

DAHLFELTCONSULTING

CONSULTANT CV WITHIN VALIDATION AND QA CONSULTANT

Name Henrik Linnemann
Nationality Danish
Gender Male
Domicile Denmark

CONTACT INFORMATION

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HENRIK LINNEMANN - CURRICULUM VITAE

PERSONAL LETTER

Our consultant Henrik Linnemann have throughout his long career, been working as Validation & QA expert for eg. Novo Nordisk in both China – Tianjin and Clayton in their portfolio or building new production facilities where the production equipment was validated as one of Henrik's top competences. Besides this he established AlfaNordic which was sold to Niras in 2021, Henrik did throughout his long career in AlfaNordic as well worked on-site in the field for a large part of AlfaNordic customers. He has gained extensive knowledge and ways to work out the best and fastest Validation and still be in compliance within all QA aspects.

STRENGTHS

Henrik has ability to keep calm in all projects he has participated in, he gain an extensive overview and ability to merge and set the right team to fast pace projects

EXPERTISE

Henrik's palette of competences are broad, but he has specialist competences in Validation, QA, Project management and a deep insight to all kind of historic

SKILLS

- ∴ Management
- ∴ Validation
- ∴ Quality Assurance
- ∴ 21 CFR Part 11
- ∴ Quality Management
- ∴ GMP
- ∴ FDA
- ∴ Quality System
- ∴ Early-stage Startups
- ∴ Board of Directors

EDUCATION AND DEGREES

- ∴ CBS - HD, Finance, General (August 2021 - June 2023)
- ∴ INSEAD - Executive Board Program (2019 - 2019)
- ∴ The Open University - Master of Arts (M.A.), Art History (2015 - 2018)
- ∴ Pathfinder | Stifinder - Leadership and personal development (Sep. 2004 – Feb. 2005)
- ∴ University of Southern Denmark - HD 1 del, Economics (Sep. 1996 - June 1997)

CERTIFICATIONS AND COURSES

- ∴ QMS Auditor/Lead Auditor (Medical Device, ISO 13485:2003 with ISO 9001:2008)
- ∴ Strategisk Regnskabsforståelse - CBS Executive Fonden
- ∴ Basic Digital Marketing - K67 UGJ YJP

LANGUAGE SKILLS

Danish	Native
English	Full Professional
Swedish	Professional Working
German	Professional Working
Norwegian	Professional Working
Portuguese	Limited Working
Spanish	Limited Working

PROFESSIONAL BACKGROUND

[DahlfeltConsulting | Senior Consultant | June 2023 - Present](#)

Senior Consultant Validation, QA Expert & Quality Assurance.

- ∴ Various Consultancy tasks within Pharma and medical Device business.

[HBL Consulting ApS | Senior Consultant | Jan. 2021 - Present \(2 years 4 months\)](#)

[AlfaNordic Academy A/S | Member Board Of Directors | Feb 2018 - Jan 2021 \(3 years\)](#)

[AlfaNordic Inc. | Chairman of the Board of Directors | Jun 2016 - Jan 2021 \(4 years 8 months\)](#)

[AlfaNordic - full part of the NIRAS Group | Member Board of Directors | May 2013 - Jan 2021 \(7 years 9 months\)](#)

[AlfaNordic - full part of the NIRAS Group | Senior Partner and co-owner | Jan 2009 - Jan 2021 \(12 years 1 month\)](#)

[A-consult | Chairman Of The Board Of Directors | Oct 2018 - Apr 2020 \(1 year 7 months\)](#) Together with the chairman of AlfaNordic I lead the proces of buying A-Consult A/S. Upon successful signing I took the role as chairman of the board of A-consult A/S during the period of merger and integration of with AlfaNordic A/S.

[AlfaNordic Tianjin Ltd | Senior Partner & Co-owner | Jan 2009 - Jul 2012 \(3 years 7 months\)](#) My work in Tianjin focused on two areas:

1. Project Validation Manager on API green field biotech project. I worked out the project validation strategy and implemented it in the project. This included the scope for the validation activities, hiring local and international engineers for the validation team and securing progress and meeting milestones. Other activities included e.g. vendor inspection and qualification and Henrik Linnemann - page 1

training of the client organisation in validation, Good Test Practice and Good Documentation Practice. I was the main reviewer and approver of validation documentation in the project.

2. Establishing a daughter company of AlfaNordic A/S in Tianjin. During my time in China I started AlfaNordic Tianjin Ltd with my business partner. We build up an organisation which serviced the former mentioned API project as well as other other smaller projects. In this process we successfully embraced the Chinese way of doing business which gave us possibilities for more business as well as participation in bidding rounds. AlfaNordic Tianjin came out a great succes having a team of recognised employees. Because of our recognition I was asked to chair the 2011 ISPE-CCPIE China Conference session for critical utility, which I happily accepted.

[PFA | Senior Quality Consultant | Dec 2006 - Apr 2007 \(5 months\)](#)

[NNE | Department Manager | Feb 1999 - Dec 2006 \(7 years 11 months\)](#)

At NNE I undertook two main roles.

1. Manager of a Quality and Validation department As manger in a global engineering company, I was commercially responsible for the performance of my department. Hence, budgeting, controlling and sales activities were focus points. Another equally crucial point of responsibility was the development of my employees, both professionally and personally. I accounted for my department's competencies especially with focus on technical skills and cGMP to be able to staff projects. In this capacity I collaborated and negotiated with consultant agencies when hiring temporary competencies for my projects. As part of the management, I naturally developed strategies for my department and collaborated with management colleagues to develop strategies for the quality and validation division in NNE.

2. Senior Validation Engineer. During my time at NNE, I positioned myself as an expert in matters regarding validation. I have carried out many projects and tasks concerning IQ, OQ, PQ and PPQ of stand-alone equipment, utilities, and process plants. But my professional interest in management and validation led me to my main work area as Project Validation Manager. In this capacity I worked on several green field projects as well as other types of projects. My responsibilities on such projects would typically be: Generating a validation concept for the projects and documenting this in a VMP. Calculate the cost of validation for carrying out such a plan. The validation plan was typically systemized according to an Object Breakdown Structure (OBS) of the overall project. Build and manage a quality and validation team to execute the VMP. Secure deliverance of quality and validation deliveries in the project.

[Novo Nordisk | QA professional - validation | Feb 1998 - Apr 1999 \(1 year 3 months\)](#)

Validation QA at a filling plant including a packaging and assembly department.

Henrik Linnemann - page 2 My main task comprised: Review and approval of IQ and

OQ protocols and reports. Department technical SME. Secure adherence to cGMP and ISO 9001. Processing of deviations, SOP's and other quality documents. Conduct internal audits.

[NKT Trådværket](#) | Laboratorieleder | Jan 1995 - Jul 1997 (2 years 7 months)

I was employed as Development Engineer to work with corrosion protection. In this work I developed protective surface treatments for screws and nails. Quickly I was promoted to Laboratory manager and managed a team of both salaried employees and skilled and unskilled employees. In addition to development tasks, the laboratory was also responsible for the company's quality control under ISO 9002 where both environmental control and corrosion testing took place. This led e.g., to my involvement in internal environmental improvement projects as well as contact and environmental reporting to public authorities. The latter arised mainly from another responsibility of mine which was the operation of the company's waste water treatment plant.

HONORS-AWARDS

- ∴ Børsen Gazelle landsvinder
- ∴ Dansk Industri Initiativpris

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