
Curriculum Vitae



Hans-Ole Hansen

DBJ-Development
Ehlersvej 18A
2900 Hellerup

HP +45 29 13 54 05

hoh@dbj-development.com

www.dbj-developmen.com

PROFILE

SENIOR PROJECT MANAGER & SENIOR AUTOMATION ENGINEER

with more than 20 years' extensive experience in the Pharmaceutical, Biotech and Environmental industries, who offers:

- Expertise in General / Vendor / Project Management, Project Engineering and Consultancy.
- Specification and installation of equipment and facility systems under GMP regulations.
- Product development, specification, production design and implementation.
- Validation of production and products also with statistical methods.
- Problem solving and road block removal.
- Practical and hands on approach.
-

STRENGTHS

- Technical design of projects CD, BD, DD.
- Preparation of tender specifications.
- Preparation of VPL (Validation Master Plan).
- Preparation of requirement and design documents such as EMS, URS, FS, FDS, SMDS.
- Preparation of test documents for DQ, IQ, OQ, PQ.
- Validation and test of process equipment.
- Preparation of SOP and training of operators.
- Cost-benefit analysis and technical due-diligence.
- Technical project management including installation strategy and fall back strategy.
- Programming according to GAMP, S88, S98 and FDA CFR P11.
- Commissioning, FAT, SAT, support and preparation of SOPs and PQ.
- Integration to other systems such as MES, PI etc.
- CE Marking and ATEX installations.

PROFESSIONAL /TRAINING

- 2006 Emerson Delta V programming course – Benima A/S.
- 2004 Procos/2 programming course – WM-Data A/S
- 2002 ControlDraw course (S-88 design tool) – NNE A/S
- 2001 SattLine programming course – Newcon A/S

- 1998 Siemens S7 programming course – Siemens A/S
- 1996 QMS (Quality Management System) NNE A/S
- 1995 GMP/GAMP course - Novo Nordisk A/S
- 1994 Danfoss Master 2000 programming course – Danfoss A/S

QUALIFICATIONS

- Bachelor of science 1988 – Electrical Engineering, HF & Programming
Danish Technical University, Copenhagen

LANGUAGES

- English
- Spanish
- Danish
- Swedish

Carer history

1998 – Date **DBJ-Development**

Denmark

Free-lance Consultant within Automation, Project Management, Pharmaceuticals, Biotech, Food, Transportation and Environmental Projects:

Consulting company within automation projects, primarily within the pharmaceutical industry. Programming of DCS (Distributed Control System) Process control systems including PLC and HMI (Human Machine Interface).

Planning, design, preparation of design documents, programming, test, qualification, validation, commissioning, customer support for automation projects.

- Technical design of automation projects CD, BD, DD.
- Preparation of tender specifications.
- Preparation of VPL (Validation Plan).
- Preparation of requirement and design documents such as EMS, URS, FS, FDS, SDS, HDS, SMDS.
- Preparation of test documents for DQ, IQ, OQ, PQ.
- Preparation of SOP and training of operators.
- Cost-benefit analysis and technical due-diligence.
- Technical project management including installation strategy and fall back strategy..
- Programming according to GAMP, S88, S98 and FDA 21CFR P11.
- Commissioning, FAT, SAT, support and preparation of SOPs and PQ.
- Integration to other systems such as MES, PI etc.
- CE Marking and ATEX installations.

Projects:

- **AJ Vaccines – Vaccine Facility**
Clients representative on large upgrade of the Polio facility in Amager.
ProjectBinder represented the client and reviewed and approved all automation design and documentation provided by the main contractor NNE on the B90 upgrade.
Customer: AJ Vaccines/ProjectBinder 09-2017 to 03-2020.
- **ALK Abello – PUF14**
Customer advisor on automation in aspect to validation of extraction line for allergy medicine.
System: iFix, Allen Bradley, Siemens..

Plant: Byg 25 Hørsholm.
 Costumer: ALK Abello / Pharma Technology 04- 2018 to 09-2018 .

- **Xellia Pharmaceuticals - Filling Plant**

Project Manager for Automation for filling facility in Cleveland Ohio. Project manager for all automated systems including Autoclaves, partswasher, vialwasher, fillingmachine, Hepa carts, freezdryers, capper, PMS and BMS.
 All systems integrated into process network with AD.
 Systems supplaid by various vendors and others by internal and external consultants.
 Total budget 140 mill USD
 System: IFix, Allen Bradley, Siemens, among others.
 Plant: Xellia Pharmaceuticals Ohio, USA 03-2017 to 07-2017.

- **BFK BMS Project**

Validation Engineer
 Adding new room sensors for class B and C to FMS (Facility Management System) for filling plant.
 Planning, Specification, Implementation, Validation.
 URS, FDS, SDS, DQ, IQ, OQ.
 System: IFix/Siemens S7.
 Plant: Filling plant Kalundborg FF
 Customer: NNEPhamaplan (Novo Nordisk) 03-2016 to 07-2016.

- **ED upgrade Project**

Engineer
 New CIP Station and new serum receiving tank.
 Specification, Design, Programming, preparation FS, OQP, test and validation,
 System: Procos 2/ Beckhoff.
 Plant: Kalundborg ED.
 Customer: NNEPhamaplan (Novo Nordisk) 03-2015 to 03-2016.

1997–1998 **Trepko filling machines for diary.**

Tåstrup, Denmark

Lead engineer filing machines for diary products.

Responsible for electrical department, design of switch boards, programming, CE marking and technical documentation.

- Responsible for electrical department.
- Responsible for PLC/HMI programming amongst others Siemens S7
- Responsible for purchase of electrical components.
- Responsible for CE marking.
- Responsible for preparing technical documentation.

1995 – 1997 **AN Instrument Consult (ANIC).**

Hillerød, Denmark

Project engineer/consultant within pharmaceutical and Biotech industry.

Primarily for NNE A/S - Packaging Automation.

- Rotation filtersystem, Novozymes BE Kalundborg.
- Destillation column, Novo Nordisk AE Kalundborg.
- Fluid bed for ingridiens factory, Danisco Haderslev.

- Validation of GEA/Niro automizer Fluidbed, Novo Nordisk C2 Måløv.

1994 –1995 **Danfoss Sytem Automation.**

Herlev, Denmark

Project engineer in SCADA/SRO department

- Wastewater treatment plants and environmental monitoring systems.
- Danfoss Master 2000 and PLCs (Square D, Siemens, DOA, etc.).

1992 - 1994 **Impodan/ Scan-Environment.**

Lynge, Denmark

Sales and project engineer.

- Sales and project engineer within solutions and equipment for public wastewater treatment plants.
- Sales and project of solutions and equipment for industrial wastewater treatment, primarily galvanizing industry, industrial lacquering and other metal surface treatments.