Hans Georg Madsen
MSc Chemical Engineering, DTU

Quality Management and Implementation

ID1063

Direct (+45) 22 89 27 72
gans.georg.madsen@medicologic.com

medicologic®
Medical Device Development

Medicologic A/S
Arne Jacobsens Alle 17
Ørestad City
DK-2300 Copenhagen
Denmark

(+45) 48 24 51 13
contact@medicologic.dk
www.medicologic.dk

Competences

- Quality Management
- Medical Device QMS
- Management representative
- In- and external audit and inspection
- Audit Management and execution
- Supplier Quality Management and audit
- Quality tools, i.e. CAPA, NCR, MR
- QMS implementation
- Lead auditor
- Quality KPI's

Key results

I have held positions such as VP of QA & RA, Director of Quality, Director of QA, and General Manager of Quality. Throughout my career, I have been responsible for leading certification and recertification projects, managing audits and inspections, including FDA inspections and MDSAP audits.

I have led teams of various sizes, including sub-teams and managers, overseeing all aspects of compliance and quality assurance in the medical devices sector. My experience spans both national and truly global contexts.

Software/Standards

Extensive knowledge in:

- ISO13485
- FDA 21CFR part 820
- MDSAP
- MDR/MDD

Software skills:

- SAP
- Documentum
- Enovia
- Salesforce
- MS Office and SharePoint

Personal Characteristics

Hans is a highly self-driven and motivated professional with a proven ability to work effectively both independently and as part of a team. He excels in collaborating with individuals at all levels of an organization and is motivated by achieving tangible results. Hans possesses strong business acumen and analytical skills.

With a background in chemistry, Hans has dedicated the majority of his career to the field of quality management. He has successfully led, maintained, and implemented quality systems in a pragmatic manner, consistently balancing compliance requirements with business objectives.

References

Medicologic A/S (present)

Senior Consultant, ISO13485 Management and Implementation

Ferrosan Medical Devices

Director
NC/CAPA/Complaints, recalls and internal audits.

BK Medical

Director
NC, CAPA, complaints, possible recall and vigilance.

Demant / Oticon

VP / Senior Director
CAPA, management review, audit management, auditing, complex CAPA, possible recall and vigilance.

Brüel & Kjær

Quality Manager
Audit Management, supplier approval and auditing. Management review. Complex complaints.

FLSmidth

GM Quality Working with supplier management and auditing, system development and improvement. Audit Management. Management review.

Thermo Fisher Scientific

Working with and responsible for QA, QC, validation, microbiological laboratory and release laboratory. Participating/responsible for NC/CAPA/complaints. Responsible for complicated complaints. Auditing. Audit Management. Management review.

Coloplast

Working with QA and QC, NCR, CAPA auditing and complaints.

Superfos (packaging)

Working with performance and reliability testing, complaint handling and customer requirement. Supplier management and contact.