JINSHA K J

Mobile: 8943496405

Email: jinshajaison@gmail.com

Summary: ·

- Quality Assurance and Technical documentation professional with one year of industrial experience, in-vitro diagnostics Medical devices manufacturing industry.
- Presently working in Quality Assurance department at Xygene Genetics Pvt. Ltd. where I am involved in planning, establishment, and execution of MDR 2017 and ISO 13485:2016 QMS within the Organization.
- Previous experience as Technical Documentation Specialist at ubio Biotechnology Systems Pvt. Ltd., where I am involved in Device Master File preparation, Preparation of Instruction for use (IFU) and Preparing Document as per standard ISO 13485:2016
- Worked as Observer trainee in Rajagiri Hospital Aluva Ernakulam., Where I am worked in microbiology department.

Current Employment Details:

Working in Quality Assurance department at Xygene Genetics Pvt. Ltd. Padamugal, Kakkanad, Ernakulam (February 2023 to till date).

Responsibilities:

- Participated in External Audit for ISO 13485:2016 and MDR 2017 Certification conducted by BSCIC Certifications Pvt. Ltd.
- Prepared documents for the release and production of Molecular Diagnostics Products (PCR)
- Implementation and maintenance of QMS to ensure product quality
- Maintenance of Standard operating procedures (SOP), and other QMS documents
- Preparing Standard Operating Procedures for various departments including Quality Assurance, Quality Control, Human Resource, Ware house & Logistics, Research and Development, IT, Sales & purchase and Manufacturing
- Implement Quality Manual and Site Master File as per the requirements of ISO 13485:2016
- Maintenance of documents
- Ensuring that all the documents are prepared as per the requirements of standard
- Released Batch Manufacturing Record (BMR) for finished products
- Prepared Certificate of Analysis and Material Safety Data Sheet for product shipment
- Conduct internal audits to assess compliance with quality standards
- Attending Management Review Meetings and prepared Minutes of Meeting
- Participate in the product related audit done by the regulatory authority and QMS audit
- Managed the audit process from initiation to closure, ensuring timely completion and adherence to audit schedules

- Managed document control processes, including document creation, revision, and approval, to ensure accurate and up-to-date documentation
- Review and approve documentation for the release of finished products
- Managed the complaint handling process, including investigation, root cause analysis, and corrective and preventive actions (CAPA)
- Maintain of records for Supplier qualification or evaluation reports.
- Played a key role in maintaining temperature logs and cleaning logs, in order to ensure the quality of manufacturing and laboratory areas.
- Maintained accurate and up-to-date documentation related to Preventive maintenance of machines.
- Issued Batch number and Product code for each products
- Maintained batch release record and master list of products and documents.
- Preparation of Company standard and standard testing procedure (STP) for Quality control department.

Previous Employment Details:

❖ Worked as Technical documentation specialist in molecular diagnostics department at ubio Biotechnology Systems Pvt. Ltd. Kinfra Hi-Tech Park, Kalamassery, Kochi, Kerala, India (August 2022 to January 2023).

Responsibilities:

- Preparation and maintenance of Device master files (DMF) as per Medical Devices Rules, 2017 (MDR 2017) standards
- Preparation of IFU's
- Preparing documents as per the requirement of standard
- Maintenance and preparation of process validation document and Design history file for manufacturing products.

❖ Worked as Observer trainee for 3 months in microbiology department at Rajagiri Hospital Aluva, Ernakulam (November 2021 to February 2022)

Responsibilities:

- Acid fast staining and gram staining of samples
- Culturing of specimens like blood, sputum, urine, tissue, stool etc.
- Fungal culture
- Single and Quadrant streak for culturing
- Covid – 19 rapid test
- Dengue card test
- Clostridium testing in stool samples
- Maintaining sample entry records
- Surveillance testing of swabs
- Handing of BACTEC machine for Blood culture
- Entering of positive results into the medical records
- Handling of centrifuge
- Detection of Rheumatic Fever

- Handling of Biosafety cabinet for culturing
- Antibiotic testing

Technical skills:

- Better understanding of the technicality involved in Quality Management
- Time management skills
- Computer knowledge-MS office (Word, Excel and PowerPoint)
- Good documentation and record keeping
- Better understanding of Medical devices rules, 2017 and ISO 13485:2016
- Good laboratory practice

Education:

- Master of Science (M. Sc) in Biotechnology from Mahatma Gandhi University, 3.81 76% (2019-2021)
- Bachelor of Science (B. Sc) in Botany from Mahatma Gandhi University, 9.00 84% (2016 - 2019)

Strengths:

- Leadership qualities
- Team work
- Multitasking Abilities
- Work ethic

Personal details:

- Date of Birth: 24/03/1999
- Sex: Female
- Nationality: Indian
- Languages known: Malayalam, English, Hindi
- Address: Kaadapurathu House Karumalloor P.O Karumalloor North Paravoor Ernakulam