DAHLFELTCONSULTING

CONSULTANT WITHIN VALIDATION, QA, AUDIT

Name	Charlotte Vissing
Nationality	Danish
Gender	Female
Domicile	Denmark

CONTACT INFORMATION

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CHARLOTTE VISSING - CURRICULUM VITAE

PERSONAL LETTER

Charlotte has a great passion for GMP, GCP, GLP, GDP, Medical Device & combination products and compliance practices, driven by an understanding and interest to support and comply with the needs of the end users of the products manufactured. Throughout her career she has gained insight, and developed a range of skills within both quality management, assurance, and validation/qualification (including CSV (computer system validation)) in the pharmaceutical & Medical device industry.

Specializing in qualification/validation, Charlotte have worked on several projects, and performed tasks and various activities to comply with the requirements given, therefore, she have gained expert insight into guidelines, standards, and regulations in the industry.

Additionally, Charlotte has been leading and/or participating in several projects, and internal/external GMP/GLP audits, reviewing and advised on SOP writing and harmonization. Through her participation in several projects, she has gained strong experience with coordinating roles, both in connection with green field projects, and establishment of production and laboratory equipment in already established factories, and as LEAN supporter in the subsequent production.

In the GDP area, Charlotte has experience with distribution of drug, drug precursors, such as cold chain, handling of complaints, return goods and destruction, euphoric substances, release of products, transport of euphoric substances and precursors, receive control, self-inspection, training of employees.

In connection with the above, she has a wide range of skills in the field of quality, where she has worked as a quality specialist/assurance within various forms of validation/qualification. In those positions Charlotte have had the responsibility of reviewing and approval of validation/qualification documentation such as:

- URS (User requirement specifications)
- RTM (requirements traceability matrix)
  - FDS (Functional Design Specification)
- QRM (Quality Risk Management documentation)
- VMP (Validation Management Plans
- VPL (Validation Plans)
- DQP's (Design Qualification Protocols)
- IQP's (Installation qualification protocols)
- OQP's (Functional qualification protocols)
- PQP's (Process Performance Qualification protocols)

- PVP's (Process validation protocol)
- LVP's (Laboratory validation protocols)
- VNC's (Validation non conformities)
- NC's (Non conformities)
- CAPA's (Correction and Preventive Actions)
- CR's (Change Requests)

STRENGTHS

- Result oriented
- Proactive
- Innovative
- Team player
- High energy level
- Excellent interpersonal skills
- Dedicated, Focused and Structured

MEDTECH / PHARMA

- Pharma + 25 yrs. experience in Validation & Quality Assurance
- Medical Device +5 yrs. experience Validation & Quality Assurance
- 20 yrs. experience in Compliance & Validation
- 20 Yrs. experience FDA approval, Medical Device and Pharma
- 15 yrs. experience SOP/CAPA
- 15 yrs. experience Complaint handling / NC
- 10 Yrs. Experience in System IT Validation
- 8 yrs. experience 510K
- EudraLex, FDA, USP, ISO 9001/14001, OHSAS 18001, DS/EN ISO/IEC 17025
- ISO 13485 (13485:2016), medical devices the 21 CFR Part 800-1299 series
- Data Integrity
- 21 CFR Part 11, USP 1058, and GAMP guidelines.

EXPERTISE

- Highly skilled in FDA & Medical Device legislation and compliance
- Auditor experience
- Large Expertise in Various aspects of Validation and QA assets
- World Wide Work experience in various customers
- Broad Validation & QA experiences from various countries World wide
- Experienced in System validation
- Have a technical and hands-on personality
- Lean optimization and change management mindset
- Result oriented mindset
- Contributes to a great team atmosphere

IT SKILLS

- Microsoft Office | Outlook | Excel | Word | Power Point
- Data Bases (Registrations database CDM and MDM)
- SharePoint (Administrator)
- Document Control System (Agile)

- Lotus Note
- Data Base (SAP)
- Vault QualityDocs
- NovoDocs
- NovoGlow
- ISOtrain
  - SCADA /LMES
- TrackWise

EDUCATION AND DEGREES

2006	HD-O, (Grad Dip. (BSc.) in Business Adm. (Management and Organization))
2003	Diploma in Business Management, Niels Brock, CBC
1999	Environmental Coordinator Technical College, Elsinore
1997	Bachelors in science in Engineering with honours, Chemistry, Aalborg Uni.

