PRITHVI BONTULA

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Summary

Biomedical engineer with 4 years of experience in the medical device industry, holding a master's degree in regulatory affairs. Certified ISO 13485:2016 internal auditor and Lean Six Sigma Green Belt, adept at developing and implementing Quality Management Systems (QMS) and driving successful regulatory submissions. Experienced in regulatory compliance across various industries with a strong foundation in quality management system. Expert in navigating regulatory frameworks for the US, Canada, and EU. Dedicated to ensuring compliance and spearheading continuous improvement initiatives across diverse medical devices, including SiMD/SaMD.

Technical Skills

- EU MDR & IVDR
- ISO 13485
- Post Market Surveillance/complaint handling
- MDSAP, Internal, and supplier audits
- Healthwatch
- Health Canada, Safe Foods for Canadians Act (familiarity)

Certifications

ISO 13485:2016 Internal Auditor
EU-MDR
Lean Six Sigma Green Belt
Food Safety Training & HACCP Certification (Planned)

Work Experience

Research Intern| VIA Global Health **Sept 2023- Dec2023**

- Worked on drafting registration guidelines for class 2 medical devices in the East African Region, specifically targeting Tanzania and Zimbabwe.
- Assisted in preparing documentation related to the software testing process, including test plans, test reports, and software validation summaries for some of the class 2 medical devices.
- At VIA Global Health, gathered and compiled comprehensive raw data on the regulatory frameworks and practical and technical requirements for exporting medical devices to all countries in the East African region.

Clinical pharmacy assistant| Shoppers Drug Mart| Part Time **Dec 2023 – Present**

- Resolved 200 customer inquiries daily to process claims, streamlining workflow and achieving a 75% increase in operational efficiency.
- Gained familiarity with pharmaceutical regulatory frameworks, building a foundation to understand food and drug regulations.
- Check inventory levels and report shortages or discrepancies. Use the register to handle billing, payments, and insurance claims, manage customer accounts, and demonstrate tech proficiency.
- Conducted comprehensive medication reviews and consultations, ensuring safe and accurate prescriptions, which parallels the rigorous standards required in food safety and consumer protection.

Products System Analyst | KAISER PERMANENTE | TCS **Jul 2019- Jul 2021**

- Develop and document test plans, test cases, and test scripts based on software requirements and specifications. Define test strategy for various testing phases, including manual and automated testing approaches.
- Execute manual and automated tests to identify defects and ensure software functionality meets specifications. Ensure thorough testing of all aspects of the application, including edge cases and negative scenarios.
- Create and maintain automated test scripts using testing tools (e.g., Selenium, TestComplete).
- Identify, document, and track software bugs and issues using bug-tracking tools (e.g., JIRA, Bugzilla). Communicate defects to development teams and follow up on bug resolution.
- Ensure that testing processes adhere to company quality standards and regulatory requirements, particularly for industries like medical devices (e.g., IEC 62304).
- Analyse test results and testing processes to identify areas for improvement.
  Stay updated with the latest testing tools, techniques, and industry trends to optimize testing strategies.

Research Intern| Defence Bio-Engineering & Electro Medical Laboratory **Dec 2018- Apr 2019**

- Developed a cutting-edge Electromyography (EMG) processing algorithm to analyze time domain parameters, enhancing prosthetic device functionality for amputated militants.
- Performed comprehensive performance and safety analysis of prosthetic devices utilizing EMG signal processing, ensuring optimal functionality and compliance with safety standards.
- Conducted extensive software testing and validation for the control systems embedded with EMG, specifically targeting software safety and performance.
- Conducted risk assessments, ensuring devices met CDSCO's performance and safety requirements.

Education

1) **Northeastern University – Toronto | Masters in Regulatory Affairs| 3.8/4 CGPA** **Jan 2022- Dec 2023**
2) **Vignan's University - Andhra Pradesh, India | Bachelor of Technology | 8.4/10 CGP** **Jul 2015- Apr 2019**
   Majors in: Biomedical Engineering | Minor in Business Administration and Project Management