QualiMed®
A Q3 Medical Company

Sr. Engineer – Quality Assurance

Position / Title
Sr. Engineer – Q.A.

Department / Area
Quality Assurance

Reports to
Team Lead – Q.A.

Language
German and English

Education
Bachelor of Science or equivalent

Experience
Minimum 3 years in a quality engineering role in Medical Device industry.
Exposure of ISO 13485, ISO 14971, MDD,EU MDR and USFDA QSR Part 820

Primary Tasks and Responsibilities

EU MDR

The position holder will act as MDR Project Lead. The position will be responsible for overall project management, including the planning and implementation, to facilitate full compliance with the new European Union Medical Device Regulation (EU MDR). The Project Manager will provide direction and understanding on the regulatory requirements of the MDR to the business unit as well as responsible to influence a wide range of functions and departments to drive the project.
The main responsibilities include;

- Develop, plan, communicate and deploy project schedules. Responsible to meet project phase deliverables and milestones
- Maintain project governance
- Partner with cross functional teams regarding common interpretation and guidance, deliverables, pace and progress to ensure a harmonized approach for achieving compliance
- Communicate effectively with senior management to ensure clear expectations, demonstrate progress and identify issues. Provide progress updates and regular reporting to business and functions leadership
- Through the implementation of project management and productivity tools, maintain and track progress and produce applicable reports
- Facilitate periodic status update meetings, take meeting minutes with action items, and follow up with SMEs on expected deliverables
- Lead the gap assessment on current QMS documentation and address the gaps for MDR compliance
- Lead the gap assessment on current technical files of legacy devices and support product manager on remediate the files for MDR compliance

Design Control

- Support on new product development and design change project to ensure compliance to internal procedure and regulatory needs
- Ensure that customer requirements are incorporated into product functional specifications
- Participate in all design reviews to provide input on process compliance and design quality indicators
- Provide quality guidance and participation in Validation, Qualification activities including, review of protocol, and identification of sample size, test method and reports
- Responsible for verifying Design transfer activities to ensure compliance to internal procedure and regulatory needs
- Provide trainings to R&D team on regulations applied to new product development and any design change

For more enquiries, please contact:
QualiMed Innovative Medizinprodukte GmbH Boschstraße 16, 21423 Winsen, Germany +49 4171 6578 0
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Risk Management

- Create and update Risk Analysis files in consultation with development team
- Provide guidance on Risk Management planning to R&D
- Facilitate FMEAs (Design and Process)

Other

- Monthly and quarterly reporting to reporting manager
- Support internal and external audit activities from various regulators, customers, and consultant as necessary

Skills / Competencies

- Knowledge of Quality System Standards/Regulations, Design Control requirements (ISO 13485, 21CFR Part 820, EU MDR, MDD93/42/EEC, ISO 14971, etc)
- Project Management
- Excellent verbal and written communication skills, teamwork skills, result orientation required
- Ability to work both independently and in conjunction with a team

Working conditions

Permanent, full time (40 hours / week)

Any specific skill requirements

EU Medical Device Regulation and USFDA exposure

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