



**NN**  
 B.Sc. Clinical Chemistry

Senior Consultant  
 Pharma Compliance and Operations

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# medicologic®

Medical Device Development

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## Competences

- Quality Management
- cGMP
- Regulatory affairs
- Project Management
- Risk Management
- Medical Device
- People leadership and management
- Process mapping
- Performance management
- Change Management

## Standards

- cGMP
- MDR 2017/645
- MDD 93/42/EC
- ISO13485
- ISO14971
- ISO11607
- FDA regulation [CFR part 820]

## References

### Medicologic A/S (present)

Senior consultant Pharma Compliance and Operations

### Novo Nordisk

Currently consulting to ensure quality compliance.

### ALK-Abello

Director of Production, IVBDD, Manager of Aseptic Production  
 Manager Quality Control, Director Quality Control

### LEO Pharma:

Project Management in regulatory Affairs, Intermediate QA  
 person writing and implementing an updated QMS.  
 Senior Manager RA, Planning & Processes, LEO Pharma

### Novo Nordisk

Associate Manager and cLEAN® Partner, Novo Nordisk  
 Senior cLEAN® consultant, cLEAN®Office, Novo Nordisk

**Phillips Medisize** Project Manager for development and commercializing a medical device towards the US market. The project team is 25-50 people all involved in different roles during the project.

## Key results

Long experience from Pharma and MD quality and regulatory affairs.

**cGMP:** Key person during audits from e.g. FDA. Maintenance of QMS content and structure. Training of people.

**QMS and Technical File** writing and updating QMS for LEO Pharma to fit a changed organization. Focus on quality and change management, NCs and CAPAs.

**Project Management** as responsible person for implementation of large projects. E.g., construction and implementation of a pharmaceutical production site. Or as member of top management responsible for the PMO in Biogen

**Change Management** leading people towards major changes with success e.g., Implementation of LEAN leadership in Novo Nordisk

**Significant leadership skills** leading teams and departments over the years in both quality control, aseptic and in-vitro production.

## Personal Characteristics

She is a competent leader, who takes responsibility for the people and the tasks from bottom to top.

She is a go-doer and has a no-nonsense attitude always finding a positive and constructive solution to a problem.

Susanne is an experienced consultant and is highly appreciated by her clients.

Privately She enjoys reading books, watching films and theatre, listening to concerts and records, and off course being a grandmother having fun with both dolls and LEGO.

My responsibility is to keep the project on track financially, and according to the overall milestones. Project management supporting engineering and product development in combination with labelling and documentation of a clinical trial variant for several markets.

**Glostrup Apotek Magistrel Production** Project Manager and responsible for coordination with the project to ensure proper implementation of the production processes and installations.

**Price Invena** QA manager with overall responsibility for production, release of products and QMS. 13485:2016 certification has been received and MDR compliance in scope.

**Biogen** Associate Director Manufacturing, Biogen Site Leadership Team member, responsible for PMO Research assistant to Professor Klaus Øllgaard, RH, Professor Sixtus Thorsen, KKHH and Bio-analyst, Clinical Chemistry, Hvidovre Hospital.