Akhilesh Kumar Sharma

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14/09/1994

OBJECTIVE

Regulatory Affairs professionals with a strong foundation in global medical device regulations and technical documentation. Seeking a challenging role where I can apply my knowledge of EU MDR, US FDA, and ISO standards to support regulatory submissions, labeling compliance, and cross-functional documentation activities. Committed to contributing to product safety, quality, and timely market access through regulatory excellence.

PROFILE SUMMARY

Currently Working on Risk file for DHF remediation team at Tata Elxsi Limited, Pune

Expertise in development of application based software solutions according to SDLC

Strong understanding of international regulations and standards, including EU MDR, FDA 21 CFR Part 820, ISO 13485, ISO 14971, and country-specific requirements; familiar with processes related to labeling, UDI management, clinical and design

worked on template, SOP and WI development for client

Proficient in idea generation, technology gap analysis and automation activities

Expertise in Labelling activity for orthopaedic Implants and instrument

Project Management Activity such as Resource Allocation, Costing, Budgeting, Training Plan

TOOLS

- Windchill
- Vault
- SAP ERP
- Adobe Acrobat Pro DC
- Microsoft Power Bi
- Microsoft Office

SKILLS

- 21CFR Part 820, ISO 13485
- DHF Gap Assessment and Remediation
- IEC 62304, IEC 82304-1, SAMD and SIMD, Gap assessment
- ISO 14971, Risk Management (dFMEA, AFMEA, uFMEA, RMP, RMW and RMR
- EU MDR, EU AI Act, EU Submission
- US fda Submission, 510(k)

EXPERIENCE

Jan, 2021 - Present
Tata Elxsi Ltd, Pune
Regulatory Affairs Specialist

1. Involved in dossier preparation and regulatory strategy for global markets, including EU MDR, US FDA, and RoW countries for Class I, II, and III medical devices; familiar with submission procedures and documentation requirements.
2. Managed technical documentation, labeling, and translation processes in accordance with ISO 13485, ISO 15223-1, and local regulatory requirements.
3. Created various medical device labels (product, patient, barcode, PICL) in compliance with ISO 15223-1, ISO 20417, and country-specific regulatory requirements. Managed UDI implementation including GTIN allocation, label content alignment, and data mapping for EUDAMED submissions. Collaborated with cross-functional teams to ensure labeling accuracy and regulatory compliance across global markets.
4. Supported development of IFU and IFP in collaboration with cross-functional SMEs including RA, Development, and Biology team.
5. Performed gap analysis for MDD to MDR as per Annex I—GSPR and Annex II & III—Technical Documentation requirements, Annex VIII: Classification, and Annex IX. Also, prepared an action plan and ensure timely closure of action items.
6. Experienced in managing change control and change management activities through Windchill, including impact assessment, documentation updates, and cross-functional coordination to ensure regulatory and quality compliance.
7. Created and reviewed packaging, carton, and shipping labels to ensure accuracy, product traceability, and compliance with regulatory requirements. Verified packaging tests to ensure product safety, labeling integrity, and suitability for storage and transportation.
8. Prepared and maintained GSPR checklists for orthopedic implants and instruments, ensuring alignment with EU MDR Annex I requirements and supporting overall technical documentation readiness
9. US FDA: Submission Preparation: Author and submit regulatory filings such as 510(k)s, PMAs (Premarket Approvals).
10. Involved in software dossier remediation activities including verification of requirements, identification of applicable standards, review of testing documentation, and establishing traceability between requirements, design, code, and software versions.
11. Good understanding of IEC 60601-1; performed impact assessments and delta analysis between different standard versions
12. Created and technically reviewed risk management documents, including risk management plans, risk analysis

- IEC 60601-1, IEC 62304
- Labelling (Label Draft, IFU and IFP)
- Validation and Verification
- Basic Understanding of Cybersecurity
- GDPR, HIPPA Regulations Guidelines
- Basic Generative AI, Machine Learning
- Microcontroller Atmega328P, Sensors and Transducers, IoT Automations
- Power Bi
- Project Management Activity

CERTIFICATION

Received Project Excellence Award Winner for "Contributing towards the success of the project
"EU MDR Compliance Services"
• Received Bravo Award and Extra Mile award for completing the deliverables on time, quick
learning attitude, proactive approach, and schedule commitment.
• Undergone all basic training of client and Tata Elxsi Engagements.
• Certification on Generative AI, AI for Everyone and ChatGPT
• Certification received in the Star of Bodhi Award
• Certification in Android app Development through Android studio/ MIT App inventor

worksheets, Design FMEA, Application FMEA, and risk management reports, also experience in design documents, such as design development plans, Input Output Verification Validation Tables (Design Traceability Matrix), usability engineering files, design verification and validation protocols/reports.
13. Good understanding of Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER); created CEPs and Summary of Safety and Clinical Performance (SSCP) for orthopedic implants in alignment with EU MDR requirements.

➔ **July 2019 - May2020**
Stemrobo Technology private limited, Noida
Innovation Engineer
1. Designed and developed proof-of-concept prototypes integrating microcontrollers and sensor modules for IoT applications.
2. Led the end-to-end product development lifecycle, from requirements gathering and circuit design to testing and validation.
3. Translated conceptual ideas into functional prototypes, accelerating project approval by stakeholders.
4. Collaborated with cross-functional teams to refine designs based on PoC results and user feedback.
5. Prepared detailed technical documentation, schematics, and BOMs for handoff to production teams.

➔ **Aug 2016 - Jan 2017**
Industry Innovation Pvt. Ltd.
Quality Control
- Checks incoming materials: keypad domes, PCB, plastic housings, rubber mats, Lipo Batteries
- Verifies supplier compliance to specs.
- Monitors assembly lines for defects (e.g., misaligned keys, poor soldering).
- Performed line audits and process check

EDUCATION

✔ **2019**
National institute of technology, Kurukshetra
M.Tech in Biomedical engineering
8.58

✔ **2016**
Galgotia College of Engineering & Technology, Greater Noida, UP
B.Tech in Electronics & Instrumentation Engineering
73.33

ACHIEVEMENTS & AWARDS

✔ Qualified Gate Exam in 2017

✔ Project Excellence award for EU MDR compliance project

PUBLICATION

✔ **IEEE Conference Paper**

Akhilesh Sharma and L. Mohan Saini, "IoT-based Diagnosing Myocardial Infarction through Firebase Web Application," 2019 3rd International Conference on Electronics, Communication and Aerospace Technology (ICECA), Coimbatore, India, 2019, pp. 190-195.

✔ **Journal of Emerging Technologies and Innovative Research [JETIR]**

"Ultrasonic radar sensor for security system", International Journal of Emerging Technologies and
Innovative Research (www.jetir.org | UGC and ISSN Approved), ISSN:2349-5162, Vol.3, Issue 4, page no. pp137-139, April-2016,
Available at: http://www.jetir.org/papers/JETIR1604028.