Susanne Thyssen Rasmussen
B.Sc. Clinical Chemistry

Senior Consultant
Pharma Compliance and Operations

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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

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.

Standards

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

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.

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.

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.