CV

Company Information

Full name	**Pharma Compliance DK ApS**
Address	Charlotte Muncks vej 10, 3 th. DK-2400 Copenhagen NV. Denmark
Mobile	(+45) 5153 9488
Email	info@pharmacompliance.dk
Web	www.pharmacompliance.dk
Company located / registered	Copenhagen - Denmark
CVR / VAT number	436 91 449

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Working experience

Date	**2023 (Jan.) – current**
Position	Consultant – own consultancy firm.
Responsibility	Providing services within QMS, Commissioning/Qualification & Validation, and IT (GxP). List of services can be found at www.PharmaCompliance.dk Projects: • NN Adobe Acrobat GxP signature (cloud) (via eWork) • NN Azure ARC rollout on-prem (phase 1 & 2) (via Aeven) • NN Container Image Security scan (NMCR) (cloud) release 1.0 & 2.0 (via Aeven) • NN Windows Server 2019 (Azure) (cloud) (via Aeven) • NN Windows Server 2022 on-prem/private cloud (via Aeven) • NN RHEL 8.9 & 9.3 on-prem/private cloud (via Aeven) • NN Azure SQL Managed instance (via Aeven) • Assist SA-Elektronik.dk with ad-hoc & minor tasks related to Computerized Equipment.
Address of employer	**Pharma Compliance DK ApS** Charlotte Muncks vej 10, 3 th., DK-2400 Copenhagen NV, Denmark.
Date	**2021 (May) – 2022 (Dec.)**
Position	Principal (IT) GxP Consultant.

Responsibility	Helping and assisting with testing efforts for Mobile app based on SaMD (Software as Medical Device) at Novo Nordisk A/S – dep. Digital Health IT (Soeborg).
	
	Perform internal audit of PharmaIT QMS – towards:
	• FDA (21 CFR Part 820) Quality System Regulation (QSR)
	• EMA (EudraLex – Vol. 4 – Chapter 1) Pharmaceutical Quality System (PQS) incl. section
	  ○ EMA (EudraLex – Vol. 4 – Chapter 2) – Personnel.
	  ○ EMA (EudraLex – Vol. 4 – Chapter 4) – Documentation.
	  ○ EMA (EudraLex – Vol. 4 – Chapter 9) - Self Inspection.
	  ○ EMA (EudraLex – Vol. 4 – Annex 11) - Computerised Systems.
	  ○ EMA (EudraLex – Vol. 4 – Annex 15) - Qualification and Validation.
	• ICH (Q10) Pharmaceutical Quality System (PQS).

Address of employer	**PharmaIT** Ny Carlsberg vej 80, DK-1760 Copenhagen, Denmark.

Date	**2019 (Jan.) – 2021 (Apr.)**
Position	IT GxP Validation Manager
Responsibility	Lead, maintain & develop compliance to ZP quality, regulatory and business req. Validation/qualification of on-premise based solutions, systems and applications. Qualification of cloud & off-premise based solutions, systems and applications. Performing qualification of IT Infrastructure and related components. IT GxP projects & cooperating with external partners. Assisting and advising dep. with interpretation of regulatory req./expectations Configuration/Change Management related to IT Infrastructure, systems & applications. Writing/updating technical and system documentation. Assist in managing IT Infrastructure & systems related to Zealand Pharma. Resolving issues related to the IT Infrastructure and applications. Advanced problem solving / Root cause analysis. Review of test documentation in connection with qualification of new computer systems. **Projects:** • Azure / O365 qualification. • Argus Safety DB (Pharmacovigilance) assist with validation efforts (where possible). • Inventory/Stock Management (in Microsoft Dynamics AX 2012 R3) (where possible). • QAD ERP (Stock Management). • eArchive for long-term storage. • SAS Analytics. • DocuSign Life Sciences module for electronic signature. • Assist Supply Chain with regulatory req. (DSCSA) for Serialization according to EMA/FDA with serialization partner TraceLink. • Validation/qualification of on-premise systems & applications (Backup upgrade, Windows, Clinical Data Repository, electronic Archive, Network, SOP revisions). **Areas of personal interest:** • Medical Devices (Part 820, ISO 13485/14155/14971, EU MDR, IEC 62304). • Modern Qualification and Validation. • Continuous Process Verification (CPV) / Traditional Process Validation (TPV) • Electronic Records & Data Integrity / Data Management & Governance. • Lean & Process optimization.
Address of employer	**Zealand Pharma A/S** Sydmarken 11, DK-2860 Soeborg, Denmark.

