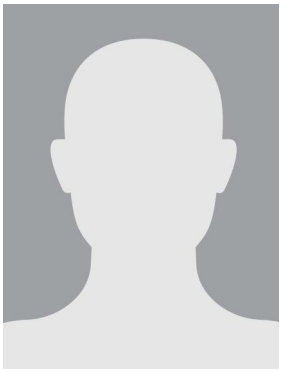

NN Female
Umeå university, Lund university

QA / RA expert, Medical Device

ID1004

Direct (+46)
nn@medicologic.com

PARTNER

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

- Project management
- Quality management
- Management Representative
- Gap Analyses
- Quality systems implementation
- Design Control
- Design Dossiers and Technical File for CE marking
- Preparation and submission of int.l registrations for Class IIa, IIb and Class III medical devices and for IVDs.
- Trained Lead auditor; supplier audits, internal audits
- Risk Management, Complaints, CAPAs
- Software Validation
- Change Control
- Vigilance
- FSCAs

Key results

- Management of QA and RA functions in several companies.
- Certification (ISO 13485) of a Swedish site of an international company.
- All development projects delivered on, or before schedule, as project manager at a large Swedish company
- Took one company from the state of a FDA warning letter and US import detention to a successful FDA inspection resulting in no observation in one year.
- Several international approvals
- Compiled Technical Files for an entire product portfolio for a large Swedish company.

Regulations/Standards/Guidance

Extensive knowledge in:

- **EU Directives:** Medical Device Directive MDD 93/42/EC, in vitro diagnostic directive IVDD 98/79/EC
- **EU regulations:** Medical device regulation 2017/245, In vitro diagnostic medical devices 2017/246
- **FDA regulations:** CFR 21 Part 820, Part 11, Part 803, Part 806
- **EU harmonized/internationally recognized standards:** ISO 13485, MDSAP, ISO 14971
- **MEDDEV guidance:** 2.12/1

Personal Characteristics

She is a dedicated person who strongly believes that every problem has (at least) one smart solution. She enjoys working in teams.

She has extensive experience in Quality Assurance and Regulatory Affairs, both as manager and hands on.

She spends her free time with family and friends, listening to music, reading, yoga and fitness in general.

References

MEDICOLOGIC A/S

Senior QA/RA expert
Consulting for Medical Device companies, e.g. transition to MDR.

HEMOCUE AB (4 years)
Regulatory manager/regulatory expert
RA advice for development projects, regulatory strategies, complaints assessment, review of design changes, compilation and updates of Technical Files.
Vigilance, FSCA. Preparation and submission of files for registration. Updates of procedures, internal audits.

OCCLUTECH INTERNATIONAL AB (2 years)
Director Quality Management, Regulatory Affairs
Overall responsibility for the quality system, certification (ISO 13485) of a new site, implementation of procedures, internal audits, release of products to market. Regulatory strategies, compilation and submissions of international registrations. Responsible for contacts with competent authorities. Management representative.

BIORA AB (2,5 years)

Director Quality Management
Overall responsibility for the quality system. Implementation of new and changed procedures, assessment of design changes, CAPAs, etc. Management representative.

RADIOMETER ApS (1,5 years)

Quality Assurance Manager
Responsible for quality assurance in development projects, review of design changes, process validation, internal and supplier audits. Implemented a new project model for product development.

ERICSSON TECHNOLOGY LICENSING (2 years)

Project manager
Management of software projects; planning, budget, schedules. Update of the project management process. Quality system auditor for the company's accredited Bluetooth Qualification facility.

GAMBRO AB (19 years)

V&V engineer, V&V manager, Development manager, QA Assurance manager
Testing and development of test methods, release of new and changed products for production, responsible for Design Control. Development of a global project model, compilation of Technical Files. Overall responsibility for the quality system, complaints handling, internal and supplier audits.
Management representative.