

DAHLFELTCONSULTING

SENIOR CONSULTANT WITHIN PROJECT MANAGEMENT
IT, PAS-X, MES, SCADA, SAP, EWM, LOGISTIC, SUPPLY CHAIN

CONTACT INFORMATION

Name Bjarne Jensen
Nationality Danish
Gender Male
Domicile Denmark

Torben Dahlfelt | CEO & owner
+ 45 3170 0881
torben@dahlfeltconsulting.com
www.DahlfeltConsulting.com

BJARNE JENSEN - CURRICULUM VITAE

PERSONAL LETTER

Bjarne is a highly skilled Project manager with a deep insight and extended understanding of complex IT systems.

He is also a Validation expert from creating the changes request to the final Validation report. As a validation expert, Bjarne has also acted as an advisor for the management, to find the right way validation wise, when the project plan has been changed, and to communicate and cooperate with the Quality department and management.

Bjarne has several years experienced of leading teams and stakeholder management and find it naturally to take the lead in teams and set direction and reaching milestones in even complex projects, one of his major achievements.

Bjarne has a high track record finding the best and most optimal solution, both for the process as well as for the economic aspects. He has his whole career been addicted to numbers and is a unique talent in IT, hereby PAS-X, SAP, MES and similar programs to manage complex projects and scope of deliverables.

Bjarne has a good sense into analytical work methods and in combination with a logical work behavior he strives to reach deadlines within time and quality. He has throughout his long career held several courses in various programs and systems. With Bjarne on your team, you get a high capacity who aims to have "the nose in the track" from initial phase to mission completed.

Bjarne have throughout his career, been heavily involved and responsible for formulation areas, from SOP/ Deviations/ CAPA and overall documentation, "GO to person" for stakeholders and he was overall responsible for the new facility FF in NN Kalundborg, in Formulation area.

He has an outgoing personality and gets his energy, passion and motivation from taking responsibility and management of individuals and teams, in combination with challenge the existing to a new pattern. Besides his business career he combines his coaching and mental trainer experiences with both horses and high-performance sports people.

STRENGTHS

- ∴ Highly skilled Project manager with years of experience with in economy
- ∴ IT Geek with an extensive knowledge to SAP BL and abroad portfolio og MES, SCADA and other IT systems
- ∴ Validation expert
- ∴ Logical with extended analytical skills

- ∴ Expert within formulation areas, Go to person and responsible for compliance, Deviations, CAPA & SOP within project and stakeholders.
- ∴ Great overview and an eye for details
- ∴ Aims to set a team who follow him and take responsibility for deliverables
- ∴ Go to work with the mindset of working hard and having a good time
- ∴ Goal oriented and perseverant
- ∴ Outgoing and a winning attitude as person and colleague
- ∴ Communicator and team player

EXPERTISE

- ∴ Global Project manager of Large IT and Automation projects, with many stakeholders
- ∴ Validation, test and documentation expert in GXP regulated IT projects
- ∴ Deep understanding of productions area, especially but not limit to Fermentation, Filling, and Purification
- ∴ Server and IT Test system manager
- ∴ TIMS Test system expansion
- ∴ Worked within various areas of Automation and IT
- ∴ Documentation, CAPA, Deviations, SOP, NC etc.
- ∴ PAS-X Expert
- ∴ Delta V Expert
- ∴ SAP EWM, warehouse, logistic, supply chain, PM on large integration systems
- ∴ Line Optimizer Connect
- ∴ PAS-X Scheduler
- ∴ SCADA experience, scoping, vendor selection, integration
- ∴ Deep understanding of productions area, Fermentation and Filling, Logistic, Warehouse, Supply chain, act as Go to person, responsible for compliance, validation, documentation and SOP,

IT SKILLS

Bjarne has a broad knowledge, understanding and experience in several IT system supporting different processes, here below:

- ∴ SAP (FI/CO, BI, Log)
- ∴ Vault Quality
- ∴ NovoDocs
- ∴ NovoGlow
- ∴ ISOtrain
- ∴ TrackWise
- ∴ Microsoft Office
- ∴ Microsoft Visio
- ∴ TIMS
- ∴ LIMS
- ∴ Solution manager and architect
- ∴ Global Remedy

etc. SAP FI/CO, SAP BI, SAP Log, TIMS, LIMS, Solution manager and architect, Global Remedy

EDUCATION AND DEGREES

1996	Process and automation operator at Novo Nordisk Building BD
2000	Educated in Economy as specialty in NN Corporate Finance
2006	HD in Economy and Process Management

CERTIFICATIONS AND COURSES

2026	Personal Leadership Program – PLPPM II - Acuity World, Education ongoing
2018	Master mental trainer & High-performance teams

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent

PROFESSIONAL BACKGROUND

2022 – Present
[DahlfeltConsulting](#) | Senior Consultant Project manager and Validation, IT Geek and specialist

Last assignment:

Validation & Project manager in Icodeck project in 018, HGH Gentofte, with following tasks:

Project & validation manager, with overall responsibility for the complete validation and documentation through the Icodeck project. In addition, close collaboration with special process support, regarding planning and execution of the project.