Date	**2016 (Oct.) – 2018 (Dec.)**
Position	Senior Quality Specialist
Responsibility	• Perform tasks related to Qualified (IT) Infrastructure for NN. • Planning and executing Validation, Qualification and Changes. • Quality Consultancy to specific projects. • Quality Awareness. • Quality GAP Examination. • Manage complex QA & validation activities. • Monthly compliance check on NN Changes (Compliance Oversight). • Assisting LoB with compliance with QMS and regulatory requirements. • Validation of Computer Related Systems in all types of environment. Actively seeking to assist with internal and external projects with knowledge/project work as/where needed. Communication with customers/external partners with the aim of reaching consensus and solution acceptance. Analyze complex issues and improve methods, concepts, techniques or processes across areas of work or function. Understanding of regulatory requirements relating key business processes of pharma, biotech and/or medical devices. Knowledge of Quality processes relation to one or more models/practices for implementation and Operation & Maintenance of IT Systems. Work with very high degree of structure and express complex and abstract issues (written or oral). **Projects:** • QC for Infrastructure platform for Amplexor/Abbot. • QC for UPN change in Novo Nordisk. • QC for BIT9 Agent qualification to ver. 8.0 for Novo Nordisk. • QC for upgrade of AD Schema to Windows 2016 for Novo Nordisk. • QC for CyberARK/PIM qualification from ver. 7.2 to ver. 9.7 for Novo Nordisk. • QC for Windows 7 (retrospective) qualification for Novo Nordisk. • QC for Windows 10 (incl. backend), AFDS & Office 365 for Novo Nordisk. • QC for Windows 10 (LTSC) for QC Laboratory area for Novo Nordisk (only start-up). • QC for AFDS Upgrade (existing solution) for Novo Nordisk. • QC for qualification of underlying Infrastructure component for Novo Nordisk. • QC for mini-qualification in transition of Novo A/S to NNIT (non-pharma). • QC for assisting LoB with CRR & IT PSE for Novo Nordisk services. • QC for raising Compliance level for specific services from Critical to Qualified Infrastructure for Novo Nordisk. • QC for assisting LoB with handling qualification & changes for Infrastructure services related to Novo Nordisk.
Address of employer	**NNIT A/S** Ostmarken 3A, DK-2860 Soeborg, Denmark.
Date	**2014 (Nov.)– 2016 (Sep.)**
Position	Production & Validation Responsible.
Responsibility	Production & Validation Responsible for BMS Computer system & Process. Responsible for User Requirement Specification & Technical Specification. Responsible for implementation & maintenance of BMS. Assisting in creation of Standard BMS requirement package. Area specialist for BMS. Ensure cGMP compliance. Member of NN Global ITQ Forum. Audit responsible for BMS. Drive and implement new guidelines and requirements concerning BMS. Facilitate cross functional cooperation. Delivery of complete, working and validated BMS package incl. documentation. Ensure daily support and consulting to production units and support units concerning BMS
Address of employer	**Novo Nordisk A/S** Brennum Park – 25C, DK-3400 Hillerod, Denmark.

Date	**2009 (Apr.) – 2014 (Oct.)**
Position	IT Site Coordinator (until 2013.11.01) & IT Infrastructure Manager.
Responsibility	Managing IT Infrastructure related to Building Management Systems (BMS) and Facility Monitoring Systems (FMS). Advanced problem solving / Root cause analysis. Active Directory and Domain Policy Management. Resolving issues related to the IT Infrastructure and applications. Configuration/Change Management and Baseline accounting. Day-to-day operation of IT Infrastructure. Ensuring continuous compliance of validated status. System Monitoring of IT Infrastructure, Applications and systems. Performing Annual Evaluation of validation status. User Management. Software and License Management. User Requirement Specifications. Review of Qualification and Validation of new computer systems and applications. Review of Qualification and Validation of new Substations (PLC/Controller) for BMS. Operating and maintaining physical IT Infrastructure (Server-to-Clients). Operating and maintaining virtual IT Infrastructure (Server-to-Clients). Cooperating with different partners, such as: NNIT Network, HP etc. Review of test documentation in connection with qualification of new computer systems. Assisting and advising manufacturing departments (dep. 111 & 193) with interpretation of IT instructions.
Address of employer	**Novo Nordisk A/S** Hagedornsvej 1, DK-2820 Gentofte, Denmark.
Date	**2006 (Jan.) – 2009 (Mar.)**
Position	IT-consultant
Responsibility	Helping users at Novo Nordisk with IT-related problems (On Site, Service Desk and Application Support). Resolving IT issues in cooperation with other departments. Providing solutions for knowledge database. Office 2000, 2003 and XP. Citrix and Anti-virus on desktop platforms. Deployment of Anti-virus definition updates to NNIT and NN. Developing and maintaining automated virus cleaning tool for infected computers. VPN, RAS.
Achievements	Open-house recruitment for new potential candidates. Participating at IT Match Making at IT-University for NNIT. Participating in the formation of an agreement between NNIT and HealthCare IT.
Address of employer	**NNIT A/S** Aslaksvej 3, building 8U, DK-2880 Bagsvaerd, Denmark
Date	**2005 – 2006 (9 months).**
Position	(Student) Employee as System Administrator for Windows and Network.
Responsibility	- Windows NT 4 server. - Access and user rights access to domain controller. - Introduction to webmail, network drives, FTP, Word, PowerPoint etc. - Helping users with IT related issues.
Address of employer	**The Ecological Council** Blegdamsvej 4B. DK-2200 Copenhagen N. Denmark.

