risk Management within the medical device industry, ensuring compliance with FDA regulations, ISO standards, and global quality system requirements.
- Applied statistical analysis and quality metrics, such as Gage R&R, SPC, CPK, and PPK, to drive data-driven decision-making and continuous improvement in manufacturing operations.
- Provided risk management inputs for regulatory submissions (FDA, EU MDR) by documenting risk analyses, safety justifications, and benefit-risk assessments.
- Continuously improved risk management processes, tools, and methodologies, ensuring alignment with the latest industry best practices and regulatory expectations.
- Ensured usability-related hazards were documented, assessed, and mitigated through iterative design controls and post-market feedback loops.
- Ensured device compliance with IEC 60601-1 electrical safety requirements for patient-connected Class II and III medical devices during verification and validation phases.
- Proven track record in project management, leading cross-functional teams across R&D, engineering, and manufacturing to execute product development, process validation, and continuous improvement initiatives.
- Supported early-stage R&D efforts by contributing to concept development, defining user needs, refining design inputs, and supporting feasibility builds and prototype evaluations.
- Developed and maintained requirements traceability matrices (RTM) linking user needs, design inputs, outputs, verification, validation, and risk mitigations to ensure full design control compliance.
- Contributed quality and verification documentation for regulatory submissions, including 510(k) updates, technical files, and product change notices.

PROFESSIONAL EXPERIENCE

Senior Quality Engineer, Evergen, Eden Prairie, MN | Dec 2025 - Present

Class III Medical devices (Collagen Solutions, Implants)

- Led DFMEA and PFMEA development for new device platforms, collaborating with R&D and manufacturing engineers to identify critical failure modes and establish proactive risk controls prior to design freeze
- Managed Design Verification and Validation (V&V) planning and execution, ensuring test protocols and reports met regulatory expectations per IEC 62366, ISO 14971, and applicable FDA guidance
- Defined and enforced transfer criteria for NPD-to-manufacturing handoffs, including process qualification (IQ/OQ/PQ), first article inspection, and production readiness reviews
- Device Master Records (DMR) and supported 510(k) / technical file submissions by ensuring complete and compliant design documentation throughout the product lifecycle
- Led development of Quality Plans supporting product transfer, manufacturing scale-up, and site introduction activities, ensuring alignment with quality system and regulatory requirements.
- Developed Risk Management Plans and risk-based quality documentation in alignment with ISO 14971 and ISO 13485 principles for product and process introduction activities.
- Defined and structured CPP/CQA frameworks to support process understanding, control strategy development, and product quality assurance.
- Established traceability between identified risks, control plans, and mitigation measures to strengthen product and process risk management.
- Supported product quality investigations, complaint assessments, and nonconformance evaluations through technical review of process data, historical trends, and quality documentation.
- Identified and defined Critical Quality Attributes (CQAs) for medical device components and finished goods, linking measurable quality characteristics to patient safety, device performance, and regulatory compliance requirements

NPD Engineer (R&D Division), Johnson & Johnson MedTech, Plymouth, MN | Sep 2024 – Dec 2025

Class III Medical devices (Reprocessing Electrophysiology Heart catheters, Ultrasonic Catheters)

