

Dahlfelt Consulting ApS

Name: Steen Ammentorp

Education: BSc. Electrical. Eng. Copenhagen Engineering University 1992
apprenticeship in Kinovox, manufacturer of professional tape recorders

Year of birth: 1965

Languages: Danish, English, Scandinavian, limited German and French

Profile:

Steen is a flexible "hands on" engineer with a solution minded and creative approach to any assignment. A wide foundation in IT, automation electronics and mechanics are the tools that has enabled Steen to solve a wide range of challenges in pharma as well as other industries.

Energy, positive drive with and understanding of the project objectives and a full awareness of the colleagues surrounding with a strong focus to keep the project on right track and the willing to do what it takes to keep a deadline. Willing to take leadership but just as Pleased not to.

Flexible in work hours and location.

Special Fields of Competences:

- IT
- GxP IT / GAMP
- Proces- and automation validation
- Program analyse
- Project management
- Planning
- Design requirements, URS, DQ
- dokumentation: FS, FDS, SDS,
- Validation, IQ, OQ,
- CR
- CIP/SIP

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- Packing
- Filing
- Autoclave
- Aseptic environment
- RFID
- Embedded systems
- Medical device
- MDR
- Technical writer
- RA activities as assessments and release to market
- RA involvement in sustain projects

Selected Projects

QA, RA and technical writer

Update documentation on medical devices to comply with MDR, gap analysis of applied standards, participate in daily RA department functions, such as release programs and assessment of changes in devices.

Review of risk analysis as well.

GN Hearing A/S 2021-2022

Therma logger

Development of world's smallest thermal logger for usage in heat study in GxP environment.

URS/Design/HW/SW design/ mechanical design of parts manufactured in 3D SLA machines, and mechanical parts for tools manufactured using 3D FDM print all designs in Solidworks.

Validation of system, and design of inhouse calibration.

Thermalogger.com A/S, 2018-2020

Autoclave validation

OQ validation of autoclave at aseptic filling plant. Very educational validation process as machines delivered was far from compliance with requirements as we entered OQ which led to impressive amount of VNC's and changes which made the validation remarkable excessive and complicated.

Line A/S 2017-2018

Packing line

IT and automation lead of full packing line with first stage of packing a blister machine.

Compose URS for SCADA system, adjust IT URS for complete packing line

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consisting of: IT requirements including 21CFR part11, serialization, vision system, and inline printer system.

Part of team writing Test steps for the IT validation as well of SCADA system, serialisation, inline printers and vision system.

nne pharmaplan A/S, 2016-2017

Aseptic filling facility

OQ preparation and Validation SCADA and underlying Siemens PLC system for the Bosch 300 vials/Min. filling line. Washer, dryer/tunnel and filling. During the time at this factory I was also involved in autoclave upgrade, Pas-X upgrade.

nne pharmaplan A/S, 2014-2016

Hygienic status module

Compose URS for hygienic status module.

Analysis of entire plant production to map all systems into one generic status module.

Design module and Implementation into all systems and validation ending by firm handover.

/URS/Analysis/Design/installation/qualification and handover.

nne pharmaplan A/S, 2012-2014

Printing solutions

Development of inkjet print technology for printing on material with low surface tension. Followed by mechanical modification of standard machinery to handle the technology.

Sailprint.eu, 2010-2012

Employment

2022-	Dahlfelt Consulting ApS, QA, RA, Validation, Technical Writer
2021- 2022	External consultant Sigma connectivity ApS
2018- 2020	Thermalogger.com
2012 – 2018	External consultant NNE (former NNE pharmaplan) assigned to NN
2010 – 2012	Sailprint.eu Special printing solutions
2004 - 2010	CODECO/LQE Public library automation
2001 - 2004	DDI Global/SSK-Europe/Simmtech/ Qualitech Database design (Evesham UK)
2000 - 2001	Xerox

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1995 – 2000 Tektronix
1993 – 1995 Own business design and manufacture electronics and consultant assignments
1992 – 1993 Dico GmbH (Nürnberg)