NICOLINE KALSBEEK

Curriculum Vitae

PERSONAL INFORMATION

Kalsbeek Consult ApS
Nicoline Kalsbeek, Ph.D.
Sandlodden 4, Lumsås
DK-4500 Nykøbing Sj

Phone: +45 61 28 82 06
Mail: nicoline@kalsbeek.dk
Web site: www.kalsbeek.dk
CVR: 40 18 22 76

LANGUAGES

- Danish and Dutch, native proficiency
- English, full proficiency
- Swedish and Norwegian, working proficiency
- German & French, basic

SELECTED IT SKILLS

MS Office, MS SharePoint, SAP, IBM Lotus Notes, LIMS (LabVantage and LabWare), SAS JMP, TrackWise

HOBBIES

Helicopter flying, Running, Biking, Reading

Summary – Experienced Leader and Quality Specialist

Nicoline Kalsbeek is an experienced leader with in depth knowledge in different business areas including the Pharmaceutical, Biotech and Medical Device Industries. With her motivating and involving leadership style Nicoline has shown excellent results as responsible for large change projects involving major changes for people and at the same time meeting business targets. Nicoline also has expert experience in QC, QA and within MDR/IVDR and ISO 13485 for medical devices and knowledge of validation requirements and processes. Nicoline can fill various roles as expert and project manager or project participant in addition to interim manager.

Nicoline's experience covers

- Pharma, Biotech and Medical Device experience
- Change Management – among others headed a large re-organization in a QC lab, where half of the activities were moved abroad with severe consequences for the people in the lab.
- People Management
- GMP
- ISO 13485 for medical device – assistance with implementation and performed internal audits
- Experienced in MDR 2017/745 for Medical Devices and IVDR 2017/746 for *In Vitro* Diagnostic Medical Devices
- FSSC 22000 (Food Safety System Certification 22000)
- FAMI-QS (Code of Practice for Feed Additive and Pre-mixture Operators)
- Quality Assurance (QA) – Customer quality agreements, setting specifications, handling stability programs, customer complaint handling, general QA support to production, deviations, change controls, CAPA's, review of analytical method validation reports
- Quality Control (QC) – OOS, OOT, deviations, change controls, CAPA's, knowledge of a broad range of analytical methods, including chromatographic methods, chemistry methods like pH, colour, appearance, water content and microbial methods
- Knowledge of requirements and principles in validation and experience with review of analytical method validation reports

- Software and Systems – among others SAP, LIMS, SAS JMP and Trackwise
- Project Management – I headed the implementation of a global control system in production as project manager
- LEAN
- Teaching and Research Expertise
- Interpersonal skills – I have asked former managers, colleagues and employees to describe me as person, and some examples are as energetic, ambitious, trusting, pragmatic, focused, goal-oriented, empathetic, respectful, caring, creates trust, fast-learning
- Global Experience with hands-on collaboration with US, Ireland, Hungary, China, India, Brazil and Germany. I have Dutch citizenship and lived almost my entire life in Denmark

Consultant Experience in Kalsbeek Consult ApS

- **Bavarian Nordic A/S, Kvistgård**
  - Interim QC Director, 2025/3-. Department with approx. 80 employees and 7 managers. Primary tasks are securing people wellbeing and analytical results for daily business and projects.

- **EvodiaBio ApS, Rødovre**
  - Interim QA Manager, 2024/8-2024-12. Primary responsibilities are general support in the QA area and assist in preparing the company for FSSC 22000 certification as a manufacturer of food additives.

- **Bavarian Nordic A/S, Kvistgård**
  - Interim Director QA Operations, Site QA Head, 2024/1-2024/7. Department with 35 employees and 5 managers. Primary tasks are to man up the area and secure QA support to the site to perform daily operations and projects.

- **GMP Konsulenterne ApS, Glostrup**
  - QA Consultant, 2023/2-2023/11. Inspection readiness and QA tasks at customer in Southern Denmark. Writing of deviations from all parts of the organization for 6 months.

- **Fertin Pharma A/S, Vejle**
  - QA Consultant, 2022/11-2022/11. Perform internal ISO 13485 audit.
  - QA Consultant, 2021/6-2021/12. Assistance with implementation of ISO 13485 for medical devices.
  - Management and QC Consultant, 2019/5-2019/9. Support to department manager and to optimizations in the raw materials QC lab.

