Tommy Roy Røsholt

Senior Consultant
MSc Engineering Management at Technical University of Denmark (DTU)
Direct (+45) 20 29 33 32
tommy@rosholt.dk
www.rosholt.dk

Competences

- Project and program Management for medical device R&D, IT and Operations.
- Strategy and implementation of Labelling programs and projects in complex and large organizations
- RFP, Selection and Implementation of label and artwork management systems
- Implementation of regulatory compliance projects throughout the value chain
- MDR and IVDR GAP Analysis
- Unique Device Identification (UDI) strategy and implementation (incl. Basic UDI-DI)
- Full Traceability for Medical Devices (end to end)
- Regulatory Master Data strategy and implementation
- Complexity Management and mass customization
- Automation and Robotics in various sectors

Key results

- Timely and successful Release of major Class II and Class III Medical Devices
- From zero to fully implemented Global labelling system in large global Medical Device organization
- UDI procedures and system developed and implemented in Class I, II and III life science companies under both FDA and MDR/IVDR and RoW.
- From MDR GAP analysis to QMS compliance full project
- FDA Design Transfer and UDI 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 Program and Project Manager experience in the areas of medical devices development, organizational fit to regulatory requirements and regulatory program execution.
Strong implementor of strategy and projects in larger complex medical device organizations across operations, quality, marketing, IT and systems.

Motivating colleagues to have fun while striving for development of the business and organizational processes.

References

Rosholt Consulting (2017 - ongoing)

Senior Consultant
Regulatory PM, Consultant and owner

SSI Diagnostica (2022-Ongoing)

PM and Consultant new labelling system (NiceLabel) and UDI

3Shape (2022 - ongoing)

Project manager Global Labeling Project
New End2End labeling project for people, processes, and systems

Radiometer (2019 – ongoing)

Project manager
PM Global labelling project across OPS, IT, QA, RA for software and hardware implementation. (Kallik)
PM UDI project EU MDR, FDA, South Korea and RoW across Global supply chain, OPS, IT, QA, RA.
PM GDSN implementation project with Global OPS/ supply chain.
PM Master Data Management ERP cloud upgrade + CPQ consult.
Consultant Claims management (software RFP and selection)

GN Hearing (2020)

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

Novartis and Sandoz (2018-2019)

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

Demant various positions (2013 – 2020)

Project Manager for
UDI and Labelling projects (FDA, MDR, RoW)
MDR GAP Analysis
FDA Program – Responsible for Design Transfer processes and UDI
PM New Label print system I Implemented in North America
NPI for Oticon and Oticon Medical releases

ETAC (2018-2021) & Guldmann (2018-2019)

Consultant
Full MDR GAB analysis
Strategy and implementation of UDI and Basic UDI-DI into QMS
Solution architect QMS general

Medical Device Education instructor (2018 - ongoing)

Instructor
UDI (FDA, MDR, RoW)
Labelling requirements (MDR)

Bila (2010 - 2013)

Project Manager
Responsible for a portfolio of larger robot automation projects from first customer contact to final installation and acceptance.
Project example: Link Dokka Norway 1.35 min.