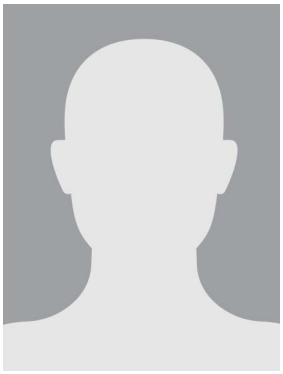

NN
Laboratory & Quality, Chemistry

Senior Consultant

ID1060

Direct (+45)
nn@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

- Verification & Validation, Laboratory testing
- Quality Assurance, Medical Devices
- Audit Management, Internal Audits, ISO 13485
- Quality Systems Implementation
- Design Control
- Nonconformance and CAPA Management
- Post Market and Complaint investigations
- Stop Shipment Evaluations
- HACCP and traceability documentation

Key results

- Nonconformance and CAPA management in certified Medical Device Company
- Certified Internal Auditor ISO 13485
- Support on Notified Body audits and Costumer audits
- Post market control of nonconforming products and Root Cause Investigations
- Extensive laboratory experience in ISO 13485 and FDA labs
- Technical documentation for clinical trial projects

Software/Standards

Extensive Knowledge in:

- **ISO 13485** Medical Devices – Quality Management Systems
  MDSAP
- FVST Guidance no. 9006 / 10th of January 2023, Feeding and HACCP
- **ISO 11608-1:2022 / ISO 11608-1:2014 / ISO/FDIS 1008-1:2021** Needle based injection systems for medical use – Requirements and test methods
- TrackWise

Knowledge in

- **CLSI guideline EP17-A2** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
- **ASTM D4169-22** Standard Practice for Performance Testing of Shipping Containers and Systems
- **EN ISO 23640:2015** In vitro-diagnostics of Medical Devices
- **ISO 10993-1** Biological Evaluation of Medical Devices
- **ISO 14971:2019** Medical Devices – Application of Risk Management to Medical Devices
- **21CFR820.20(f)** Code of Federal Regulations
- **FDA-2020-D-0957** Design Control – Guidance for Medical Device Manufactures

Personal Characteristics

Well structured, with a strategic approach on complicated tasks. Strong coordination skills, with an eye for details.
Focused and goal-oriented mindset combined with a positive and holistic and inclusive approach, to ensure that chosen solutions include the best solution for stakeholders.

In her freetime, Stine is spending time with the family and working on her family farm, and breeding and training horses.

Over the last 16 years my main focus has been on measurement, analysis and improvement in various job roles.

Variation from documentation and validation of test methods in laboratories as well as product release, validation and recalibration of equipment and documentation for QMS and audits relating.

Over the last years the focus has transitioned to control of nonconforming products in relations to MDR, MDSAP and ISO

13485 with branches to design control, change control, risk management, design verification and revalidation and recalibration of machines and equipment.

References

Mediologic A/S (2024 – present)

Senior Consultant
Consulting for Medical Device Companies

Freelance Consultant (1 year)
Consulting for Medical Device and Medico Companies, e.g. Design control and technical file documentation for clinical trial projects.
HACCP and traceability documentation for compliance.

Novozymes (7 years)
Laboratory Technical Staff
Testing and release of product, costumer auditing and development of laboratory testing procedures.

Convatec (3,5 years)

Quality Assurance Engineer, NC/CAPA Lead

Control of nonconforming product, RCA and CAPA, internal auditing and costumer/notified body auditing, Post market action and complaint investigations. Stop Shipment evaluation and Quality System implementations.

Chr. Hansen (5 years)
Laboratory Technical Staff, Equipment responsible

Testing and release of product, responsible for documentation, FDA and costumer audit preparations for technical equipment. Implementation, installation and verification of laboratory equipment.