

+91 9962669913

jayabalachennai90c@gmail.com

LinkedIn:
linkedin.com/in/jayabalasubramanian-chandran-5b1109210

JAYABALASUBRAMANIAN CHANDRAN

Assistant Manager – Plant Operational Quality Excellence

PROFESSIONAL SUMMARY

Plant Operational Quality Executive with over 14 years of progressive, hands-on experience in Medical Device and Healthcare Manufacturing. Proven track record of steering Quality Assurance (QA), Quality Control (QC), Supplier Quality, Process Quality, and Regulatory Affairs to champion manufacturing excellence and global compliance. A strategic organizational builder adept at launching maiden Quality Management Systems (QMS) from the ground up, directing complex New Product Development (NPD) quality ecosystems, and securing flawless execution across top-tier international regulatory audits (US FDA, CDSCO, CE/EU MDR, ANVISA). Recognized for architecting robust operational transformations that optimize value, eliminate plant rejections, scale production yields, and nurture a strict corporate culture of total compliance, accountability, and continuous process simplification..

WORK EXPERIENCE

Nov 2024 | Present

Assistant Manager – Plant Operational Quality Excellence

Motherson Health & Medical System Limited

- Strategic Functional Leadership: Direct the overall Plant Operational Quality framework for a state-of-the-art CDMO medical device facility, ensuring complete alignment between customer specifications, global standards, and business throughput metrics.
- Cross-Functional Operations Oversight: Provide end-to-end quality command across diverse manufacturing lines, including Incoming Quality Control (IQC), Analytical Laboratory, Wiring Harness, High-Level Assembly (HLA), Sheet Metal Fabrication, Machine Shop, Paint Shop, Final Assembly, and Final Quality Control (FQC), QA & RA .
- Audit Defense Mastery: Anchored and successfully defended the facility during high-stakes external regulatory audits, achieving successful outcomes for ISO 13485:2016, CE Mark (EU MDR), and CDSCO inspections with zero major non-conformances.
- Audit & Inspection Anchor: Serve as the primary plant representative for customer, supplier, internal, and regulatory certification audits, establishing structured workflows that guarantee the timely closure of all audit findings and CAPAs.
- Advanced RCA & Lifecycle Validation: Spearhead high-impact investigations for CAPAs, Non-Conformances (NCR), Deviations, Customer Complaints, and Out-of-Specification (OOS) results utilizing robust 5-Why and Fishbone methodologies; authorize validation protocols across equipment and processes (IQ/OQ/PQ).
- NPI & Supply Chain Governance: Govern critical Design Transfers, New Product Introductions (NPI), and customer technology transfers while leading global supplier qualifications and corrective actions to de-risk the supply chain.
- QMS Architecture & Continuous Improvement: Develop, implement, maintain, and continually improve a comprehensive Quality Management System in strict accordance with ISO 13485:2016, FDA 21 CFR Part 820/QMSR, CDSCO MDR 2017, ISO 14971, EU MDR 2017/745, and Brazil ANVISA regulations.
- Customer Quality & Performance Tracking: Drive customer satisfaction through effective complaint handling, preventive quality planning, and proactive quality improvement initiatives to meet organizational KPIs.
- Team Leadership & Culture Building: Build and mentor a high-performing quality team while fostering a factory-wide culture of quality, compliance, accountability, and operational excellence.

EDUCATION

- Master of Science (M.Sc.) | Periyar University, Tamil Nadu (2012 – 2016) DE
- Bachelor of Science (B.Sc.) | SRM College of Arts and Science, Chennai (2007 – 2010)

CERTIFICATIONS

- ISO 13485:2016 Internal Quality Management System – Internal Auditor Training Course (Cert. No: IN/9931/94139), TUV SUD South Asia Pvt. Ltd. (July 2021)
- EU MDR and Design Control Awareness Training (Cert. No: TUVSA/AC/CT/2019/0995/O/0002/MHS 01/1/0003), TUV SUD South Asia Pvt. Ltd. (December 2019)
- ISO 14001:2015 Internal Environmental Management System (EMS) Auditor Course (Cert. No: IN/0712/60823), TUV SUD South Asia Pvt. Ltd. (February 2021)
- ISO 50001:2018 Energy Management Systems Auditor Course – TUV SUD South Asia Pvt. Ltd.
- Endorsed Chemist for Testing in Form 28 Drug Manufacturing License – Certified by the Tamil Nadu Director of Drugs Contro

LANGUAGES

English,Tmail

ACHIEVEMENTS

- Motherson Health (Present):
- QMS Transformation & Audit Leadership: Led the development and implementation of a new QMS subsystem from the ground up, strengthening plant-level quality governance, compliance, and operational controls.

- External Audit Leadership: Successfully led and supported ISO, CE/EU MDR, and CDSCO external audit defenses, with zero major non-conformities.

- Helmier Pvt. Ltd. (Past):
- Management Representative (MR): Appointed as the organization's Management Representative, leading the end-to-end establishment and implementation of the facility's first ISO 13485 Quality Management System from the ground up.

- QMS Implementation: Established core quality processes, documentation, compliance controls, and organizational readiness for ISO 13485 certification.

- B.Braun Medical India (10-Year Bedrock): Regulatory & Technical Expertise: Held Form 28 Approved Chemist endorsement under the Tamil Nadu Drugs Control administration, supporting regulated pharmaceutical/medical-device operations.