CERTIFICATIONS AND COURSES

2022	Startup Spanish course. Online: Romansk Hus
2001-2019	Yearly GMP update, courses. Different providers
2016	ISPE 2016 Europe GAMP®-Data Integrity Conference. ISPE
2009	Quality Auditor, conducting audits using ISO standards, Dansk Standard, DS
2009	Accident Causation & Prevention basic course, Novo Nordisk A/S
2007	Site Denmark 5 module Leadership Programmers, Novo Nordisk A/S
2003	Good Automated Manufacturing Practice edition 4, GAMP 4, Novo Nordisk
2003	Pathfinder Trails: development, transformation, coaching Pathfinder Trails
2002	Presentation Technique, Novo Nordisk Engineering A/S
2002	Project Management course, Novo Nordisk Engineering
2002	GMP training by Mr. John Y. Lee, Novo Nordisk Engineering
2001	Microbiological contamination of Active Pharmaceutical Ingredients, Novo Nordisk A/S
2001	Fourth. CEFIC/APIC European Conference on Active, Pharmaceutical Ingredients, Concept Heidelberg
2001	GMP Compliance for Active Pharmaceutical Ingredients, Concept Heidelberg
2001	Quality Management System course, Novo Nordisk Engineering A/S
2000	GMP course, and good test practice for validation and qualification, Novo Nordisk Engineering A/S

2000	Management decided by circumstances, Greenland Contractors A/S Thule Air Base	

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent
Spanish	Written & spoken	Business

PROFESSIONAL BACKGROUND

2023 – Present

DahlfeltConsulting | Senior Validation Specialist

- Supporting companies being in compliance within Medical Device & Pharma in Quality Assurance
- Secure compliance throughout Validation, new suppliers & vendors
- Communications with Notify Body, FDA and Authorities
- Handling of CAPA
- Complaint handling
- Change request
- Overview of Standards and GAP assessment for new/updated standard
  - Mainly carrying out validation of robots, decoration machines, but also plastic components (parts for insulin and wegovy pens)

Feb. 2022 – Dec. 2022

GE Healthcare Norge A/S | Process Engineer

Responsible for preparation of cleaning validation report for cleaning of a holding vessel T106 after production of Clariscan batch in the sterile department. Furthermore, responsible for preparation of a URS for the new ''Combined vial wraparound label and cap labelling machine'' for upgrade of line 5 to meet requirements for supply of vials/bottles to the Japanese market. Also, carrying out the update of line 5's FMEA risk assessment and validation plan in relation to this "Combined vial wraparound label and cap labelling machine".

Sep. 2020 – Dec. 2021

ThermoFisher, Oslo, Norway | Senior Validation Expert

Responsible for the qualification of various kind of laboratory instruments (Med. Devices) (such as: Attune Acoustic Focusing Cytometer, NucleoCounter 3000TM, FlowCam 8000, Benchtop Centrifuge, using ISO13485:2016. Carried out, in coordination with the instrument owners, the preparation of the required documentation (Risk assessments, URS, IQ-protocols, OQ-protocols, and reports, PQ-protocols and reports, and carrying out the qualification tests, additionally taking care of review of test results, and the belonging documents such as, change requests, technical descriptions, SOPs of the instruments. At the same time, coordinating the cooperation between QA and R&D departments.

Dec. 2019 – May 2020

Stryker ESCS BV, Venlo, NL | Senior Validation Specialist

In connection with the new MDR, that came into force the 26th of May 2020, replacing MDD (93/42/EEC and 90/385/EEC). My assignment here was to ensure the company's existing ISO9001 system was excluded, and helped with their upstarted process, dividing their QMS into 2 QMS, that should fit into ISO 13485:2016 and the 21 CFR 800 series, that is required for medical devices. That implied among other things: Update of the Quality System Manual participating workshops ensuring implicated departments became clear about their tasks, planned their process mapping and procedure writing, supply chain mapping, and in close cooperation with implicated employees, mapped their daily work processes and established their procedures.

