Tommy Roy Røsholt

Senior Consultant
MSc Engineering Management at
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Competences

- Project and program Management
- Implementation of regulatory compliance projects throughout the value chain
- Unique Device Identification (UDI) strategy and implementation
- Basic UDI-DI strategy and implementation (MDR)
- Strategy and implementation of Labelling processes
- Full Traceability for Medical Devices (end to end)
- Regulatory Master Data strategy and implementation
- Implementation of labelling systems
- 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
- 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**
- **MDD 93/42/EC, IVDD 98/79/EC,**
  [Medical Device & In Vitro Diagnostic Directive, and QSR]
- **MDR 2017/245 and IVDR 2017/246** [Medical Device & In Vitro Diagnostic Regulative]
- **FDA regulation**
  [CFR 21 part 820, part 11]
- **GS1 Standards** [GTIN, GLN, GDSN]

Personal Characteristics

Strong Project Manager with experience in the areas of medical devices development, organizational fit to regulatory requirements and regulatory program execution. Strong implementor of projects in larger complex organizations.

Driven by strategic development of the business and organizational processes. Worked with various regulatory project implementations under FDA 21 CFR 820, MDD/MDR, MDSAP and ISO13485.

References

Rosholt Consulting (2017 - ongoing)

Senior Consultant
Regulatory PM, Consultant and owner

Radiometer (2019 – ongoing)

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

Demant various positions (2013 – Ongoing)

Project Manager for
UDI projects (FDA and MDR)
FDA Program – PM Design Transfer and UDI
PM Label print system
NPI for Oticon and Oticon Medical releases

Novartis and Sandoz (2018-2019)

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

Guldmann (2018-2019)

Consultant
Full MDR GAB analysis

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

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