Rasmus Sichlau
M.Sc. Human Biology, Copenhagen University

Senior Consultant, Medical Device Compliance

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Competences

- Design Control
- Risk Management
- CAPA
- Design verification
- Design validation
- Human Factors / Usability
- Requirement Engineering
- Product maintenance
- SAMD/SIMD/MDSW
- Customer complaint investigation
- Inspection preparation and presentations
- Device accessories
- Process optimization and cLEAN
- Batch review and release of products as delegated QP

Key results

Working with medical devices since my graduation has given me a holistic insight into the industry. I started my career in a medical device production as a delegated QP. I have extensive experience in product maintenance and R&D thus giving me valuable insights into the entire value chain.
I have a diverse profile with my biotechnological education combined with experience from both production, R&D and regulatory assignments. My background and career combined allows me to work with a wide range of subject areas from biologics over electronics to medical devices.

Software/Standards

- ISO13485:2016
- MDR (device regulation)
- IVDR (In Vitro Diagnostics Regulation)
- FDA regulation [CFR part 820]
- ISO14971 (risk management)
- IEC 62366 (Device Usability)
- IEC 62304 (Device Software).
- IEC 82304 (Health Software)

- Microsoft Windows
- Microsoft Office 365
- Microsoft project
- Microsoft Visio
- Agile

Personal Characteristics

I carry great concern for my co-workers and try my best to create a fun and positive environment. I thrive in a dynamic setting with short deadlines and difficult situations.
I enjoy being challenged by skilled colleagues as well as complex assignments in a busy environment. I am continuously trying to improve both at a personal and professional level.
As I have been working as quality representative most of my career, I am used to giving direction and setting boundaries according to the company guidelines. I am used to work in complex stakeholder situations in international companies with great diversity.
I am tech savy and a quick learner and can thus easily adapt to working with diverse and complex devices and software.

References

Medicologic A/S (present)
Senior consultant

WSAudiology

Quality Responsible, R&D

Development projects of hearing aids (medical device class IIA) and accessories (class I).
FDA inspection preparation work. Remediation of FDA and audit findings. Pre-verification, verification and validation protocols and reports. Test statistics setup for the entire R&D area. Local and global CAPAs. Requirement engineering. Complaint handling.
Risk management.

Agilent Technologies Denmark Aps
Quality Specialist, Solutions
IVDR submission work overseeing technical file creation, risk work, technical description of devices, human factors analysis of existing products, requirements and verification. Day to day work including change management and review and approval.

Radiometer Medical APS
R&D Engineer
IVDR submission work for a blood gas device. Preparing the STED, setting up tests, aligning with the clinical team and coordinating with subject matter experts within several areas.

Novo Nordisk A/S
Quality Engineer
Assisting device projects in adhering to internal and external requirements such as those arising from ISO 13485, FDA and MDR. Deviation handling, process optimization and improvement projects, data and protocol review, change control and CAPA handling, document reviews and training of personnel.

Novo Nordisk A/S
QA Professional
As a delegated QP releasing semi-finished and finished products to the market. Batch review, presentation at handling of customer complaints and deviations.