Education

2004 – 2006	(not completed) M.Sc. in e-Business at IT-University of Copenhagen.
2003 - 2004	B.Sc. in Media and Computer Science from Aalborg University.
2002	Unemployed.
1999 - 2001	New Media Manager from Copenhagen Technical School.
1996 - 1999	Higher Technical College (HTX).
1994 - 1996	Metropolitan College (Mathematical branch).
1985 - 1994	Public school (Hillerodgade school).

Courses, seminars and expos

2025 (Jan)	*Medical Device Cybersecurity – introduction* • Embed Cybersecurity: Integrate into medical device engineering. • Secure Connectivity: Address network & cloud security needs. • Strategy: Anticipate cybersecurity risks. • Protect Interests: Safeguard patient safety & data privacy. • Regulatory Updates: Navigate US/EU cybersecurity requirements. (1½ hour) (Alex Wirth chief security strategist – Medcrypt.com)(IDA Copenhagen V.)
2024 (Apr)	*Planning and Executing of Quality Audits* • The future of audits - Regulatory thinking. • The use of AI in audits. • Remote Audits. • Remote Data Access. (2 hours) (Thomas Bo Sølver / Jesper Madsen Wagner - NIRAS)(IDA Copenhagen V.)
2023 (Nov)	*Gå hjem-møde for ITQA – beskrivelse/description:* This first meeting is GMP, the topics and content will be relevant to all GxP areas. We will present a selection of the proposed changes to GMP Annex 11, which are described in the **Concept Paper** that has been open to public consultation, and we will draw parallels to **GCP** in the form of the recently entered into force Guideline on Computerized Systems and Electronic Data. There will be presentations from the industry and time to discuss solutions. (2½ hours) (Ib Alstrup - Inspector)(DKMA Copenhagen S.)
2022 (Apr)	*USP Stakeholder Forum (webinar/webex)* Session will cover the new USP General Chapter <1220> Analytical Procedure Life Cycle: - Introduction to the USP General Chapter <1220> - Rationale behind its creation, - Regulatory views of the chapter, - Potential use cases in the industry. Incl. short case study to illustrate the application of Quality Risk Management (QRM) to procedure development and definition of the Method operable design region (MODR). (45 min) (Amanda Guiraldelli Mahr – Scientific Affairs Manager at US Pharmacopeia)
2020 (Apr)	*Everything you need to know about FDA's upcoming guidance on CSA* • Pain points of CSV, as identified by the industry to the FDA. • Overview of key elements of the FDA's draft CSA guidance. • How CSA addresses the current CSV pain points. • Key lessons learned from implementing CSA at numerous clients. • Links to prior FDA & Compliance Group co-presentations, as well as upcoming webinars. • Live Q & A. (1 hour) (Francisco Vicenty / Khaled Moussally / Stephen Cook)(FDA webinar via compliancereg.com)
2020 (Feb)	*Update from the FDA on CSV Changes* • Why the FDA is moving from "validation" to "assurance". • What Computer Software Assurance means to you. • Examples of risk evaluation and acceptable records. • Live Q & A. (1 hour)(Francisco Vicenty)(FDA webinar via readytalk.com)
2020 (Feb)	*Validation, measurement and calibration according to cGMP* • Regulatory req. • Qualification of measure systems MS • Installation of measuring equipment • Systems for handling of measure equipment • Possible vendor agreements • Validation, temperature regulated facilities. (1½ hours) (Mai-Britt Olafsson / Benny Nordstrøm / Sanne Berggreen)(AlfaNordic Herlev)

