Asger Dahlgaard
B.Sc. ME Engineering

Senior Consultant and Principal Advisor
Management and change management

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Competences

- Management
- Change Management
- PRRC (MDR) & EU authorized rep.
- Quality Management and Implementation
- IT-system for QA
- Process optimizing
- Process validation
- LEAN
- GMP (Good Manufacturing Process)
- Project Management and Program Management
- Audits/ Inspections (FDA / MDSAP) TGA, CFDA and others
- Management Review

Key Results

Management of corporate QA function in both a large Danish and US Medical Device/IVD company

Securing compliance and well performed Audits - no major observations
Aligning QA strategies with Business goals -

Training and implementation of SOP's in global scale

MDSAP certification, Legal entity transfer, Preparing for IVDR and MDR

Standards

Extensive knowledge in:

- **ISO13485 og 14971**
  [Medical Device QS and Risk Management]
- **FDA regulation**
  [CFR part 820, CFR part 11, UDI]
- **Guideline**
  [ICH Q7, Q9 and Q10, GAMP 5, GHTF Process validation]

Personal Characteristics

Asger is a pragmatic and straight forward person that believes in an open and honest dialogue, he enjoys working with others. Has many years hands-on experience in implementation and integration of management systems and LEAN.

Spends his free time with family, boating, skiing, diving, kiting and running

References

MEDICOLOGIC A/S (2021 - present)

Senior Consultant and principal Advisor
Medical Device and in vitro diagnostics.

Agilent Technologies

Quality Director
Overall responsible for the QMS including Management representative and management review. Both internal and external audits including dialogue with FDA and Notified bodies. Furthermore, responsible for Vigilance, complaint, Post Market surveillance, Product release, CAPA and NCR and Document control. Both IVDR and MDR including campaign diagnostics

MEDICOLOGIC A/S

Program Manager - Management Consulting for medical device companies

COLOPLAST A/S

Quality Director for process development, 1½ years
Overall responsible for the development of quality related processes globally. Achieved an improvement in change control process; "Right first time" from 55 to 88%. Lead the implementation of a fully electronic validation system. That replaced all paper-based validation documentation. Responsible for Vigilance and recalls.

Director for QEHS Concepts, 2 years
Main global responsibility was Risk Management, validation, calibration, maintenance. Re-designed and implemented a new risk management system, which linked product risk with process validation and post market surveillance. Implemented the first standalone cleanroom monitoring system.

Corporate Quality Development Manager, 4 years
Lean specialist that conducted 16 global LEAN events. Development of overall procedure for transfer of production to low-cost countries. Standardization of all calibration activities including a cost reduction of 25%.