DAHLFELTCONSULTING

CONSULTANT WITHIN QA, QC, CLINICAL, PROJECT MANAGEMENT

Name	Pernille Dissing Sørensen
Nationality	Danish
Gender	Female
Domicile	Denmark

CONTACT INFORMATION

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PERNILLE DISSING SØRENSEN - *CURRICULUM VITAE*

PERSONAL LETTER

Pernille is a Senior Life Science Consultant with extensive project management and leadership experience from the Pharmaceutical, Biotech and Medical Device Industry in Denmark, EU and US.

Pernille has more than 30 years of experience with team and department lead, project management in various business areas, heading cross functional and multidisciplinary teams, responsible for pipeline products from concept stage, product development, clinical trials and safety assessments, to manufacturing, global registration and marketing.

She is highly experienced within the fields of quality control with key competencies including establishment and management of classified laboratories, development and validation of analytical methods, equipment qualification, tech transfer and production support. Pernille also has significant experience with quality assurance procedures, regulatory matters and throughout her career she has gained extensive experience and insights to a portfolio of IT systems.

STRENGTHS

Pernille is creative, innovative, solution oriented and flexible by nature. She has an analytical and structured approach to new projects and challenges; she always keeps an open mind to the task with significant cooperation, communication and interpersonal skills.

EXPERTISE

- Leadership and Project management in Pharmaceutical, Biotech and Medical Device/Combination Product Industry
- Establishment and management of classified laboratories
- Product and process development
- IT, Data handling, software validation, Part11, GAMP5 compliance. Statistics.
- *In vitro* diagnostics
- Cell technology, cell therapy, biologicals, API, liquid formulations
- Development and validation of analytical methods, equipment qualification
- Tech transfer, process optimisation and scale-up, production support
- Risk management,
- Raw material qualification, Supplier management
- Batch review, product release, deviations, CAPA, CR
- Clinical trials, efficacy and safety studies, toxicological evaluations, stability studies, pharmacovigilance
- Compliance, GMP regulations (FDA, EMA, ROW), ICH Q2 (R1) ISO guidelines etc

- Medical device regulations, MDR 2020, CE marking, 510k
- Medical writing: reports, reviews, peer reviewed publications, patents, applications, quality and clinical material, SOPś.

- Microsoft Office | Outlook | Excel | Word | Power Point
- Data Bases (Registrations database CDM and MDM)
- SharePoint (Administrator)
- Document Control System (Agile)
- Lotus Note
- Data Base (SAP)
- Vault QualityDocs
- NovoDocs
- NovoGlow
- ISOtrain
- TrackWise

EDUCATION AND DEGREES

1988 - 1992	University of Copenhagen PhD, Cellular/Molecular Biology
1978 - 1986	University of Copenhagen MSc, Biochemistry

SELECTED CERTIFICATIONS AND COURSES

2013	Project Management	Mannaz
2013	Lean Innovation	Mannaz
2012	GMP	Origio
2012	Excel	Origio
2012	Project Management	Connector
2009	Risk Management	Origio
2008	Biological Evaluation	Medico Industrien

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent
Scandinavian		Medium
German		To some extend

PROFESSIONAL BACKGROUND

Apr. 2023 - Present

DahlfeltConsulting | Senior Consultant

Supporting our customers with extensive insights & knowledge from Pharma, Medical Device & IVDR

2023 - Present

FUJIFILM Diosynth Biotechnologies, PQA, Hillerød | via DahlfeltConsulting

PQA Lead QC, establishment of QC facility

2023-2023

ALK, Hørsholm | via DahlfeltConsulting

Senior Project Consultant

Project: Impact of autoclaving of Jext® drug product cartridges on Jext® adrenaline auto-injector functionality, impact on dose accuracy

2023-2023

Contura, Måløv | via GMP Konsulenterne

Senior Project Consultant

QC support, optimising endotoxin analyses, suitability test of an analytical method, Kinetic chromogenic endotoxin test of Bulkamid (polyacrylamide hydrogel)

2023 - 2023

Novo Nordisk, Device Manufacturing Development, Hillerød | via Rambøll

Senior Project Manager, Senior Consultant

planning and coordinating packaging line delivery to Novo Nordisk globally,

Development and upscaling of prephase concept.

