ANNISH LOURDHURAJ J

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Address: 138A, Pillair Kovil street, Indirani Nagar, Mudakusalai, Madurai-625016.

SUMMARY

A highly spirited, skilled and accomplished Quality Engineer with around 4 years of professional experience in the field of Design and Development of Medical Devices as per ISO 13485 MQMS and ISO 14971 Risk Management standards and remediating DHF, FMEA documents, regulatory reporting to FDA, Complaints evaluation. Seeking to leverage my technical skills to utilize in my upcoming environment.

ACADEMIC PROFILE

Course	Institution	Year	Percentage
B.Tech (Biotechnology)	Kalasalingam University	2015-2019	72%

PROFESSIONAL EXPERIENCE

Engineer, **L&T TECHNOLOGY SERVICES**, Mysuru (2022-2023)

Responsibilities:

- Implementation & sustenance of complaints management system. Work for complaints intake centre, Complaints management centre and product assessment centre using **TrackWise and SAP**.
- Responsible for evaluation of received complaints to determine FDA reportability. Experienced in writing MDR records and creating MEDWATCH Form 3500A to submit to the FDA per 21 CFR part 803 for adverse events
- Responsible for product assessment activities like conduction of full-scale investigation of received complaints by performing Product identification and inspection, Product history review, Complaint history review, NC/CAPA history review, Labelling review, Additional documents review and Risk assessment
- Follow up for additional, missing information and Product return details.
- Provide, precise the accurate conclusion and assign appropriate IMDRF codes and FDA product problem codes.
- Closing the complaint records by providing valid investigation summary.

Member Technical Staff, **HCL TECHNOLOGIES LTD**, Madurai (2019-2022)

Responsibilities:

- Working as Quality engineer by remediating DHFs and FMEAs.
- Responsible for creation and remediation of Risk management reports, DFMEA, UFMEA and PFMEA documents.
- Mapping of International Medical Device Regulators Forum (IMDRF) codes for different product families as per Risk Management plan.
- Remediating Overall complaints report by Categorization of Harm, Procedural steps and Mapping IMDRF codes.

- Preparing Defect Diagram lists by investigating complaints using Track wise tool.
- Worked in preparing list of Adverse from product families.
- Performed remediation activities for DHFRs and DIRs as per Client input requirement.
- Performed organizational activities by preparing documents for PCI Audit, Weekly status report, Delivery track records, Execution approach, Work estimation record, CAR report, CC Register for deliverables, Final Inspection Report and Customer Deliverable Note.
- Experience in maintaining documents and 5 why analysis and Audit supporting documents.
- Knowledge in working for 5 why analysis ,7 Quality tools and Six sigma.

Trainer, **FOCUS ACADEMY FOR CAREER ENHANCEMENT**, Chennai (2019)

Responsibilities:

- Experience as Trainer in Verbal and Basic Technical.
- Good knowledge in training up the students for placements and interviews.
- Experienced in assignments as Lab trainer and Co-ordinator.
- Received good appreciations and feedbacks from students and Management.

CERTIFICATION

- ISO 13485:2016 Internal Auditor for Medical Devices Quality Management System from TUV SUD South Asia.

WHITE PAPER

- Published " Codes usage in FMEA's (DFMEA, UFMEA & PFMEA)" in HCL Technologies

TECHNICAL SKILLS

- TrackWise, SAP
- ISO 13485, ISO 14971, US FDA 21 CFR part 803, EU MDR 2017/745, EU MDR 2017/746
- MS Office

PERSONAL DETAILS

- **Father's Name :** John Xavier L
- **Date of Birth :** 11.10.1997
- **Language Known :** Tamil, English & German
- **Nationality :** Indian
- **Marital Status :** Single

DECLARATION

I hereby oblige that the above descriptions and facts are true to the best with my knowledge.

Place: Signature

Date: **Annish Lourdhuraj J**