- Provided technical guidance to R&D, product development, and manufacturing teams in Design Assurance, Design Controls, Risk Management, and Regulatory Compliance for Class I–III medical devices.
- Developed, established, and maintained quality engineering methodologies, procedures, and compliance practices aligned with ISO 13485, ISO 14971, FDA QSR, and EU MDR.
- Led the Risk Management process, including updates to the Risk Management Plan, creation of complete Risk Management Files, execution of risk evaluations, and authoring Risk Management Reports per ISO 14971.
- Established and maintained requirements traceability, creating and updating traceability matrices for design inputs, design outputs, verification, validation, and risk controls.
- Collaborated with R&D to refine and document Design Inputs, ensuring traceability to user needs, intended use, and risk mitigations.
- Supported development, prototyping, and early-stage feasibility and functional testing, including test method development and execution of engineering builds.
- Led the creation, execution, and documentation of Design Verification and Validation (DV&V) protocols and reports, ensuring adherence to design control requirements.
- Collaborated with cross-functional teams to ensure design verification and electrical safety testing were conducted per IEC 60601-1 standards for device-specific requirements.
- Spearheaded comprehensive risk assessments and gap analyses for medical devices in strict accordance with ISO 14971:2019, ensuring all potential hazards were identified and mitigated.
- Conducted detailed Risk-Benefit Analysis (RBA) to balance product efficacy with patient safety, leveraging statistical tools and methodologies (SPC, DFMEA) to support data-driven decisions.
- Developed and maintained robust Risk Management Files (RMF), integrating detailed risk assessments and control measures to meet FDA, EU MDR, and ISO compliance standards.
- Work in synergy with quality assurance and regulatory teams to identify critical hazards and ensure compliance with industry standards, such as ISO 14971 and ISO 13485.
- Designed and implemented inspection and testing procedures for incoming materials, sub-assemblies, and finished devices.
- Led or supported development of test methods, test fixtures, design verification protocols, and engineering builds to support design evolution and manufacturability.

Manufacturing Quality Engineer II, Smith & Nephew Inc, Fremont, CA | Sep 2022 – Sep 2024

Sports Medicine orthopedics (Meniscus Repair Medical devices).

- Spearheaded the implementation of risk control and mitigation strategies, resulting in improved product safety and streamlined regulatory submissions.
- Contributed to regulatory submissions by providing comprehensive, well-documented risk management analyses, supporting successful market authorizations.
- Continuously enhanced risk management processes, tools, and methodologies, fostering a culture of safety and compliance across the organization.
- Utilized problem-solving methodologies such as 5 Whys, 6M and Failure Mode Effects Analysis (FMEA) to systematically analyze non-conformance events and prevent recurrence.
- Assessed the risk associated with non-conformance events by evaluating the impact on product quality, patient safety, and regulatory compliance, and determining the appropriate risk level in alignment with ISO 14971 standards.
- Ensured that all manufacturing processes adhered to applicable regulatory and quality system standards, including FDA QSR, cGMP, ISO 13485, and other relevant industry regulations.
- Collaborated with suppliers to communicate technical requirements, request improvements, and resolve quality concerns, enhancing supplier quality and performance.
- Managed the qualification and validation of new equipment and processes, driving improvements in manufacturing efficiency and enabling cost-saving initiatives.
- Created and maintained detailed work instructions for in-process and final product inspections, ensuring consistency and compliance in testing procedures.
- Played an active role in internal and external audits, leading efforts to address audit findings and implementing corrective and preventive actions (CAPA).
- Prepared and presented key quality data during quarterly management reviews, facilitating the integration of quality systems to streamline operations and enhance compliance.
- Developed and maintained comprehensive quality metrics to monitor product quality trends and process performance, driving continuous improvement initiatives.
- Conducted thorough root cause analyses of post-market quality issues, implementing corrective and preventive actions to improve product safety and reliability.

Quality and Reliability Engineer II, TE Connectivity, Plymouth, MN | Mar 2022 – Sep 2022

Class III Medical Devices (Catheters, Stents, Implants).

- Led comprehensive risk assessments and gap analyses to identify, evaluate, and mitigate potential hazards throughout the product lifecycle.
- Conducted detailed Risk Benefit Analysis (RBA) to balance product benefits with associated risks, ensuring optimal safety and efficacy.
- Developed and maintained robust Risk Management Files (RMF) in alignment with ISO 14971:2019, documenting risk assessments, control measures, and residual risks.
- Provide process validation program oversight to ensure adequacy of validation activities and documentation in terms of regulatory compliance and technical/statistical soundness.
- Review engineering studies, process validation protocols, and summary reports (Installation Qualification, Operation Qualification, Performance Qualification and Test Method Validation).
- Provide guidance to others for the generation of clear, concise, and defensible protocols and reports.
- Identified and implemented process improvements for existing manufacturing processes utilizing appropriate engineering principles.

