DAHLFELTCONSULTING

SENIOR CONSULTANT CV WITHIN RISK, QA, AUDIT

Name	Lene Bastholm
Nationality	Danish
Gender	Female
Domicile	Denmark

CONTACT INFORMATION

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LENE BASTHOLM - CURRICULUM VITAE

PERSONAL LETTER

Lene has worked as a leader in QA for medical devices through the last 7 years, mainly being responsible for risk management, validations (process validations as well as software validation), CAPA processes as well as audit management. Throughout her career she has worked both with pharmaceuticals as well as with medical devices and due to that Lene has an understanding of both areas. She is motivated by making a difference – in processes, quality, in audits and in the leadership of staff.

STRENGTHS

- Excellent insight and experience in all phases in Medical development and overall compliance in combination with Risk management and the validation process afterwards to be in compliance

EXPERTISE

- Risk Management, ISO 14971
- Medical Device Manufacturing, ISO 13485
- Medical Device Regulation (EU MDR)
- Audit management front room and back room
- GMP annex 13

IT SKILLS

- MS Office
- TrackWise
- TrackWise Digital

EDUCATION AND DEGREES

1990-1996	MSC Pharm, Royal Danish School of Pharmacy (Now part of University of Copenhagen)

Master thesis at: École Supérieure de physique et chemie industrielles, Paris, France

CERTIFICATIONS AND COURSES

2020	Sterility Assurance Seminar, Sterigenics
2019	EU Medical Device Regulation, Pharma 4 ever Risk Management ISO 14971, Pharma 4 ever
2017	Risk Management for medical devices, three circles
2016	Leadership, Dansk industry, 3 modules total 9 days ISO 13485, Bureau Veritas - ECA – GMP for medical devices

2015	GMP refresher, Pharmacon	
2014	GMP refresher, Industri Farmaceut foreningen	
2013	Insights discovery	
2011-2012	Management at Takeda – 3 modules total 9 days, Learn to lead.	
2010	DS/EN ISO 9001:2008 Lead auditor training, ISO Consult Lean introduction in Takeda, Valcon	

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent
German	Understanding and basic speaking	
French	Understanding and basic speaking	

PROFESSIONAL BACKGROUND

Nov. 2023 - Present

DahlfeltConsulting | Senior Consultant

Consultancy tasks within Risk management and all kind of QA and QC activities within Pharma and medical Device.

Feb. 2023 – Oct. 2023

BK Medical a GE Healthcare Company | Director QA

Responsible for Quality in Herlev site, covering production and R&D

Management Representative including being responsible for Management Review for the site.

Person Responsible for Regulatory Compliance (PRRC) for site

Responsible for Quality Management System in BK medical, Herlev

Responsible for NC& CAPA process including implementation of GE Healthcare tools and processes.

Responsible for internal audit processes and execution.

Overall responsible for receiving Notified body MDSAP, MDR and FDA audits. Running Front Room.

Working with integration of GE Healthcare processes and tools in BK Medical

Responsible for collaboration with Notified body on audits and audit follow-up, including audits of subsuppliers.

Jun. 2019 – Jan. 2023

Unomedical a ConvaTec company | Associate Director Quality Compliance Engineering

Responsible for Risk Management in Infusion Care/Unomedical globally. Training of staff in Risk
Management – both ISO 14971 and internal procedures. Review and approval of all risk
management documents (Process, Use and Design FMEcAs, Risk Management Plans, Risk Management reports). Conducting Product Risk review of all product families.

Building and adjusting processes and procedures covering Infusion Care globally within Risk Management ensuring that processes were in line with ISO14971 and EUMDR requirements and adequately covered the products and production processes.
Ensuring validation processes and procedure to meet the EU MDR and FDA requirements. Review and approval of validation documents for manufacturing processes and equipment.
Front and Back Room responsible in Notified body and authority audits and inspections.

Updating documentation and processes to comply with EU MDR.

MDR and MDSAP audits without NCs within my area of responsibility.

Overseeing updates of documentation to comply with EU MDR.

Responsible for development, hiring and firing of staff.

May. 2016 – Jun. 2019

Unomedical a ConvaTec company | Product Quality Engineering

Responsible for Risk Management in Infusion Care/Unomedical globally. Building risk management processes.
Training of staff in Risk Management – both ISO 14971 and internal procedures.
Review and approval of all risk management documents (Process, Use and Design FMEcAs).
Establish Product Risk review of all product families.
Approval of quality documents related to in R&D, Change and Capacity projects.
Review and approval of EO sterilization validation documents. Training QC in review of sterilization batch documentation.
Evaluation of sterilization batch documentation when errors happened during processing.
Ensuring validation processes and procedure to meet the EU MDD and FDA requirements.
Review and approval of validation documents for manufacturing processes and equipment
Participating in ISO 13485, MDSAP, FDA, and costumer audits both as auditee and as backroom responsible.

Sep. 2014 – Apr. 2016

Ferring Pharmaceuticals | Associate Director IMP

Participation in cross organizational development of processes.
Responsible for internal IRT (Interactive Response Technology) project that included development of internal and cross organizational processes and procedures.
System owner for Clinicopia (IT system).
Receiving inspection from authorities.
Selection and audit of suppliers.

Apr. 2011 – Aug. 2014

Takeda Pharma (former Nycomed) | Head of Clinical Trial Supply project management

Responsible for a department that was partly located in Germany and partly in Denmark.

Part of CMC center Roskilde management team.

A part of Global Clinical Trial Supply Chain Management Team (global leadership team, members from USA, Japan, and EU).

Development of strategy, vision and mission.

Member of IVRS (Interactive Voice Response System) steering committee.

Responsible for suppliers (all packaging and distribution tasks were outsourced).

Responsible for staff.

Motivation of staff to ensure transfer and finalization of tasks during closure of department and site.

Receive audits from authorities.

Participate in selection and audit of suppliers.

Aug. 2004 - Mar. 2011

Nycomed | Clinical Trial Supply manager

CTS responsible for GMP/GCP interfaces.

Responsible for packaging, labeling, and distribution tasks, in-house as well as outsourced tasks.

Responsible for packaging design, blinding, and distribution strategies for studies in EU, US, CIS, Asia, and Latin America.

Participate in Investigator meetings to train trail personnel.

Overall responsible for IVRS/IWRS systems in the company.

Delivery of input for randomization strategy and setup of kit lists.

Participation in authority inspections.

Project responsible (input for CMC and clinical teams).

Core Project Team member.

SOP approver.

Responsible for alignment of processes between Germany and Denmark.

Okt. 2003 – Jul. 2004

Novo Nordisk | Clinical Trial Supplier coordinator

Okt. 1996 – Sept. 2003

H. Lundbeck | Team leader and trial supply coordinator