



Curriculum Vitae

Jeppe Kjems

Position: Owner, CU-Engineering
Volunteer, CU Safe Water

Education: ETM, Engineering Technology Management, 2000,
M.Sc., Dairy Engineering, 1986

Year of birth: 1958

Languages: Danish, English, Portuguese, German, Spanish



Summary

35 years of international Project Management, Direct Production, Process and Mechanical Engineering experience of which +25 years are from Pharmaceutical, Biotech. & Critical Utility. Projects undertaken at CU Engineering CU Safe Water, Novo Nordisk A/S, NNE A/S, Niras A/S. Chairman of ISPE Nordic Critical Utility Steering Committee 2013-2015. Member of ISPE Global Critical Utility Steering Committee 2011-2015. Chairman of the special interest group "FarmaVand" 2009-2018. Speaker at several ISPE and FarmaVand conferences. Reviewer and contributing writer of several ISPE guidelines for Critical Utility Systems. Having a M.Sc. in Dairy Engineering combined with cultural understanding from years of international Production and Engineering gives a unique platform for success.

I have participated in voluntary work for +20 years. The first "CU Safe Water" project started 2016 in Uganda. Since then, I cooperate with "Engineers Without Borders", "Dairy Without Borders" and several NGO's having local representation e.g., Water Mission and World Hope International. "CU Safe Water" supports UN Sustainable Development Goal No. 6 "Safe Water Supply".

I have had the following responsibilities:

- Project Manager, Fundraiser, Entrepreneur and Communicator on voluntary projects
- Novo Nordisk A/S Critical Utility Specialist (Subject Matter Expert), responsible for global technology network and support for CU production unit's world wide
- Senior Project Manager, responsible for the process and mechanical design, installation and Validation of a green field Insulin Filling Plant in Brazil
- Department Manager for up to 40 professional engineers at NNE A/S
- Project Manager on various types of projects
- Leading Business Process Re-engineering
- Project Engineer on Critical Utility Commissioning and Qualification projects
- Plant Engineer responsible for operation and maintenance

Key competences:

- Project Management and cultural understanding
- Subject Matter Expert in Critical Utilities, CIP/SIP and Sanitary Design
- Microbiological background

Fields of Work

Voluntary in Safe Water Projects

Project Management, Design, Fundraising, Cultural understanding and Communication.

Consultancy, Critical Utilities and CIP/SIP for production facilities

Specialist / Subject Matter Expert supporting pharmaceutical green field projects and running production facilities, C&Q and optimization.

Critical Utility Specialist - SME

Chairman for Global Critical Utility Technology Network, Better Practice work.

Senior Project Manager

Critical Utility and CIP/SIP, green field project Insulin Filling Plant incl. Insulin product transfer from Denmark to Brazil.

Chemist

Development of the fermentation process for a GLP-1 product for clinic trial phase III & IVa.

The resulting product is on the market under the name "Victoza" for Diabetes treatment.

Manager

Managed two departments within NNE A/S:

- Critical Utilities (WFI, PW, Critical Steam & CIP/SIP) for API & Finished Pharmaceuticals.
- Fermentation and Powder Handling.

Main tasks involved organising people and projects, development of technical and non-technical competences and standardisation of design practices.

Whilst being a manager within NNE A/S I did the following in addition to the above:

- Undertook project committee work as NNE representative.
- Responsible for BPR project related to the engineering design process.
- Assisted departments completing Conceptual Design and Basic Design and was the overall responsible for technical and Peer reviews.
- Development and sourcing of new technology.
- Attended audits of process equipment suppliers in the capacity of technical specialist.

Lectured at international and domestic conferences.

Project Manager

Project planning and organisation of complete GMP projects from Client Brief/Design Basis/User Requirement Specification and Validation through to Hand over.

Project Engineer

Work included mainly Commissioning and Qualification activities with the emphasis on data collection during the construction phase for the preparation of installation and operation test plans (IQ & OQ) as well as for the writing of SOP's.

Plant Engineer

Support and product optimisation and installation of new equipment.
Project Manager for two green field projects and responsible for the start-up of one of the facilities including implementation of preventive maintenance system.

Significant Experience / References

Safe Water Project, incl. 5 Water Kiosks

Borehole well with solar pump, Safe Water treatment and storage.
In cooperation with NGO's Engineers Without Borders DK, World Hope International (SL), Water4 & Water4Ever (SL).
CU Safe Water, Grafton, Freetown, Sierra Leone - (2020 -2022)

20-30 Safe Water Projects for Masai villages incl. Water Kiosks

Borehole wells with solar pumps, Safe Water treatment, storage and distribution incl. Water Kiosks.
In cooperation with "LoveSpring" (DK), "Save the Children, Arusha" (TZ) and "Water Mission" (TZ).
CU Safe Water, Longido & Monduli districts, Tanzania - (2020 -)

Mini Dairy and Safe Water Project

Mini Dairy in the Masai village of Lesoit incl. borehole well with solar pump and Water Kiosk.
In cooperation with "Dairy without Borders" (DK), Paicodeo (TZ) and Water Mission (TZ).
CU Safe Water, Kiteto district, Tanzania - (2019 -)

