

# DAHLFELTCONSULTING

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Gender Male  
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## Personal Letter

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Søren Roed Pedersen naturally seeks constructive and sustainable solutions with humor and offbeat ideas. Søren's 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 communicator, (project manager). To look at things in a quality- and business-like context has become increasingly interesting over the years, as a big part of his work life is about good business with correct quality, i.e. the right solution.

## Strengths:

- URS, ERS, IRS, FMEA, including but not limited to IQ documentation
- Project management
- Test documentation and archive
- Deviation reports
- FMECA
- Bulk production, drying, mixing of dry products
- Cleaning validation
- Scrum Master
- Agile lean expert
- Drying sterilization of equipments
- Aseptic production
- CAPA / Non Conformity

## Expertise:

- GMP Specialist
- Overall pharma knowledge
- Risk management FMECA
- Medtech General knowledge ISO13485

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## 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

## Professional background

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DahlfeltConsulting ApS

Apr 2022 – Current

Senior Consultant Project leader, Automation lead, Lean, commissioning

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Rungsted School

2020 - 2022

Freelance School teacher, substitute

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AlfaNordic, Now part of Niras

2012 - 2020

Senior Consultant

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.

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- Project manager for implement Bio-reactors.

2014-2015 Posted 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.
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Alectia (Birch & Krogboe)

2009 – 2012

*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.
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Buch & Holm

2007 – 2008

*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.

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- Preparation of marketing strategy.
- Supplier relationship management

Preparation of various customer propositions.

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ALK-Abello  
1999 – 2007  
*Development technician*

Conducted tasks like:

- Initiation of a 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 swab technique and single analysis.
  - Conduction of IQ, OQ, and PQ on washing machines, freeze-dryers, and production plants.
  - Preparation of various SOPs.
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Novo Nordisk A/S 2H Bagsværd  
1992 – 1999  
*Production technician*

Conducted tasks like:

- Production of insulin bulk.
  - Teaching in aseptic working techniques.
  - Supervisor of the filling machine.
  - Preparation of various SOPs.
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Alpharma A/S  
1986 – 1992  
*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.
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## Language skills

## Level

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English – Written and spoken

Fluent

Danish Native– Written and spoken

Fluent

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## Education and degrees

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1986, Pharmaconomist , Pharmacon

2000, Chemistry, Technical college Hilleroed

2012, Project manager and Lean master, CPH Business school

2018 Certified Scrum Master, Agile Lean House

## Certifications and courses

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Year	Courses	Place
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

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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	Altox 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