- **Chr. Hansen A/S, Copenhagen and Hørsholm**
  - QA Optimization Consultant, 2022/6-2022/8. Optimized and implemented release processes.
  - Interim Senior QA Manager, 2022/1-2022/5. Department with 20 employees and 1 team leader. Also headed release team with delivery challenges, many additional consultant resources were hired to perform tasks.
  - Management and QA Consultant, 2020/11-2021/2. Review of method validation reports for microbial test methods and general support to department manager.

- **ADM Denmark A/S (former Deerland Probiotics & Enzymes A/S), Hundested**
  - GMP Quality Consultant, 2021/6-2024/9. General GMP support to Quality Director.

- **AGC Biologics A/S, Søborg**
    - Interim QC Senior Manager, 2021/6-2021/10. Department with 20 employees and 1 team leader performing HPLC and other chromatographic analyses.

- **LEO Pharma A/S, Dublin, Ireland**
    - Interim QC Senior Manager, 2019/10-2020/6. Department with 50 employees and 5 team leaders, performed reorganization from 5 to 3 groups.

- **2cureX A/S, Copenhagen**
    - QA Consultant, 2021/12-2022/2. Performed internal ISO 13485 audit and assisted in final ISO 13485 certification audit.
    - QA Consultant, 2019/7-2021/6. Assistance with implementation of ISO 13485 for medical devices and advice on IVDR 2017/746 for *In Vitro* Diagnostic Medical Devices.

- **InProTher ApS, Copenhagen**
    - Quality Consultant, 2019/9-2021/8. General advice in relation to quality tasks and issues. Assisted with several quality agreements with partners.

Past Job Experience

- **Xellia Pharmaceuticals ApS, Copenhagen**
    - Senior QC Manager, 2017/1-2019/2. Department with 75 employees and 4 team leaders. Headed big reorganization with moving half of the activities in the lab abroad. Many employees were laid-off and at the same time delivery to business was secured.

- **Novozymes A/S, Bagsværd**
    - Senior Department Manager, Assay Technology and Optimization, 2013/12-2016/12. Department with 20 employees, performing optimization and automation of analytical methods for the global QC labs.
    - Product Quality Manager, 2011/8-2013/11. Responsible for all quality related issues for specific enzyme groups: customer agreements, complaint handling, setting specifications, handling of stability programs, production support, direct customer interaction etc.
    - Team leader, QC lab., 2007/10-2011/7. Department with 55 employees in 4 teams, in several periods, I headed 2 of the 4 teams (12-24 employees).

- **Copenhagen Technical School (now Next)**
    - Head of HTX, 2006/1-2007/9. Headed school with 25 teachers and 350 students. One of the main achievements was implementation of a large reform passed in parliament of Denmark 6 months earlier (indførelse af studieretninger).

- **School of Conservation, Royal Danish Academy**
    - Associate Professor, 1993/11-2005/12. Teaching and research with special focus on SEM analysis and analysis of pigments and colorants.

Education

- **Private Pilot License Helicopter – PPL(H)**
  - HeliFlight, Roskilde Airport, Denmark, 2015.
- **Diploma of Engineering Business Administration – EBA**
  - Copenhagen University College of Engineering, Ballerup, Denmark, 2012.
- **Ph.D. Physical Chemistry (X-Ray Crystallography and IR/NMR Spectroscopy)**
  - University of Copenhagen, Denmark, 1993.
- **M.Sc. Chemistry and Geology (X-Ray Crystallography)**
  - University of Copenhagen, Denmark, 1988.

Selected courses

- Technical Documentation for Medical Devices According to the MDR, *Medicoindustrien/BSI, 2022, 1 day*
- MDR Auditing - Training of Internal Auditors in Relation to MDR, *Medicoindustrien/Medidee Services SA, 2022, 1 day*
- MDR requirements for Subcontractors, *Bureau Veritas, 2020, 1 day*
- Become Internal Auditor (Bliv Intern Auditor), *Dansk Standard, 2020, 1 day*