# Sai Avinash

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**SUMMARY:**

* Around 6 years of experience in the field of Automotive and Medical Manufacturing Industries as a Quality/Validation engineering.
* Experienced quality engineer with immense knowledge of methodologies for process optimization, risk management, NCMRs, quality management of suppliers and problem-solving strategies with the ability to work independently, evaluate conditions, recommend proposals and create solutions consensus.
* Good understanding of the validation protocols (IQ/ OQ/PQ).
* Successfully implemented Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP).
* Experience in the development of all validation documents, including validation plan, gap analysis, SAT, FAT, PFMEA, design requirements, traceability matrices, validation of test methods (TMV), DOEs, standard operating procedures (SOPs) and overview reports of validation.
* Experience in reviewing Corrective and Preventive Actions (CAPA) and emphasizing and suggesting the remediation plans to mitigate the non-compliance.
* Investigation and resolution for deviations/variances. Initiated change controls for each validation process.
* Gained experience in conducting internal & external audits, performing GAP analysis and root cause analysis.
* In-depth knowledge of the concepts of; design control, engineering change control, statistical techniques, verification and validation methods/protocols, risk management, design history files (DHF), device history and master records (DHR/DMR), CAPA, 510(k), complaint handling, etc.
* Good knowledge in US and International regulations including relevant parts of FDA 21 CFR 820, 210, 211, 801, ISO 13485, ISO 9001 and EU MDD Regulatory Standards.
* Implemented Direct Failure Mode and Effects Analysis activities for both Design and Process FMEA's.
* Well acquainted with concepts of Six Sigma, Lean manufacturing, Kanban, 5S and kaizen principles.
* A Green Belt certified in the application of Lean Six Sigma.

**TECHNICAL SKILLS:**

* **Continuous Improvement**: Statistical Process Control (SPC), Design of Experiments (DOE), Six Sigma (DMAIC & DMEDI), 5 S & 5 why’s Principles, Lean Manufacturing, APQP, 8D Methodology, Gauge R&R, PDCA continuous improvement.
* **Risk Management:** FMEA (PFMEA, DFMEA & UFMEA), Root-cause analysis.
* **Process Control:** Standard operating procedure (SOP’S), Unit operations.
* **Software’s:** MINITAB, MS OFFICE, MS VIZIO, SAP.

**PROFESSIONAL EXPERIENCE:**

## Title: Manufacturing Engineer/Validation Engineer

## Client: Cook Medical, IN Jan ’2020 - Present

**Responsibilities:**

* Well acquainted with concepts of Six Sigma, Lean manufacturing, Kanban, 5S and kaizen principles.
* A Green Belt certified in the application of Lean Six Sigma.
* Work with value stream managers, operations, quality and planners to evaluate work center & operation job steps consolidations by profit center
* Experience in evaluating quality critical (CTQ) features and updating product specification documents or inspection requirements, risk management files
* Revise work centers, descriptions, profit center, queue & move times
* Responsible to change the control of Routings and Bill of Materials (BOMs)
* Provide validation support by applying, but not limited to, the manufacturing quality toolset: FTA, FMEA, DFMEA, PFMEA, IQ, OQ, PQ, research, monitoring plans, verification/validation plans, development of validation protocols, Cpk, Cp, SPC, DOE, analysis of process data, and DMAIC.
* Develop and execute IQ, OQ and PQ protocols for product, processes and equipment.
* Responsible to review existing validation reports and identifies gaps for GMP compliance.
* Write reports summarizing results and statistics for all equipment, product, or process validation projects.
* Participated as an active member on design transfer remediation teams, router update teams, DMR (Device Master Record) update teams etc.
* Monitor and drive corrective action and continuous improvement activities that directly impact performance measures.
* Provide day-to-day engineering support for production, processes, development of planning for design control and design transition activities.
* Change Management, Revise operation codes, Job step, CTQs, and Impact Analysis forms.
* Responsible for reviewing and updating the inspection plan, job orders, reviewing XA time standards as necessary based on assessment, validation reviews (working with validation engineers), reviewing process flow charts with new work centers, and following validation reviews until closure
* Interface with departments of Manufacturing/Process Engineering, R&D, and Regulatory to solve process problems and enforce modifications and apply knowledge of process control tools, statistical sampling, and other analytical techniques to optimize product quality and flow through the production line.
* Identify, analyze, and manage risk through product life cycle with use of FMEA and other risk management tools.
* Incorporated FDA/EU MDD guidance and external standards into functional test methods and their validations.
* Set up design and development process as per 21 CFR 820.30, ISO14971 & ISO13485 requirements.

