Shwetha B K

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Career Snapshot

- Nov-2022 : Sequoia Healthcare Pvt Ltd
  Quality Engineer
- Mar-2021 : Elexes Medical Consulting
  Quality Engineer
- Sep-2019 : Biorad Medisys
  Quality Officer-QA

Education

- 2017 : Rajiv Gandhi Institute of Technology (VTU University)-B E(Bio medical)- Bangalore
- 2013: BGS PU College - Chikkaballapur
- 2011: M Ramaiha Vidhya Samasthe School-Chikkaballapur

Career Objective

To secure a job where I can utilize my knowledge and skill base for the organization as well as for my growth. To also work on anything which blends Medical device industry which are related to Quality and Regulatory Affairs. Expendable team player looking for a long term career opportunity.

Career Precise

- Competent progressive professional with 9+ years of versatile experience in Quality Management system Implementation, Facing Audits, Team co-Ordinator, training new joinees, Interacting with the customers, PMS Process, PMS Plans & Reports.
- End to end project in charge of QMS projects, Regualaory reporting.
- Understanding of Indian MDR (CDSCO), ISO 13485, NABL, BIS, FDA, EUMDR Regulations.

Skill Landscape

Professional:

- Quality Assurance Officer with total experience of 9 years in Medical Device Manufacturing industry.
- Well versed with ISO 9001:2015, ISO 13485:2016, ISO 14971:2019 and 93/42/EEC standards and Directive.
- Skilled and hands on Quality Management System, Regulatory Affairs and Document Control.
- Experienced in administering, Team lead and managing projects involving audit and Quality Assurance to meet standard requirements.
- Acted as the single Point of Contact for multiple client facing roles for Establishing the quality management system,Quality Complaint, Incoming Inspection and Feedback Management.
- Understanding of all aspects governing operational and production activities and up to date knowledge of latest technological advancements, regulations/ guidelines and statutory compliances in the industry.
- Ability to use sound judgment, decision-making skills and thrive in a deadline intensive environment, multi-task, perform under pressure and meet deadlines. Leader & team builder with proven ability to motivate team members towards achieving production targets.

Others

- Excellent verbal and written communication skills.
- Team Management skills : Training and Work allocation

Key Responsibilities : Sequoia Healthcare Pvt Ltd (Nov 2022 – Present)

Quality Engineer:

- Responsible to setup the quality management system as per ISO 13485.
- Worked on NABL certification for radiology product.
- Induction training and subject oreinted training for the new joinees on system management.
- Worked on Manufacturing License, Import License and Test Licenses as per Indian MDR.
- Organizing the Management Review meetings and performing the Internal audits.
- Worked in BIS certification for the radiology product.
- Implementing PMS Procedure, Colleting PMS Data, reports and providing risk inputs from the PMS Output.
- Responsible for Preparation of Final Inspection Report, Declaration of Conformity.

Key Responsibilities : Elexes Medical Consulting (Feb 2021 to Nov 2022)

Quality Specialist:

- End to End project in charge for QMS projects.
- Setting up Quality Management System of various Medical Device Organisation as per ISO 13485, 21 CFR 820, and EU MDR-Including drafting/Reviewing/Revamping SOPs & Forms, assisting in record generation phase, supplier assessment & audit.
- Worked in change management, root-cause analysis, CAPA implementation, ensuring compliance both in terms of regulatory and quality (ISO 13485. 21 CFR 820, ICMED 13485 etc).
- Provided Training in the established QMS and helped in record generation.
- Interacting with the clients on establishing the QMS in there Organization.

Key Responsibilities : Biorad Medisys Pvt Ltd (Sep'2019 to Feb'2021)

Quality Officer:

- Preparation, review and approval of required SOPs.
- Preparation of related checklist, Certificate of Analysis, Batch Release Reports,Declaration of conformity,Technical files & Registration Documents.
- Tracking and supporting training activities.
- Responsible for conducting Internal Quality Audit (IQA),Management Review Meeting (MRM).
- Maintenance of related records & documents & external Audit handling -ISO 9001, ISO 13485.
- Responsible for Instruments and Equipment Calibration and related record maintenance.
- Co-ordinate and follow-up of Corrective and Preventive Actions (CAPA)
- Return Goods Analysis.
- Manage audits (Technical file review audit, Surveillance audit, Desktop audits etc.) from notified bodies such as bsi / Intertek regarding ISO 13485:2016, ISO 9001:2015 and CE / ICMED regulatory requirements.
- CA & PA verification and rejection control.
- Customer complaints analysis and related record maintenance.
- Authorized to take necessary action to stop non-conforming products and to reject materials if the material is not meeting Specification.
- Continuous Monitoring, reporting and analyzing the quality and standard parameters to ensure product specification requirements.