2019 - 2019

Chr. Olesen Pharma (COP) | Chief Quality Consultant

For COP (My Danish permanent costumer), I am carrying out Active Substance Master File (ASMF) for Diazepam, performing review corrections/updating of this draft version of this ASMF, provided by a Chinese supplier. Since July 2020 I have been working on a statement to the Danish Medicines Agency. Working on preparing a CEP for Diazepam.

June 2019 – Sep. 2019

Interpharma, IPP (Prague) | Validation expert & GMP Specialist

Carrying out CSV, Computer System Validation of a Cary 60 UV-Vis Spectrophotometer, using SW CaryWinUV. In details the job was to carry out the IQ, OQ and PQ for this equipment, meaning ensuring the preparation of the belonging protocols, test sheets, and carrying out the tests, in corporation with laboratory employees, and the IT manager of the company.

April 2019 – June 2019

Chr. Olesen Pharma (COP) | Quality Consultant

Responsible for the following: Establishing and carry out self-inspection in the company's QA dept. and ensure the following evaluation of this. Update of COP's GDP, QMS handbook, re training of employees. Establishing of a procedure for how COP get DMA to carry out GMP audits, of their API suppliers in China.

2018 – 2018

AlfaNordic A/S, Consultant | Brenntag Nordic, Validation Specialist

Ensure the preparation of qualification documentation for laboratory equipment, including incubators and secure test planning. Furthermore, initiating implementation of a zetasizer nano zs measuring equipment, and planning of the future method validation. During her time at Bavarian Nordic, she worked in the Process Support Department. The assignment was hired for were the following:

- Review of logbooks in some of the sterile production areas, a broad review to ensure the validated state of each equipment, so the company would be able to write the yearly equipment review.

2017, 2018

AlfaNordic A/S, Senior Consultant | Chr. Olesen Pharma, Validation Specialist

Responsible for ensuring establishing, and implementing of COP's GDP, QMS handbook. Including training of relevant employees.

2016 – 2017

AlfaNordic A/S, Senior Consultant | Novo Nordisk, Validation & Quality Specialist

Working as consultant at the Novo Nordisk A/S 1R (Purification Pilot project), CMC QA (Chemistry Manufacturing and Control development), as Quality Specialist. Hired in for a specific job having the responsibility of the following:

- Reviewed and carried out meetings and ensure approval of DQR for following systems: HVAC, Transformation stations, buffer mix systems, EtOH system, mobile tank system, LHU (Liquid Handling Unit), nitrogen systems, clean room, CIP systems.
- Review and approval of IRTP (acceptance tests), and IQP installation Qualification tests/IQR of the above-mentioned systems within 1R.
- Review and approval of ORTP (acceptance tests), and OQP function Qualification tests/OQR of the above-mentioned systems within 1R.
- And in connection with that ensure correct filling out of, and approval of VNCs, taking care of review/approval of URS, RTM, CCA, RRA and SOP's the above-mentioned systems within the 1R Pilot Plant.

2013 – 2015

Leo Pharma | Validation Specialist

Responsible for daily operations (e.g. deviations, change requests, update of SOPs, training), as well as validation/qualifying activities in finished goods production area.

- Responsible for validation/qualification activities within sterile production and packing.
- Responsible for the revalidation program for the sterile department, meaning cleaning validation, validation of autoclaves, and other thermal validation activities.
- Responsible for the warehouse area in general, the responsible party from My department who took part in our global validation/qualification project.

2013 – 2013

AlfaNordic A/S, Consultant | FEF Chemicals, Validation Specialist

Improvement of cold storage, which means temperature mapping, validation and qualification, preparation required paper documentation.

- Responsible for validation/qualification activities within a new renovated cold storage.

2011 – 2012

AlfaNordic A/S, Consultant | Novozymes (TEDA, Tianjin, China)

Quality support consultant, coaching employees in general Good Manufacturing Practice, coordination of Quality Assurance activities during Performance Qualification process:

- Responsible for training of Chinese employees in handling of deviations/change requests/corrective and preventive action.