Critical Utility SME for Vaccine Manufacturing

Subject Matter Expert (SME) on PQ3 of Critical Utility systems (WFI, PS, Sterile Gasses) for a Pharmaceutical Sterile facility.
Bavarian Nordic A/S, Denmark - (2019-2020)

Critical Utility SME for Tablet Manufacturing

Subject Matter Expert (SME) on PQ3 of Purified Water system for a Novo Nordisk A/S Pharmaceutical Tableting facility.
Niras A/S, Denmark - (2018-2019)

Safe Drinking Water project in Uganda

Voluntary project through the NGO's "Verdens Børn" and "Juveniles Welfare Service" (UG). First phase implemented Oct. 2017. Second phase implemented 2019. Rainwater harvest and storage for making Safe Drinking Water for a school in Kakundi.
CU Safe Water, Uganda - (2016-2019)

Critical Utility and CIP SME for Insulin manufacturing

Subject Matter Expert (SME) on Critical Utilities incl. Lab. Water and CIP Systems for a Novo Nordisk A/S green field Pharmaceutical Tableting facility - *TIC DKK 1.0 billion. Niras A/S, Denmark - (2015-2018)*

Basic Design Critical Utility systems

Clean Utility Lead on new Pre-Treated-Water (PTW), WFI and Clean Steam Systems to be exchanged in an existing Pharmaceutical Filling Plant - *TIC DKK 42 million NNE A/S, Denmark - (2015)*

Technical Support

CIP/SIP User Responsible for Novo Nordisk A/S during the Basic Design for APX, a new Pharmaceutical Filling Plant - *TIC DKK 2.1 billion Alectia A/S, Denmark - (2015)*

Facility Review and Technical support of Critical Utilities

Subject Matter Expert (SME) for Critical Utility Systems for Pharmaceutical Filling Plant. *Exir Pharmaceutical Co, Iran - (2014)*

Technical Support

Subject Matter Expert (SME) support for Pure Steam System Insulin Filling Plant. *Novo Nordisk Pharmaceuticals SAS, France - (2013)*

Chairman ISPE Nordic CU steering committee

Chairman of International Society of Pharmaceutical Engineering (ISPE) Nordic steering committee for "Critical Utilities".
Nordic CU network - (2013-2015)

Technical Support

Subject Matter Expert (SME) support for Design, Installation and Validation of new Supply Water System for API production.
Novo Nordisk A/S, Denmark - (2013)

Technical Support

Subject Matter Expert (SME) support for Purified Water in API facility.
PolyPeptide Laboratories Ltd., Sweden - (2013)

Audit High Purity Water systems

Subject Matter Expert (SME) support for audit of Purified Water and WFI System for Insulin Filling Plant.
Eskayef Ltd., Dhaka, Bangladesh - (2012)

Pure Steam Generator project

Project Manager and Subject Matter Expert (SME) for Front-end design, Installation and Validation of a new Pure Steam Generator in Insulin filling Plant.
Novo Nordisk A/S, Denmark - (2012-2013)

Process Performance Qualification of API

Subject Matter Expert (SME) support for preparation of Process Performance Qualification (PPQ) - a green field project for Active Pharmaceutical Ingredient (API) production.

Novozymes A/S, China - (2011)

ISPE Global CU steering committee member

Member of ISPE global steering committee for "Critical Utilities".

Global CU network - (2011-2015)

Validation of Purified Water system

Subject Matter Expert (SME) at commissioning and validation of a Purified Water system - a green field project for API production.

PolyPeptide Laboratories Ltd., India - (2011-2012)

Audit High Purity Water system

Technical audit responsible at Critical Utility assessment of Insulin Filling plant.

Torrent Pharmaceuticals Ltd, India - (2011)

PQ of Critical Utility systems / production support

Responsible for preparation and execution of the PQ for WFI, Critical Steam and Process Air (sterile compressed air) on a new Insulin Filling plant, securing the robustness of production equipment and coaching of the Chinese personnel.

Novo Nordisk A/S, China - (2010-2012)

De-rouging of High Purity Water system

Environmentally friendly De-rouging of a High Purity Water system without use of detergents.

Novo Nordisk A/S, Denmark - (2010)

Critical Utility Specialist / Subject Matter Expert

Chairman for Global Critical Utility Technology Network at DFP, Novo Nordisk. Optimization, Water & Energy saving, Critical production. Participating in Concept brief & Conceptual Design, Troubleshooting / Failure Investigations, Commissioning & Qualification (DQ/IQ/OQ/PQ). Support for Greenfield Insulin Filling Plant, China. *TIC DKK 2.000 million.*

Speaker at International and Domestic CU meetings e.g. International Society of Pharmaceutical Engineering (ISPE).

Novo Nordisk A/S - (2008-2010)

Senior Project Manager - Multi functional Office and Lab. Building. TIC DKK 50 million

Responsible for converting an Insulin packing area to a creative open office area with integrated Laboratory and Pilot function for Manufacturing Development (5A-Ba).

