Tommy Roy Røsholt
MSc Engineering Management (DTU)

Labelling, UDI and Traceability Specialist

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Competences

- Unique Device Identification (UDI) strategy and implementation
- Strategy and implementation of Labelling processes
- Full Traceability for Medical Devices (end to end)
- Implementation of labelling systems (QMS + Technical implementation)
- Regulatory Master Data strategy and implementation
- Basic UDI-DI strategy and implementation (MDR)
- Project and program Management
- Implementation of regulatory compliance projects throughout the value chain
- Complexity Management and mass customization
- Automation and Robotics in various sectors

Key results

- UDI procedures and system developed and implemented in Class I, II and III life science companies under both FDA and MDR
- Full labelling readiness procedures and labels developed and implemented
- FDA Design Transfer procedures developed and implemented in major Class II company. from zero to successful first FDA inspection
- Prepared and performed MDSAP Audits (operations) Class IIa and IIb
- Full MDR GAB analysis performed for various Medical Device companies
- Transfer of EC certificates in major life science company

Standards

Internationally recognized standards:

- **ISO13485; ISO15223; ISO20417:2021**
- **MDR 2017/745 and IVDR 2017/746 + MDD 93/42/EC, IVDD 98/79/EC** [Medical Device & In Vitro Diagnostic Regulative]
- **UDI** [EU, FDA, worldwide]
- **FDA Regulation - Medical Devices** [CFR 21 part 11 and 800 and beyond]
- **GS1 Standards** [GTIN, GLN, GDSN, Digital Link]

Personal Characteristics

Life science and healthcare enthusiast with strong Project Manager experience in the areas of medical devices development, people management, organizational fit to regulatory requirements and regulatory program execution. Strong implementor of projects in larger complex organizations.

Driven by strategic development of the business, systems, and organizational processes. Worked with various regulatory project implementations under FDA 21 CFR, MDR/IVDR, MDSAP and ISO13485.

References

Medicologic (2019 - ongoing)

Senior Consultant
Project Manager and Consultant.

SSI Diagnostica (2022-Ongoing)

PM and Consultant new labelling system (NiceLabel)

3Shape (2022 – ongoing)

Project manager
PM Strategic labelling project
Systemic process changes by implementation of labelling/artwork management software and related QMS procedures.

Radiometer (2019 – ongoing)

Project manager
PM UDI project EU MDR, FDA and South Korea
PM Strategic labelling project and GDSN implementation

GN Hearing (2020)

Consultant in Basic UDI-DI procedure update and implementation in QMS and related systems

Demant various positions (2013 – 2021)

R&D and NPI PM for Oticon and Oticon Medical development and releases
Program manager UDI projects (FDA and MDR)
PM Design Transfer and UDI - FDA Program
PM New Label print system

Novartis and Sandoz (2018-2019)

Project Manager QA/RA
Certificate Transfer Project for Combination Product division

Guldmann (2018-2019) & ETAC (2018-2019)

Consultant
Full MDR GAB analysis

Medical Device Education instructor (2018 - ongoing)

Instructor
UDI (FDA and MDR)
Labelling requirements (MDR)

Bila (2010 - 2013)

Project Manager
Responsible for a portfolio of Larger Robot automation projects