CAROLIN GEORGE

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Notice period: 2 weeks
Residential Status: Singapore PR

Experienced Quality Assurance Specialist with a strong background in Quality Management Systems (QMS), medical device manufacturing, customer support, and regulatory affairs within the medical device industry. Proficient in Design History File Remediation, Risk Analysis, and ISO standards including ISO 13485 and ISO 14971. Certified ISO 13485 Internal Auditor with a proven track record of contributing to quality improvement and regulatory compliance across leading medical device manufacturers

WORK HISTORY

Quality Assurance Specialist - Articares Pte Ltd, Singapore [Oct 2024 to April 2025]

- Responsible for managing, implementing, and maintaining the Quality Management System (QMS) in compliance with ISO 13485 and relevant standards, reporting directly to the CEO.
- Management Representative and Person Responsible for Regulatory Compliance (PRRC) for the organization.
- Passed ISO certification audit for Quality Management systems (QMS) with zero Non-conformances.
- Maintain Approved Supplier List (ASL) and assist the product development team in supplier selection, qualification.
- Conduct supplier on site audits, qualification and re-evaluation on regular basis.
- Monitor production processes and ensure quality controls are in place to meet design and compliance requirements.
- Lead complaint handling and Engineering change management.
- Coordinate with the R&D, regulatory, and manufacturing teams to address quality issues and support product development.
- Lead root cause analysis and implement corrective actions for quality issues.
- Oversee document control, ensuring all records are maintained as per company standards.
- Assist in external audits and inspections by regulatory bodies (NMPA, EU and USFDA etc.).
- Train staff on quality procedures and ensure continuous improvement in QA processes.

Manufacturing Engineer- Vivance Pte Ltd, Singapore [Aug 2022 to Oct 2024]

- Manage the build and testing of a novel medical device for dialysis with patented technology.
- Inspect finished products for quality and adherence to customer specifications.
- Prepare documentation for customer and maintain Design History File as per ISO 13485 quality requirements for the outgoing instruments.
- Calibrate or adjust equipment on regular basis to ensure quality production.
- Plan and lay out work to meet production and schedule requirements of the team.
- Develop, build, or test prototypes or new products, processes, or procedures.
- Draft the work instructions and associated documentation for production.
- Support in inventory management and Device Master Record management.
- Conduct Verification and validation activities for the device assisting the Validation engineer.
- Assist Quality engineer in planning and executing Internal audits and preparation for

external audits.
- Assist QA Department in maintenance of Approved Supplier List (ASL) and coordinating Supplier Re-evaluation and audits.
- Assist QA Department in instrument final inspection and release and maintaining the DHRs.

Manufacturing Specialist Cum Team lead- Agilent Technologies, Singapore [Jul 2020 to Aug 2022]

- Build and test the LCMS and Micro Array scanner instruments and troubleshoot the problems using tools and other devices.
- Inspect finished products for quality and adherence to customer specifications.
- Prepare documentation for customer and maintain Design History File as per ISO 13485 quality requirements for the outgoing instruments.
- Calibrate or adjust equipment on regular basis to ensure quality production.
- Prepare production documents, including inventory reports, or productivity reports for all product lines.
- Plan and lay out work to meet production and schedule requirements of the team.
- Assist engineers in developing, building, or testing prototypes or new products, processes, or procedures.

Customer Support officer- VFS Global Pte Ltd, Singapore [May 2018 to Apr 2020]

- Building customers' interest in the services and products offered by the company.
- Taking ownership of complaints and queries and following through to resolution.
- Addressing customers concerns with speed, accuracy, and professionalism.
- Manage call centers and provide customer support in high-call volume environments.
- Train new employees in how to use the client software and procedures.
- Prepare daily reports and maintain the process flow record.
- Maintain a friendly and positive attitude to effectively handle unhappy customers.
- Listen attentively to customer needs and provide multiple solutions to address customer concerns to ensure positive customer experience.
- Received a 100 percent customer satisfaction rating.

Consultant Engineer- For Cook Medical- HCL Technologies Pte Ltd, India [Aug 2015 to Jun 2017]

- DHF remediation support for Cook Urology and OHNS products.
- Gap analysis for the Design History File for single use devices and Design History File Remediation.
- Collation of existing design documents and gap assessment.
- Prepare documentation for Design History File Remediation and design inputs for regulatory submissions to the local and international health authorities for new product registrations and/or new establishment licensing.
- Identifying and collating user needs from various sources (Internal teams and literature)
- Complaint analysis to identify the potential failure modes.
- Provide post market regulatory support through product feedback, complaint analysis and Manage Post market surveillance activities.
- Deriving of the Design input requirements from the applicable standards, marketing, and clinical requirements
- Providing the acceptance criteria for design input requirements.

- Risk Assessment and Risk management for existing medical devices using Preliminary Hazard Analysis (PHA) and Failure Mode Effect Analysis (FMEAs).
- Working knowledge on Quality Management Systems including ISO 13485, ISO 14971, 21 CFR Part 820, MDR.
- Implement and maintain the Quality Management System as per GDPMD requirements.

Customer Support Application/ Service Engineer- Imago Systems, India (Authorized Service Dealer for Philips) [Mar 2014 to Jul 2015]

- Perform Preventive/ Break down Maintenance & routine calibration of medical equipment.
- Support Sales team for inspection & installation and application training for Physicians and medical personnel.
- Promote the products to clients by leveraging knowledge of competitive products.
- Organizing exhibitions and trade fairs for healthcare sector.
- Improvement of Marketing strategies to promote sales growth.
- Maintaining relationship with clients and potential customers.
- Providing customer feedback to the organization by collating Voice of customers (VOC) to resolve customer issues and identify market trend for business growth.
- Collaborate with manufacturing, marketing, application, and service team to ensure efficient customer support.

Clinical Engineering Trainee-TriMedx India Pte Ltd
July 2013 to October 2013.

- Attending Break down call along with one senior Biomedical Engineer.
- Carry out the Preventive Maintenance and calibration of medical equipment and documentation.

SKILLS

- Certified ISO 13485 ISO 14971
- 21 CFR 820
- Medical Device Regulatory Affairs
- Design History File (DHF) Remediation
- Medical Quality Management System (MQMS)

EDUCATION

- **B.E Biomedical Engineering**

  Anna University Chennai, India (CGPA-8.23/2009-2013)
- **Graduate Certificate in Medical Device Regulatory Affairs (MDRA)**

  National University of Singapore (NUS) (CGPA 4/2022-2023)