The primary task throughout the project was the preparation of documents, including:

- Master validation plan and report
- Validation plans and reports
- Writing and preparing CR cases
- DER and DQR (as needed)
- Creating and updating user requirements
- Writing deviations
- Q-Cases for QA
- Test reports

In addition

- Preparation and implementation of test plans within IT department
- project management
- Coordination, management and collaboration with QA
- Meeting coordinator (Status, clarification and planning meetings)

Systems involved in the project:

- PAS-X
- DeltaV

Primarily Project management and IT related tasks, incl. full integration in new facility (filling line, CIP/SIP etc, upgrade of existing systems in close collaboration with

búvendors, Line of Business, PMO, participation in compliance and settlement of Documentation and Validation acc. to regulated standards in production area.
Various Consultancy tasks within Pharma and medical Device.

2018 – Present (leisure time)

["Power-Mind" | Self-Employed high-performance trainer](#)

Mental trainer and Personal coach

Stress Management for Teams

2019 - 2022

[Slangerupgaard/Healthy Horse | Aqua trainer etc.](#)

Designing vendor material and participation in vendors and exhibition, Marketing GEEK

2016 - 2018

[Novo Nordisk A/S Kalundborg | IT System Manager, IT Infrastructure](#)

Key Responsibilities but not limited to:

- ∴ Server virtualization support.
- ∴ Full responsible for central and De-central servers on-site Kalundborg
- ∴ Patch update & Documentation
- ∴ Develop and execute Documentation in SOP, Validation, Deviations, CAPA etc
- ∴ IT & Automation Support 24/7.
- ∴ Responsible for expand of TIMS (test system)
- ∴ IT-compliance responsible
- ∴ Test, validation and documentation in GMP area

2015 – 2016

[Novo Nordisk A/S Kalundborg | IT-project manager](#)

Filling facility (Filling, Formulation, Inspection, Wash & Sterilization)

Key Project responsibilities but not limited to:

- ∴ Daily prioritize of maintenance tasks in IT & Automation
- ∴ Daily sparring and communication to all involved stakeholders and deliverables
- ∴ Daily team meeting, status and prioritizing
- ∴ Weekly status reporting on managements meetings
- ∴ Root Cause analyze together with stakeholders and management
- ∴ QMS and NC responsible for IT & Automation task
- ∴ IT & Automation Support 24/7
- ∴ PAS-X implementation and support
- ∴ Process support during production validation
- ∴ Process and Equipment validation
- ∴ Documentation creation, review and approval. SOP, CAPA, Deviations
- ∴ Process description (SOP)

Key Production responsibilities but not limited to:

- ∴ Equipment maintenance and validation
- ∴ Documentation update and review

2007 – 2015

[Novo Nordisk A/S - SAP BI](#) | [Advanced Business Analyst & Project manager](#)

Key responsibilities but not limited to:

- ∴ Overall Project manager for various IT project in:
 - Denmark, various sites
 - Kaluga, Tianjin
 - Prism to SAP
- ∴ Daily support and troubleshooting SAP BI.
- ∴ Vendor specification of deliverables
- ∴ Develop & test and various documentation IT Programs
- ∴ System & Data analyses, troubleshooting and optimization
- ∴ Educate & teach stakeholders in general use and optimization of SAP BI.
- ∴ Sar box specialist within Compliance and audit readiness
- ∴ Coordination and daily planning towards tasks with NN India

2005 – 2007

[NNIT / Pharma IT Lyngby](#) | [Business Analyst](#)

Key responsibilities but not limited to:

- ∴ System supporter and Project manager (LIMS, Prism)
- ∴ Secure safe communication between stakeholders' user & developers
- ∴ System analyzing & troubleshooting, Root Cause
- ∴ Responsible for level of compliance in (GXP) in Test & documentation of IT structure
- ∴ Implementation of Sar box

2001 – 2005

[Novo Nordisk A/S Bagsværd/Sorgenfri](#) | [Business Analyst](#)

Key responsibilities but not limited to:

- ∴ Overall Responsible for economy in production and involved areas
- ∴ Budget and process support, alignment with stakeholders
- ∴ Price calculation and variations for various deliverables
- ∴ Project responsible for overall budget in:
 - Lean optimization in stock (SAP BI)
 - Responsible for negotiation of prices in raw product area (SAP BI)

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Kålungsvej 45 | DK 3520 Farum

+45 3170 0882 | CVR 43105019