FAIZAL AL SALAM S

Mob No: +91 8940757786 Email: faizalalsalam1@gmail.com

CAREER OBJECTIVE

To obtain a challenging role in Medical Device Regulatory Affairs where I can utilize my skills and knowledge to ensure compliance with regulations and standards and contribute to the development and commercialization of safe and effective medical devices with strong leadership qualities.

TECHNICAL SKILLS

- ISO 13485 & QMS
- Complaints Handling
- Post Market Surveillance (PMS)
- Quality- Failure mode effect analysis (FMEA), Corrective action and Preventive action (CAPA)
- SAP and Track wise Tool
- Medical device Reporting (MDR)Microsoft Power automate.
- Microsoft Power BI
- Root Cause Analysis (RCA)

EXPERIENCE

SigTuple – Executive Regulatory & Quality (QCRA) – Mar 2024 to Present

- **Software used:** JIRA, IMSXPress, SQL.
  Executive Regulatory & quality of premarket submission & post market surveillance on FDA, EU & CDSCO.
- Played major role as Auditor of Internal quality audits & Auditees of Surveillance Audits and Design & Development approvals.
- Handling of DHR files – Verification protocols & reports, User & system requirements, Clinical performance report, Risk management reports and IQ OQ PQ records. DMR files- Label & Packaging, LHR, Testing procedure, Assembly instructions, Service manual, User manual, Installation guide, Bill of materials. CAPA Initiation and Quality objectives tracking.
- Preparation of SOP and maintaining external document log, SOP log, Product complaint log and checklists.
- Collaboration with Design and development, Production and Engineering department heads for the system release of documents by Redline and Blackline with Management approved documents.
- Hands on experience in CDSCO Sugam Portal License approvals.

HCL Tech - Regulatory Analyst - Aug 2021 to Feb 2024

- **Software used:** Trackwise, SAP, Power BI
- Evaluating the complaints and reportability of the complaints as per EU regulations and US-FDA Regulations
- Responsible for processing complaints in various streams of complaint handling such as complaint remediation, Medical Device reporting (MDR) and closure.
- Supported as quality reviewer till date which includes overall quality checks before final submission to FDA based on ISO 13485 Quality management system, 21 CFR Part 820 (QSR), ISO 14971 Risk Management systems.
- Using the SAP tool for finding the additional details like product failure, Serial creation date, software version, plant description etc.
- Medical device reporting for various regions i.e., US, Canada, Australia and Saudi Arabia as per regulatory requirement through Track wise.
- Well exposure towards MDR, Hazard mapping, Risk management, FDA requirements, Med watch3500A reporting, Device history File, Complaint History review, 510k submissions (PMS), IMDRF codes, eMDR and SeMDR creations, validations and verification of complaints.
- Hands on experience in investigations of various events like serious injury, malfunction, and service as per VOC, VOP and customer follow-ups.
- Responsible for completing the good faith efforts to obtain the additional information based on customer follow- ups.

- Prepare the Toxicological Risk Assessment (TRA) studies in accordance with ISO 10993. Do the toxicological studies of in-vitro, in-vivo studies, literature review for depending on molecules specific queries and classification of device categorization and review the study reports.

V-care Health Clinic - Biomedical Engineer - Oct 1 2020 to May 31 2021

- Provide on-site technical support for medical devices, including troubleshooting, repair and preventive maintenance.
- Collaborate with cross-functional teams, including sales and clinical support, to ensure customer satisfaction. Provide training to customers and internal stakeholders on the use and maintenance of medical devices.
- Taking care of on-site branches based out of Tamil Nadu, Karnataka, Telangana Andhra Pradesh.
- Devices: Cosmetology devices.

EDUCATION

- Sengunthar College of Engineering - BE/Medical Electronics Engineering - 7.1 – 2016 -2020
- Veveaham Higher secondary school - Higher Secondary - 7.4 – 2015 - 2016
- Veveaham Higher secondary school – SSLC - 9.3 - 2013-2014

PROJECTS

- **Device to identify Autism Spectrum Disorder**

  In this project, we presented a new tool for physicians to detect ASD children. This tool is based on electro dermal activity that characterizes each disorder. We have developed a device capable of measuring the GSR of children and stream then wireless to smartphone. Based on the levels of GSR, diagnosis and treatment can be established. Autism disorders

ACHIEVEMENTS & AWARDS

- Best Team Leader Award 2019 - Rotary Youth Leadership Award 2019
- Young Talent Award (By – Becton and Dickinson for easing the process flow)
- Technical Champion Award (By – Becton and Dickinson for end-to-end automation)

PERSONAL STRENGTHS

- Self-Motivation and Teamwork

PERSONAL PROFILE

Date of Birth	: 25/03/1999
Marital Status	: Single
Nationality	: Indian
Known Languages	: Tamil, English

REFERENCE

Manikandan C - "HCL Tech"
RM & Lead
manikandanc@hcl.com
+91 9698242999

Muthukumaran - "Vcare Health Clinic "
Head of Biomedical Engineer Department
muthukumaran.bme@gmail.com
+91 9597081091

DECLARATION

I hereby solely declare that the above furnished statements are completely true.