

Curriculum Vitae

Jeppe Kjems

Position: Owner, CU-Engineering
Education: ETM, Engineering Technology Management, 2000,
M.Sc., Dairy Engineering, 1986
Year of birth: 1958
Languages: Danish, English, Portuguese, German, Spanish



Summary

I have +25 years of international Project Management, Process and Mechanical Engineering experience of which +20 years are from Pharmaceutical, Biotech. & Critical Utility projects undertaken at CU Engineering, Novo Nordisk A/S and NNE Pharmaplan.

Chairman of ISPE Nordic Critical Utility steering Committee.

Member of ISPE Global Critical Utility steering Committee since 2011.

Leader of the interest group "FarmaVand" since 2009.

Speaker at several ISPE and FarmaVand conferences.

Reviewer and contributing writer of several ISPE guidelines for Critical Utility Systems.

Having completed a M.Sc. in Dairy Engineering and Engineering Technology Management, I have a broad process related background based on technical understanding and microbiological knowledge.

I have had the following responsibilities:

- 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 commissioning of a green field Insulin Filling Plant in Brazil
- Department Manager for up to 40 professional engineers at NNE Pharmaplan (former known as Novo Nordisk Engineering A/S)
- Undertaken project committee work at NNE Pharmaplan
- 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, maintenance, various capital works and Project Manager for 2 green field projects

Key competences:

- Subject Matter Expert - Critical Utilities & CIP/SIP
- Process Optimisation
- Project Management
- Microbiological background

Fields of Work

- **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. Insulin product transfer from Denmark to Brazil.
- **Chemist**
Development of the fermentation process for NN2211 related to clinic trail phase III & IVa. The resulting product is on the marketed under the name Victoza for Diabetes treatment.
- **Manager**
Managed two departments within NNE Pharmaplan:
 - Critical Utilities (WFI, PW, Critical Steam & CIP/SIP) and other Process Utilities 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 Pharmaplan I did the following in addition to the above:
 - Undertook project committee work as a NNE representative.
 - Responsible for BPR project related to the engineering design process.
 - Assisted my 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 and Project Manager**
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

- **Critical Utility and CIP SME for Insulin manufacturing**
Subject Matter Expert (SME) on Critical Utilities and CIP Systems for a Novo Nordisk A/S green field Pharmaceutical Tableting facility - *TIC DKK 1.0 billion.*
Alectia A/S, Denmark - (2015-)
- **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 Pharmaplan 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-)
- **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-)
- **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 /Critical 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, Trouble shooting / 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 VIa 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 - (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 - (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 - (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 - (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 - (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, BC & BD in Kalundborg.
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, US, Guatemala, Sweden, Norway, Jordan and Australia.

Employment

- 2010 -** **CU-Engineering - Denmark**
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 trail 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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