- Cleanroom Validation: Led turnkey cleanroom validation activities, including qualification and validation of critical controlled environments.

- Sterilization Validation & Cost Optimization: Contributed to Gamma sterilization validation and process optimization, receiving a Best Performance Award for Cost Optimization for achieving significant operational cost savings.

GLOBAL REGULATORY FRAMEWORKS & STANDARDS

- ISO 13485:2016 – Medical Device Quality Management Systems
- US FDA 21 CFR Part 820 / QMSR – Quality System & Regulatory Compliance
- EU MDR 2017/745 – Medical Device Regulatory Compliance
- CDSCO Medical Devices Rules (MDR 2017) under the Drugs & Cosmetics Act, 1940
- Brazil ANVISA RDC 751/2022 – Medical Device Regulatory Framework
- ISO 14971 – Medical Device Risk Management
- ISO 14644 – Cleanroom Classification & Qualification
- IEC 60601 – Medical Electrical Equipment
- IEC 60320 – Appliance Couplers
- ISO 9001, ISO 14001, ISO 45001 & ISO 50001 – Integrated Management Systems
  Quality, Validation & Regulatory Operations
- Validation Lifecycle – IQ/OQ/PQ, process validation, equipment qualification and validation protocols/reports
- Supplier Quality Management – Supplier qualification, audits, development, performance monitoring and corrective actions

WORK EXPERIENCE

Dec 2023 – Nov 2024

QA / QC/ RA Manager (Management Representative)

HELMIER PVT. LTD. (MEDICAL DEVICES)

- Maiden QMS Greenfield Implementation: Formally appointed as the Management Representative (MR) to design, build, and deploy the facility's maiden ISO 13485:2016 Quality Management System from scratch, converting unmapped workflows into highly compliant frameworks.

- Executive Board Governance: Functioned as the primary office holder reporting directly to executive board leaders regarding overall QMS health, process optimization parameters, and operational compliance metrics.

- NPD Quality Gate Engineering: Engineered specialized quality checkpoints and validation models for New Product Development (NPD), establishing rigid downstream gates to guarantee smooth, low-risk technology transitions from design down to production.

- Regulatory Certification Architecture: Directed end-to-end plant readiness for critical regulatory frameworks, cementing standard operational practices for ISO 13485, CDSCO MDR-2017, and electrical safety standards (IEC 60601, IEC 60320).

- Metric & KPI Stewardship: Designed and optimized the factory's primary Quality Performance Dashboard; configured key metrics (KPIs) to monitor shop-floor variances in real time and establish definitive guardrails for corrective actions.

- Audit Leadership & Risk Mitigation: Led routine internal audits and rigorous external supplier compliance audits, structuring data-driven root cause evaluations (5-Why / Fishbone) to permanently eliminate recurring defects.

- Cross-Functional Team Management: Supervised and mentored a professional team of QA/QC/RA engineers and technicians, driving systematic waste minimization, a strong safety culture, and strict regulatory awareness.

Jun 2013 – Dec 2023

Senior Executive – Quality Assurance

B.BRAUN MEDICAL INDIA PVT. LTD.

- MNC Quality Stewardship & Progressive Growth: Rose through foundational and increasing responsibilities over a decade-long tenure at a premier global medical device manufacturer, maintaining rigorous compliance with GMP, ISO 13485, ISO 14971, CDSCO MDR 2017, and Environmental Health and Safety (EHS) frameworks (ISO 14001, ISO 45001, ISO 50001).

- Statutory Governance Appointment: Formally recognized and appointed as an Endorsed Chemist for Testing in the Form 28 Drug Manufacturing License by the Tamil Nadu Director of Drugs Control, serving as a primary authorized signatory for statutory release and regulatory compliance.

- Cleanroom & Facility Validation Triumphs: Engineered the blueprinting, structural setup, and full qualification (IQ/OQ/PQ) for major, brand-new ISO 14644 Cleanrooms, production change rooms, and specialized microbiology laboratories.

- Sterilization Validation Expertise: Authored, reviewed, and executed high-stakes validation protocols and monthly trends for industrial Gamma and Ethylene Oxide (ETO) Sterilization processes in compliance with ISO 11137 and ISO 11135 standards.

- Industrial Cost-Saving Milestone: Received the corporate Best Performance Award for Cost Optimization by successfully re-engineering and streamlining Gamma Sterilization validation protocols.

- Advanced Sampling Plans & IQC: Derived, established, and deployed a plant-wide modernized, statistical raw-material sampling matrix for Incoming Quality Control (IQC), accelerating warehouse intake speeds while improving defect detection.

- Shop-Floor Excellence & Continuous Audit: Led strict shop-floor compliance programs, including 5S audits, full-lot traceability mapping, and visual management systems to systematically eliminate waste, scrap, and floor rejections.

- Change Management & QMS Documentation: Prepared, reviewed, and finalized high-stakes Quality Assurance documents, Standard Operating Procedures (SOPs), and validation protocols while managing the lifecycle closure of Change Controls, Deviations, Customer Complaints, Out-of-Specification (OOS) results, and CAPAs.

- Digital SAP QMS Management: Responsible for the complete maintenance, setup, and configuration of Quality Management (QM) Master Data through SAP, ensuring absolute data integrity across software-validated QMS frameworks.