Ajithkumar R

Vigilance Reporting Specialist

My Contact

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Hard Skill

- Salesforce, Trackwise, WebTrader, eSubmitter
- SAP
- Design Tools: Solidworks (Certificate No. ON030516059), Creo (Certificate No. 37ON030615005), NX CAD (Certificate No. ON031016124), AutoCAD (Certificate No. 18RDZRRDZ5)
- Excel Automation (Power Query, Macro Basics, Pivot Table)
- ISO 13485, ISO 14971, 21CFR(Part803 and 820), EU MDR 2017/745
- Post Market Surveillance - PMS
- Basics of Power BI
- Basics of SQL

Soft Skill

- Observation
- Decision making
- Communication
- Multi-tasking

Education Background

- KGiSL Institute of Technology
  B.E. in Mechanical Engineering with 7.43 CGPA
  Completed in 2018
- AVB Matriculation Higher Secondary School
  H.S.C with 88.5 %
  Completed in 2014
- Infant Jesus Convent Matriculation Higher Secondary School
  S.S.L.C with 86%
  Completed in 2012

Achievements

- Participated and Won second prize in Rally Car Design Challenge -2018 organized by Polaris in February 2018 at Bikaner, Rajasthan.
- Received a Client Appreciation for MDR Report Writing.
- Received a “SPOT AWARD” for outstanding performance at work.

About Me

Conscience driven individual with **5+** years of experience in Medical Device Regulatory Affairs and Mechanical Sector seeking for a challenging career in an organization to explore and constantly look upon potential opportunities to engage for self and organizational growth. Having knowledge in Regulatory Affairs, Post Market Surveillance(PMS) and Mechanical Design.

Professional Experience

L&T Technology Services | Vigilance Reporting Specialist
May 2023 - Present
Client : Philips - UK

- Handled Therapeutic device like IGT (Image Guided Therapy) Systems.
- Evaluating the reported incident and deciding on reportability of the event.
- Performing GFE (Good Faith Efforts) to acquire information from the service engineer or the customer about the reported incident.
- Performing full scale Investigation process by reviewing Risk Management Files, Complaint History Record(CHR) and Device History Record(DHR) in SAP and salesforce.
- Submission of regulatory reports(initial and final reporting) for various medical device regulatory agencies of countries like United states(MDR), EU Countries(MIR), APAC regions, Canada, Australia(IRIS), etc. without exceeding the due date.

HCL Technologies Ltd. | PMS Analyst
Feb 2020 - May 2023 (3Years 4Months)
Client : Becton Dickinson(BD) - US

- Handled Medication Management Device like Infusion Pump, Medstation, Anesthesia Station.
- Gathering and collection of initial information of medical device complaints/cases from all intake sources.
- Analyzing and investigating the complaints/cases and Performing follow-up with customer for required additional information.
- Evaluating Device History Record (DHR) and Complaint History Record(CHR) for incident of Medical Device on SAP tool.
- Performing CAPA and Risk Management(DHF).
- Analyzing complaints/cases for medical device reportability determination in accordance with regulatory guidelines.
- Preparation and Submission of MDR to FDA with appropriate IMDRF Coding and narration.
- Having familiarity in ISO 13485, ISO 14971, 21 CFR(Part 820 and Part 803), EU MDR 2017/745 Standards.

Craftsman Automation Ltd. | Graduate Engineer Trainee
May 2018 – July 2019 (1Year 1Month)

- Designing all types of Cranes like EOT, X-Y, Jib, Monorail Cranes (Using Solidworks).
- Creating 3D Models and Preparing Manufacturing Drawings for 3D Models.
- Creating Clearance Drawing and General Appearance Drawing for Cranes (Using Draftsight and AutoCAD).
- Creating Bill of Materials (BOM).
- Standardization of EOT Crane Components.
- Reverse Engineering.