Mads Marker
MSc Chemical Engineering, DTU
MBA, Bocconi University, Italy

QA / RA Expert, Medical Device

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Competences

- Quality management & Management representative
- PRRC (MDR) & EU authorized rep.
- Executive management, strategy
- Gap Analyses
- Set up of KPI's for QMS processes and business.
- Distributor Management (ref. MDR article 14)
- Quality systems implementation (ISO13485/ QSR part 820)
- Design Control
- Design Dossiers and Technical File for CE marking.
- FDA 510(k) submission
- Communication with authorities
- Preparation and submission of international registrations for medical devices and for IVDs.
- Trained Lead auditor; supplier audits, internal audits
- Risk Management, CAPAs
- Software Validation, Process- and sterilization validation
- Change Control

Key results

15+ years in the medical device industry. Worked in big corporations as well as extensive experience with MedTech startups.

Various Director roles within QA and RA functions in several international companies

Built and certified ISO 13485 quality management systems

International registration of various devices

Creation of regulatory and quality strategies for MedTech startup companies

Achieved CE mark of an active implantable medical device

Global Director of multi-site QA operation. Oversight of 150+ FTEs

Regulations/Standards

- ISO 13485 - Medical devices - Quality Management
- ISO 14971 - Medical devices - Risk management
- ISO 10993 - Biological evaluation of medical devices
- ISO 14155: Clinical Investigation – GCP
- IEC 62366-1 Usability
- **EU Directives:** Medical Device Directive MDD 93/42/EC, in vitro diagnostic directive IVDD 98/79/EC, AIMDD 90/385
- **EU regulations:** Medical device regulation 2017/745, In vitro diagnostic medical devices 2017/746
- **FDA regulations:** CFR 21 Part 820, Part 11, 803, 806
- ISO 14155: Clinical Investigation – GCP
- ISO 15223-1 Labelling of medical devices
- ISO 11135 - Sterilization of health-care products ETO
- ISO 11137-1 Sterilization using Gamma Radiation
- ISO 11607-1; -2 Packaging

Personal Characteristics

Mads has a broad experience within MedTech Quality Management and Regulatory Affairs. By education an engineer and an MBA, which in combination gives both a holistic approach and the ability to dive deep into technical aspects. Mads has hands-on experience with every aspect of quality management and Regulatory Affairs from the startup world and extensive management experience from large international corporations.

In his free time Mads is a passionate father of 3 and therefore spends more time watching sports than exercising – although he does some yoga, mountain biking and running when time permits. Mads is an avid skier and loves to travel to Spain to practise his Spanish language and enjoy Mediterranean food.

References

Medicologic A/S (present)

Senior Consultant

Droplet IV (2023- present)

Head of QA/RA: MedTech startup within Infusion Therapy.
Build QMS and achieve FDA 510(k) clearance and subsequent CE mark of the class IIa device.

Convatec Infusion Care (2022 - 2023)

Sr. Director, QA: Global responsible for Quality. Sites in DK and Mexico. Budget responsible for 150+ FTEs

Radiometer Medical (2019-2022)
Director QA/RA
QA: responsible for Distribution QA
RA: responsible for international registrations

UNEEG Medical (2008-2019)

Head of QA/RA
MedTech Startup. Creation of QMS, CE mark of an active implantable medical device

PA Consulting Group (2006-2008)
Management Consultant
Consultancy within business strategy and Organizational Design

IBM (2001 - 2006)
IT specialist (2001-2003)
Worked with the Tivoli SW suite.
Business consultant (2003-2006)
Worked on integration of Mærsk Data into IBM