NPI Quality Engineer, Phillips-Medisize, Hudson, WI | Nov 2019 – Mar 2022

Class II Medical Devices (Plastic Injection Molding Medical devices)

- Responsible for the validation and qualification of manufacturing equipment and processes leveraging standard qualification approaches (IQ/OQ/PQ).
- Lead the team in Reviewing and Executing the Gage R & R, MSA, Bias study and Process capability studies during the new product development stage.
- Lead the team in support of new product development process and ensure on-time completion of deliverables including design verification and validation test plans and reports.
- Lead the team of (Quality, Manufacturing, Process, Warehouse SME's) in designing and developing the PFMEAs to identify critical risks involved in the process flow.
- Designing and identifying the concrete detection controls to address each critical path line items prevent the Risk.
- Developed and managed test protocols and reports for Process Validation, verification and validation testing for

- products under development or in production.
- Worked to develop new and improve existing products and processes.
- Competency in leading the development and execution of Operational Qualification (OQ) & Performance Qualification (PQ) validation protocols.
- Designed, run, and evaluated experiments on systems and processes.
- Analyzed manufacturing processes and workflow for continuous improvement opportunities.
- Responsible for planning, organizing, and managing the overall activities of receiving/outgoing quality functions.
- Experienced in validating test methods and processes utilized in the manufacturing of medical device products pertaining to medical device regulations including FDA 21 CFR Part 820 compliance and ISO 13485, 14971.
- Participated and lead the internal quality audits. Served as backroom SME in submitting and reviewing the Validation documents submitted for FDA Audits.
- Lead material review board (MRB) actions to evaluate the non-conforming products and their processes to determine the root cause of the defective products and implement corrective action.
- Lead the quality team in performing the Stock keeping Unit Tasks and setting up the Material master, QIR's, Routing, Vendor setup and verifying procurement related tasks for a given Work order.
- Provided input for root cause analysis & problem-solving support for CAPA, NCMRs and customer complaints.
- Provided support to Premarket activities such as complaint investigations, complaint trending, CAPA and SCAR processes as necessary.

Manufacturing Engineer, Calcite systems, SC | Mar 2019 – Nov 2019

Pharmaceutical - Class I Medical Devices

- Performed Time studies and analysis in developing production standards.
- Implement 5S on workstations across all Production and Logistics units.
- Standardized work procedures for equipment processes across all Production units as required.
- Supported Production Supervisors with implementation of Kaizen events.
- Developed manufacturing processes in production flow, equipment and achieved product reliability.
- Managed and monitored all continuous improvement of distribution operations.
- Lead manufacturing improvements, process changes, and technology changes including Developing solutions to product related issues through problem solving and root cause analysis techniques.
- Map current processes and develop metrics and identified ways to reduce waste, improve workflow.

EDUCATION

Master's degree in industrial engineering, Lamar University, *Beaumont, Texas* |

Master's degree in mechanical engineering, Andhra University, *Vizag, India* |

ADDITIONAL TRAINING & CERTIFICATES

ASQ CERTIFIED QUALITY ENGINEER (ASQ-CQE)

CERTIFIED LEAN SIX SIGMA GREEN BELT (LSSGB)

TECHNICAL PROFICIENCIES

SIX-SIGMA | ROOT CAUSE ANALYSIS | PARETO ANALYSIS | KAIZEN | WASTE ELIMINATION | INVENTORY CONTROL | STRATEGIC PLANNING | 5S | 5 WHY'S | SUPPLY CHAIN MANAGEMENT | DESIGN | PROJECT MANAGEMENT | STRATEGIC PLANNING | QUALITY PLANS | INSPECTION AGREEMENTS | BOM | TIME STUDIES | MOST | PFMEA | DFMEA | VALIDATION | COST BENEFIT ANALYSIS | APQP | GR&R | MEDICAL DEVICE INJECTION MOLDING | MANUFACTURING & UTILITIES, IQ/OQ/PQ VALIDATION.

SOFTWARE PROFICIENCIES

AUTOCAD | MATLAB | MICROSOFT OFFICE | MICROSOFT EXCEL | SIMULATION ARENA | VBA | SAP | ERP | MINITAB | BASIC-C | SOLIDWORKS | MICROSOFT PROJECT | CAD | CAM | AUTODESK INVENTOR | GD&T PRINTS | | BLUEBEAM.