

DAHLFELTCONSULTING

CONSULTANT WITHIN VALIDATION, QA, STERILISATION, ASEPTIC AND PROJECT MANAGEMENT

CONTACT INFORMATION

Name Søren Rooed Pedersen
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Gender Male
Domicile Denmark

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SØREN ROOED PEDERSEN - CURRICULUM VITAE

PERSONAL LETTER

Søren Rooed Pedersen naturally seeks constructive and sustainable solutions with humor and offbeat ideas. Søren interest in other people and new professional subjects is big. To get the best out of other colleagues is something he gives a high priority and it comes very naturally to him.

He has worked within GMP for many years, furthermore as a mentor, communicator and project manager. A big part of his work life is about good business with correct quality, i.e., the right solution.

Søren has also worked with management of project documentation. The GMP mindset is in his DNA. Looking at things in a quality and business context has become more interesting for him over the years.

STRENGTHS

- ❖ URS, ERS, IRS, FMEA, including but not limited to IQ documentation
- ❖ Project management specialist
- ❖ Test documentation and archivation
- ❖ Deviation reports
- ❖ Validation
- ❖ FMECA
- ❖ Bulk production, drying, mixing of dry products
- ❖ Cleaning validation
- ❖ Scrum Master
- ❖ Agile lean expert
- ❖ Drying sterilization of equipment
- ❖ Aseptic production

EXPERTISE

- ❖ Project management in regulated areas
- ❖ GMP Specialist
- ❖ Overall Pharma specialist
- ❖ Pragmatic work attitude
- ❖ Risk management FMEA/FMECA

❖ Medtech General knowledge ISO13485

IT SKILLS

- ❖ Scrum master
- ❖ Vault QualityDocs,
- ❖ novoDocs
- ❖ novoGlow
- ❖ ISOtrain
- ❖ Microsoft Office
- ❖ TrackWise
- ❖ Microsoft Project
- ❖ Microsoft Visio and more
- ❖ SPL (systemic problem solving in deviation) incl. A3, C3 and fishbone methodology

EDUCATION AND DEGREES

- 2018 Certified Scrum Master, Agile Lean House
- 2012 Project manager and Lean master, CPH Business school
- 2000 Chemistry, Technical college Hillerød
- 1986 Pharmaconomist , Pharmacon

CERTIFICATIONS AND COURSES

- 2018 Certified Scrum Master Scrum Alliance, Agile Lean House A/S
- 2015 Risk Management training, FMEA AN
- 2015 Medical Devices training AN
- 2014 Project Management training CBH Nord. Lyngby
- 2014 GMP updating course Pharmakon
- 2009 Cell culturing theory and practice seminars Tecan Nordic AB, Sweden
- 2008 International sales training Weiss, Merignac. France
- 2008 Product training, Martin Christ. Osterode, Germany
- 2008 Product training, Waldner Labor Waldner, Wangen, Germany
- 2005 Protein chemistry, basic CVU Øresund
- 2005 Tangential flow filtration Colly Company A/S
- 2005 Excel basic ALK- Abelló A/S
- 2005 Weight seminar Saab technologies
- 2004 Scale up, design and optimization of the tangential flow filtration Millipore
- 2003 API-Practice (Annex 18) Pharmakon, Hillerød
- 2002 GMP – Basic Pharmakon, Hillerød

2001	GMP – Basic (Clean room)	Pharmakon, Hillerød
2001	Filtration course	Colly Company A/S
2001	Integrity testing certification course	Millipore A/S
2000	GMP for aseptic production	Pharmakon, Hillerød
2000	Danish environmental Protection Agency	Alttox A/S
2000	Seminar: The working environment	LO FTF AC
2000	Prism inventory control	Novo Nordisk A/S
1997	Effective training	DSB
1996	Integrity testing certification course	Millipore A/S
1994	Training techniques	Riis Consulting
1989	Basis management.1.	Danish employers' association

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent

PROFESSIONAL BACKGROUND

2023 - Present

[DahlfeltConsulting | Senior Consultant](#)

Senior Consultant Project manager, Validation, QA, Aseptic/API, Risk manager, QA, Auditor

2022 – 2023 June

[CPHPharma Aps | Senior Consultant](#)

Posted at Fujifilm Diosynth, Site Hillerød. Clean Utilities as a CQV engineer.