2009 – 2010

Dong Energy (Currently Ørsted) | Exploration & Production area, Auditor

Exploration & Production area, Auditor Planning, Execution of internal and external audits including subcontractors and Suppliers. In the Oil, Gas, wind energy industry acting as consultant, provided recommendations with reference to ISO 14001, ISO 9001 & OHSAS 18001 systems and standards.

- Responsible for external supplier and subcontractor audits and internal audits as well.

2007 – 2008

Novo Nordisk A/S | Team leader, Insulin Filling

Implement Lean management projects, including defining dept. goals. conduct staff development interviews, employee competence development and training. Ensures the daily resources within day-to-day operations, ensures continuously improvements e.g. Right first-time regarding batch documents, and improvement of batch change over time, recruitment of new employees cooperates with QA, technical and process support.

- Responsible for management of a team of 21 employees in the insulin filling and inspection department Area.

2006 – 2007

Novo Nordisk Engineering A/S | Quality-Validation Coordinator

Managed the coordination of all quality activities across the project organizations. In charge of project resource administration:

- Responsible for validation and qualification of process equipment, buildings, installation, Operational, performance qualification and process validation.
- Preparation of validation/qualification and approval of other quality documents.
- Managing training of quality employees.

2004 – 2006

Novo Nordisk A/S | Process chemist and Quality-Validation Coordinator

Daily contact and close cooperation with process operators, and in connection with inspections. Working with coordination of various tasks related to the Danish

Medicines Agency Inspection. Daily corrections of process deviations, and shared responsibility for implementing LEAN in production.

- Responsible for start up the production of hemophiliac medicine production.
- Responsible for review of batch documentation
- Responsible for training of colleagues

2000 – 2004

Novo Nordisk Engineering A/S | Quality-Validation Coordinator

Establishing different pharma facilities, meaning process plants, pilot plants, laboratory areas. In charge of coordinating the quality activities across project organizations, in charge of administrating the project resources. Validation and qualification of process equipment and buildings, which means installation, operational, and performance qualification and process validation.

- Responsible for preparation and approval of quality documentation managing training of quality employees.
- Responsible for acting as internal consultant in a Novo Nordisk production for 1 year, carrying out process deviations in close corporation with QA, to ensure requirements is covered in the quality of protocols and reports regarding to validation and qualification of process equipment.

1999 – 2000

Greenland Contractors A/S | Project Manager, Thule Airbase

Development & implementation of ISO14001 Environmental Management system. (Also used time updating existing OHSAS18001 and ISO9001, was not a requirement in the project, but the extra time I had I made useful):

- Responsible to ensure all departments developed a real environmental mindset.
- Responsible in close corporation with Danish certification authority to ensure the certification of the ISO14001 Environmental Management system.

SELECTED ACHIEVEMENTS

- Establishing QMS procedures for Medical Devices, a body-worn activity sensor for health and research, ensuring requirements, using ISO 13485:2016, QSR- 21 CFR 820, 21 CFR 860

- Worked with Novo Nordisk A/S as QA rep. in the world biggest insulin bulk plant (API facility), handling all processes, validation of, Recovery, of new insulin types Aspart & Detemir.

- In both QA and QC positions worked with different kind of continuous improvements

Acted as Quality Coordinator between disciplines and suppliers in related subjects and issues, and as Insulin Filling Team Leader, responsible for a team of 21 employees.

- Carried out validation/qualification activities within Medical Device & Pharma projects/production/sterile production, also CSV for laboratory equipment, all in different companies, national and international.

- Educated Chinese Engineers in handling of Non-Conformities in China, within a Chinese Novozymes A/S facility.

- Establish (validation and commissioning of production facilities) of NN A/S' hemophiliac medicine production facility, establish large cold storage at pharmaceutical facilities.

- In charge of coordinating quality activities across project organizations, during establishing of mentioned pharma facilities, and the corresponding process equipment.

- As Project Manager developed and implemented (got it certified by DS), ISO14001 EMS, and started up the development, implementation of OHSAS18001, both at Thule Air Base.