Novo Nordisk A/S, Denmark - (2008-2009)

Senior Project Manager - Insulin Filling Plant. TIC DKK 1.700 million

Responsible for Critical Utilities & CIP/SIP installations as well as the product transfer of NovoMix30 from Denmark to Brazil. Budget responsibility DKK +100 million.
Novo Nordisk A/S, Brazil - (2004-2008)

Health Care Fermentation - Fermentation Chemist

Support of NN2211 IVa Campaign in Pilot Plant and production for Clinical trial phase III. The Insulin product "Victoza" was launched in Europe, Japan & US 2009/2010.
Novo Nordisk A/S, Denmark - (2002-2003)

Health Care Insulin Pilot Plant, 20 liters fermenters. TIC DKK 32 million.

NNE project committee representative.
Overall responsible for the project delivery to the customer's satisfaction (quality, price and time). Coaching the project manager. The project was executed under operating conditions.
Novo Nordisk A/S, Denmark - (2001-2002)

Health Care Insulin, Launch Plant modification. TIC DKK 35 million.

NNE project committee representative.
I was overall responsible for the project delivery to the customer's satisfaction (quality, price and time). Coaching and challenging the project manager. The project was executed under operating conditions.
Novo Nordisk A/S, Denmark - (2001-2002)

Health Care Insulin Pilot Plant, Multicolumn modification. TIC DKK 9 million.

NNE project committee representative.
I was overall responsible for the project delivery (quality, price and time). Coaching and challenging the project manager. The project was executed under operating conditions.
Novo Nordisk A/S, Denmark - (2001-2002)

Health Care Cell Cultivation Pilot Plant, Upgrade non-GMP to GMP. TIC DKK 24 million.

NNE project committee representative.
I was overall responsible for the project delivery to the customer's satisfaction (quality, price and time). Coaching and challenging the project manager. The project was executed under operating conditions.
Novo Nordisk A/S, Denmark - (2001-2002)

Conceptual Design - CIP systems for Fermentation facilities

Project Manager.
Perform analysis including logistics for two new CIP-system designs for two complete fermentation plants.
Novo Nordisk A/S, Denmark - (1997)

Health Care Insulin filling, WFI system

Project Manager.

Production capacity analysis of WFI Still and distribution system. Design, Installation, Commission & Qualification and handover of a new WFI-system.

Novo Nordisk Pll, the US. - (1995-1996)

Health Care Insulin filling, WFI-system

Project Manager.

Design, implementation and validation of a new WFI system in an existing production.

The primary tasks were to complete the design and installation of the system, as well as Commissioning and Qualification under an accelerated schedule, which succeeded.

Novo Nordisk A/S, Denmark - (1994-1995)

Health Care upgrade and retrospective validation of CU systems

Project Engineer.

Writing and executing IQ test plans as well as writing SOP's.

Novo Nordisk A/S, Denmark - (1993-1994)

International experience:

I have been working in the following countries for more than one month:

China, Brazil, India, USA, Norway, Jordan, Australia and Uganda.

I have been travelling 75 countries in 7 continents

Employment

- 2010 -** **CU-Engineering - Denmark**
Critical Utility Specialist - Subject Matter Expert.
Voluntary Safe Water specialist at “See You Water” since 2016
CEO and Owner.
- 2008-2010** **NOVO NORDISK A/S - Denmark**
Critical Utility Specialist - Subject Matter Expert.
Chairman for Global Critical Utility network.
- 2004-2008** **NOVO NORDISK A/S - Brazil**
Senior Project Manager, Filling plant MOC.
Responsible for Critical Utilities, CIP/SIP and Insulin product transfer.
- 2002-2003** **NOVO NORDISK A/S - Denmark**
Chemist, “BioProcess Pilot Plant”.
Supporting the “Victoza” fermentation for the IVa campaign in Pilot Plant and
production for Clinical trial Phase III in Kalundborg.
- 1993 - 2002** **NOVO NORDISK ENGINEERING A/S - Denmark**
2002 - 2002 **Manager, “Process and Building Engineering - Fermentation, Powder &**
Synthesis” (35 employed)
- 1999 - 2001** **Manager, “Fermentation and Powder Mechanical Engineering” (40**
employed).
- 1996 - 1999** **Manager, “Fermentation & Powder Handling” (32 employed).**
- 1994 - 1996** **Manager, “Process Utilities” Starting a new department for Critical Utilities,**
which grew from 5 to 35 employees.
- 1993 - 1994** **Project Engineer**
Validation of Critical Utilities.
- 1991 - 1993** **AAGE CHRISTENSEN A/S - Denmark. Sales Engineer**
- 1989 - 1991** **DAN-EGG PRODUCTS A/S - Denmark. Plant Engineer / Project Manager**
- 1986 - 1989** **APV ANHYDRO A/S - Denmark. Sales Engineer**

Comprehensive CV can be forwarded upon request.

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