## Title: DHF Remediation Engineer/Quality Engineer

## Client: Boston Scientific, IN Sep’2019 – Dec’2019

**Responsibilities:**

* The Risk Management Plan, Hazard Analysis, DFMEA, PFMEA, UFMEA, SFMEA & Risk Management Report for the Catheters provide expertise in the development of risk management documents.
* ●Responsible for designing and implementing Master Validation Plans, Risk Assessments, Organizational Qualifications, Qualifications for Success and Overview Reports for Validation.
* Developed and executed IQ, OQ and PQ protocols for product, processes and equipment within the facility.
* Performed GAP Analysis and prepared Remediation Plans to address the gaps identified.
* Involved in validation process coordination within cross functional departments such as Technical Operations, Engineering, Quality Assurance, and Regulatory affairs.
* Responsible for Creation, evaluation, and validation of product and process test methods and test method validations.
* Developed and implemented processes consistent with the Continuous Improvement System through Lean Manufacturing.
* Evaluated test protocols and reports to ensure that the testing is sufficient to meet regulatory requirements and quality objectives.
* Developed functional Test Methods for design verification, process characterization, process validation, and finished product.
* Planning, strategizing, and executing validation activities.
* Incorporated FDA/EU MDD guidance and external standards into functional test methods and their validations.
* Responsible for maintaining Quality System Regulations including Document Control and Record Control.
* Developed documentation for all aspects of validation including risk assessments, and quality and regulatory assessments for the Drainage Catheters.
* Set up design and development process as per 21 CFR 820.30, ISO14971 & ISO13485 requirements.
* Responsible for checking deliverables of the Design History file and updating the deliverables. The DHRs were modified, ECOs were created and the component sketches were updated by Tech Analysis Overview Minutes.
* Validation and Verification Activities for Medical devices - Performed assessments on previously validated process validation documents.
* Established and maintained procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability.
* Coordinated to update/change product drawings, tolerances, and adjust inspection sheets with R&D, Regulatory, Design Controls, Product Development and Operations engineering teams and set up sheets to provide deliverables for validation.

## Title: Quality Engineer II

**Client: Manu Power PVT Limited, India Jun’2017 – Dec’18**

**Responsibilities:**

* Performed activities related to sustenance engineering/support to manufacturing assembly line that includes improve process yield, improve efficiency and reduce scrap, create and maintain all documentation, continuous improvement in the process, monitoring defects, disposition to nonconformance reports, resolution of failures and lean projects.
* Worked on implementing product transfers and process changes through process validation, test protocols and medical device test reports, producing all process-related documents (e.g. PFMEA, Manufacturing Procedures), fixtures and tooling produced.
* Utilize established protocols to perform validation/qualification tests and provide detailed and accurate analysis of test results, identifying validation failures and areas of non-conformance.
* Developed and maintained product documentation for new and existing devices.
* Design for manufacturing of machined and injection molded components.
* Performed Material Review Board investigation and participated in CAPA.
* Worked on Design History Files on multiple new development projects.
* Worked on multidisciplinary teams with members from regulatory, quality, and manufacturing to meet project deadlines.
* Develop and implement remediation solutions to close CAPA files.
* Update and maintain Validation Protocols, forms and records to meet cGMPs and federal regulatory requirements.
* Prepared test protocols and final reports for the verification and validation testing of new products.
* Worked on Design improvement & optimization and study of feasibility of manufacturing.
* Updated Design FMEAs to ensure implementation of proper risk mitigations for hazards and risks associated and monitored effectiveness of controls.
* Participated in design review meetings.
* Remediated past Design History Files per FDA standards and compliance.
* Drive continuous improvement of legacy products to increase manufacturability and performance
* Determine root cause and corrective actions for process failures using Fishbone diagrams, FMEA, Gauge R&R analysis and other statistical tools.
* Developing, among other papers, technical analyses, risk analysis, process mapping, DOE's, difference analysis, statistical rationales, discrepancy reports.
* Provide guidance on the development of verification and validation plans, test and sampling methods sample size determination and acceptance criteria.

**Title: Design Quality Engineer**

**Client: Rachana Machines PVT LTD, India. Feb’15 - August’16**

Responsibilities:

* Involved in Manufacturing Design (DFM), process development, Experiment Design (DOE), methodology, CAPA & NCMR.
* Worked as a design quality engineer managing design and quality end deliverables with suppliers.
* Good working knowledge on Supplier PPAP process
* Conducted extensive and ongoing risk-based assessments of supplier corrective action solutions while recommending and implementing client-specific consultations.
* Responsible for supplier management, including qualifying new suppliers, improving marginal supplier performance, conducting root cause analysis for non-compliant suppliers, author Supplier Quality Agreements and oversee process of Supplier Scorecard ratings.
* Mitigated AR risks by collaborating with Purchasing to resolve complex supplier quality solutions.
* Created and reviewed DHF.
* Provided Impact Assessments of products, procedures and documentations due to interdepartmental changes.
* Performed reviews of Protocols, IQ, PQ and OQ validation reports, change order and change requests by following standard documentation practices.
* Conduct design reviews, FMEA, design verification and particulate assessment at different stages of product cycle.
* Supported Product Development Design Engineering for Risk Management remediation.
* Responsible for the construction and organization of a Design History File.
* Authored Design Input Requirements and performed design verification testing.
* Authored and lead PFMEA and DFMEA efforts.
* Market Research, prepared design inputs, experiments and created Design History File (DHF) documentation for medical devices, initiated and carried out product development activities.

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## Title: Manufacturing Engineer

**Client: Kenna Metal PVT Limited, India Feb’14 – Jan’15**

**Responsibilities:**

* Overtime analysis of process variation and assessment of the efficacy of modifications and efficiency of the communicated process.
* On the implementation of Lean Manufacturing, 5S and Continuous Improvement Mechanism, a brief review was conducted based on DMAIC methodology to monitor the process and improve the quality of the product.
* Lead Kaizen events to improve efficiency on the production process.
* Used the Statistical Process Control (SPC) chart to identify the common cause and special cause variations by plotting graphs using MINITAB software.
* Successfully worked on the manufacturing floor and scheduled production processes, after reviewing the daily POs and creating the work-orders, approving the manufacturing drawings and confirming design tolerances.
* Created and maintained inspection drawings, control plans, and work instructions to refine production and quality.
* Designed and developed gauges, tooling, and inspection procedures to improve manufacturing processes.
* Performed tests and analyzed data to ensure quality and improve manufacturing efficiency.

**EDUCATION:**

* University of Michigan, MI, USA
* MSE in Mechanical Engineering GPA: 3.54/4.0