∴ Handling of deviation and punches during FAT, SAT

2020 - 2021

[CompanRungsted School | Substitute school teacher](#)

2012 - 2020

[AlfaNordic \(now part of Niras\) | Senior Consultant](#)

2019 – 2020

On sick leave

2016-2018

Posted at Chr. Hansen, Site Roskilde. Global Engineering

Tasks included:

∴ Participant and preparation in FMEA, URS, ERS, IRS and other document for DQ.

∴ Management of all project documentation for Line 4 project incl. test documentation and archivation.

2015-2016

Posted at Novo Nordisk, IM1 in production support department

Tasks included:

- ∴ Preparation of deviation reports, (NC and CR) in Novoglow.
- ∴ Completed SPL (systemic problem solving) in regard to deviations (A3, C3, and fish bone analysis).
- ∴ Participant in projects regarding several QAP points.

2015-2015

Posted at SSI in production support department

- ∴ Participant in projects regarding FMECA for filling line.

2015-2015

Posted at Bavarian Nordic, KV in technical service department

Task included:

- ∴ Review and preparation of URS, reports and protocols of initial validation on -50C freeze containers.
- ∴ Project manager for implement Bio-reactors.

2014-2015

3Posted at Novo Nordisk, GE in production support department

Task included:

- ∴ Preparation of deviation reports. (NC-1), NC-3 corrective actions.
- ∴ Participant in projects regarding several QAP points.

2012-2014

Posted at Novo Nordisk, KA in washing support department

Tasks included:

- ∴ Preparation of deviation reports. (NC-1), NC-3 corrective actions, DO-teaching, and SOP-updates).
- ∴ Conduction of strategy meetings
- ∴ Completed SPL (systemic problem solving) in regard to deviations (A3, C3, and fish bone analysis).
- ∴ Participant in projects regarding several QAP points.
- ∴ Initiated GAP analysis of compliance deviations, E-logs, and documentation.
- ∴ Review of CM (washing curves on container and pipes)
- ∴ Statistics regarding deviations and E-logs

2009 – 2012

[Alectia \(Birch & Krogboe\) | Senior Consultant](#)

Drying and Sterilization equipment - The oldest consultant engineer company in Denmark. Employed in the Process Solution department.

Conducted tasks like:

- ❖ Design of a bulk production. Drying and mixing equipment for production of materials used in diesel engines
- ❖ Improvement of handling of powder for production in fermenter
- ❖ Project manager on SWC (the Smartest Way Concept), an internal project in preparation for selling competences and engineer services to newly established biotech companies and other small research-based companies
- ❖ Preparation of URS for autoclave and washing machines in regard to projects on sterile centres of hospitals
- ❖ Review and preparation of reports and protocols of initial validation on pipes and container systems
- ❖ Health checks of supplies (water, compressed air, and containers) to a food factory
- ❖ Preparation of network strategy
- ❖ Various minor development projects for the universities
- ❖ Preparation of various propositions and project descriptions

2007 – 2008

[Buch & Holm](#) | Product Manager

Responsible of project related sale of freeze-dryer, autoclave, drying, sterilization equipment, and laboratory equipment, etc.:

- ❖ Training of specialist and technicians in equipment and principles
- ❖ Design of various laboratories
- ❖ Consultancy of costumers regarding requirements and design of equipment and facilities
- ❖ Preparation of marketing strategy
- ❖ Supplier relationship management
- ❖ Preparation of various costumer propositions

1999 – 2007

[ALK-Abello](#) | Development technician

Conducted tasks like:

- ❖ Initiation of new pilot facility. Extracted water samples, particle detection and swab samples
- ❖ Bench Scale and Lab Scale production of API
- ❖ Development of spray cooling/drying principle for API granules
- ❖ Passing of technology to bulk production of semi-automated API production
- ❖ Teaching of swap technique and single analysis
- ❖ Conduction of IQ, OQ and PQ on washing machines, freeze-dryers and production plants
- ❖ Preparation of various SOPs

1992 – 1999

[Novo Nordisk A/S 2H Bagsværd](#) | Production technician

Conducted tasks like:

- ❖ Production of insulin bulk
- ❖ Teaching in aseptic working techniques
- ❖ Supervisor of the filling machine
- ❖ Preparation of various SOPs

1986 – 1992

[Alpharma A/S](#) | Team Leader Production store

Conducted tasks like:

- ❖ Day-to-day management of raw material storage room with 10-15 employees
- ❖ Identification of incoming goods
- ❖ Storage management and shipping
- ❖ Account of alcohol and psychedelic drugs
- ❖ Control of outgoing goods for production
- ❖ Preparation of various SOPs

DAHLFELTCONSULTING

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