2022 - 2022

Cooper Surgical (DK) R&D – Product Engineering | via GMP konsulenterne

Senior Project Consultant

Stability studies of human IVF products

Support of product registration (China)

Update to MDR

2022 - 2022

ARTSMedia (DK) | via Nordic BioConsulting

Senior Project Consultant

QMS support

Preparation of clinical evaluation documentation

Global registrations of human IVF products

2021 - 2022

Xellia Pharmaceuticals (DK), Final handling | via Kuatro Group Aps

Senior Project Consultant

Environmental Monitoring

Quality support

2021 - 2021

Radiometer Medical (DK) | via GMPro Partners

Senior Project Consultant
Design Control (blood gas analyzers)
Stability testing
Updating documentation to MDR 2020

2020 - 2021
AGC Biologics (DK), Mammalian Manufacturing | via GMPro Partners Aps
Senior Project Consultant
Bioassay specialist (PCR,ELISA etc)
QC/QA support, deviationsa, CR,CAPA
Process transfer and process validation
Process risk management

2019 - 2019
Arctiko (DK) | via AlfaNordic
Senior Project Consultant
Refrigerators/freezers for medical supplies
Regulatory support and guidance,
Upgrading to MDR 2020

2019 - 2019
Valcon (DK)/Thermofisher (SE) | via AlfaNordic
Senior Project Consultant
Regulatory support
Global labelling of immunodiagnostic devices , Label design

2019 - 2019
Scanpharm (DK) | via AlfaNordic
Senior Project Consultant
Implementation of GMP, compliance advisor for quality departments,
Preparation of GMP documentation, ICH Q2 conformance, pharmacopeia standards,
Preparation and validation of SOPś, QC analytical methods, HPLC equipment.

2018 – 2019
Croda Healtcare (DK) | via AlfaNordic A/S
Senior Project Consultant
Environmental monitoring
Qualification of QC and manufacturing equipment (Zetasizers, Air samplers, HPLC etc), filling lines support
Validation of QC analysis for raw material, in-process and finished products.
Software validation and compliance

2017 – 2018
Spectrum Therapeutics (DK) | via AlfaNordic A/S

Senior Project Consultant

Documentation and application to the Danish Medical Agency for approval to culture and handle medical cannabis.

Handling of license to import of cannabis and seedlings from Canada

2017 - 2017

FUJIFILM Diosynth Biotechnologies (DK) | via AlfaNordic A/S

Senior Project Consultant

Batch review/release of finished products, QP

Preparation of templates and SOPs

QA support,Complaints handling, deviations and batch review, CAPA

2016 - 2017

BASF (UK) | via Oxford Global Resources

Senior Project Consultant

Development of supplier quality management system, QC risk management, contract laboratories and service suppliers

Development of quality risk management systems

2016 -2016

Polpharma (PL) | via Oxford Global Resources

Senior Project Consultant

Establishment of QC laboratory and implementation of GMP system.

Method/equipment development, validation, qualification.

Transfer of analytical methods, RD to QC.

2016 - Present

Nordic BioConsulting | Owner

Independent Life Science consultancy within qualification, validation, compliance and project management.

2015 - 2016

Pharmacosmos A/S (DK)

Manager, Cryopreservation Business Development and Sales

Development of cryopreservation products for cells, primarily immunocells for cancer therapy, clinical studies, CAR-T. Pre-clinical studies, stability studies and shelflife determinations. Preparation of quality documentation, business development, global marketing and sales activities related to cryopreservation activities.

2014 - 2015

Nordic StemMed

Partner, CSO

Development of serum free media for stem cells, stem cell therapy, pre-clinical studies, safety studies. Cardiovascular diseases.

Business development

2004 – 2013

CooperSurgical Fertility (DK/US)

Head of Department, Lab Manager, Project Manager, Senior Scientist

Development and production of Medical Device and combination products. Development of serum free products for human IVF, stemcell culture and stem cell therapy. Clinical trials, safety assessment and safety studies, tox evaluations, Product approvals, global marketing activities, pharmacovigilance. CE marking, 510(k), Medical device regulations, MDR2020, UDI, EU and global labelling Development and implementation of bioassays for QC testing and product release. Manufacturing support, aseptic filling. QA procedures and risk management.

1991 – 2004

Bioneer A/S (DK)

Senior Scientist, Project Manager

Design and validation of analytical methods for DNA/RNA/immune based diagnostics for human diseases. Development of novel technology for retrovirus characterization. Identification of a retrovirus associated with development of MS. Development of neural stem cell culture and differentiation conditions. Development of encapsulated cell biodelivery for AD.

PUBLICATIONS

27 peer reviewed papers/patents, for details see LinkedIn profile LINK