2019 (Dec)

Patient engagement in R&D at Zealand Pharma
• FDA Expectation to patient involvement in R&D.
• "Common Issues in Drug Development FDA Guidance for Industry".
• Patient Preference Information (PPI).
• Patient Reported Outcome (PRO).
• EMA Regulatory Science Strategy (RSS) 2025.
• Advancing patient centred access to medicines in partnership with healthcare systems.
• FDA/EMA patient engagement cluster.
• The NORD Handbook - Rare Disease Collaboration Handbook.
(1½ hour Lunch presentation)(Eva Bøge, Trine B. Moulvad, Mike Hall)(ZP Sydmarken)

2019 (Nov)

EU MDR
Medical Device Regulation (MDR) or 2017/745 The Medical Devices Regulation will change the everyday lives of all players who are part of the supply chain: Manufacturers, Person Responsible for Regulatory Compliance, importers & distributors of medical devices.

• MDR and the change management ABC.
• Good implementation practice.
• Tips and tricks.
(1½ hours)(Ole Markersen)(AlfaNordic Herlev)

2019 (Oct)

Multiplicity and Duplo - Multiple endpoints in clinical trials
• Statistical Challenges for Small sized Clinical Trials
(1 hour Lunch presentation)(Kim Mark Knudsen)(ZP Sydmarken)

2019 (Aug)

FDA Shares a New Approach to CSV - A "Straight from the Source" Webinar
https://zoom.us/recording/play/W2Fq8oTF2mZ5otP23fKpNqEbyVa3ISLTXtAkp4c5mmA0h3GOb9Qi8noZhlXc5_OF?continueMode=true&tokenMeetingId=Andgs7WlkgyyXAxCtX7ckZjRzOx-yBDCF4v1JoVi5LWwIumekTziMw
(1 hour webinar)(Francisco Vicenty – Program manager CDRH Office for Compliance)

2019 (Apr)

Siemens Polarion (implementations partner: Taipuva)
• How Polarion helps companies in regulated industries incl. demonstration.
• Polarion implementation and experiences at Radiometer Medical.
• Agile Co-creation of Next Generation Medical Devices by Innokas Medical.
(2 hours)(Tapio Tuomola)(Taipuva) (Copenhagen)

2019 (Jan)

Serialization
Topics:
• The need for aggregation to cover the supply chain needs.
• Anti-Tampering Device (the overlooked security req.).
• Your own organization readiness & ownership after 9th of Feb. 2019.
• Business advantages with serialization.
• Compliance & Quality in general (Code grading, reconciliation, re-pack, decommission, returned goods, stock management, alarm management).
(2½ hours)(Lars Olsen)(Sigma)(PharmaDanmark Hellerup)

2018

Cloud Data/Outsourcing of Data
Cloud solutions in regulated industries, can be a complex size to handle, but often provides significant business value.

From compliance perspective, there are many considerations to taken before the most important data in the company is 'put out in the city'. Cloud can be used with advantage in a number of areas, if the risk factors are handled correctly.

Topics to be addressed:
• Architecture and types of clouds.
• Vendor Management.
• Data classification.
• Strategic enablers.
(Kasper Nørgaard Andersen - Alfa Nordic) & (Jens Seest - Novartis)
(1½ hours)(AlfaNordic Herlev)

2018

Microsoft Tech Summit
(1 day)(Bella Center, Copenhagen)

2018

TMLS Basics Training.
A hands-on TMLS training session.
The training will include how to
• Create Document Requirements.
• Create Test Cases, and use parameters and configurations.
• Create Test Sets (Planning & Reporting).
• Execute Runs.
• Defect Management in TMLS.
• Set up approval workflow and approve items.
(7 hours) (Pia Nøhr Ellegaard)(NNIT HQ)

2018 *Environmental requirements for GMP Production.*

- In connection with GMP production, there are requirements to the purity of the product, as well as the environment, where the product is produced.
- This introduction will have focus on the existing and the coming requirements for facilities for GMP production.
- Background in Eudralex/EU GMP Annex 1, FDA Aseptic guide, ISO 14644/14698 and in part, of how to live up to these requirements in practice illustrated via concrete case.

(Lene Blicher Olesen)(Alfa Nordic) & (Christian Larsson)(Novo Nordisk)
(1½ hours)(AlfaNordic Herlev)

2018 *GxP Basics covering.*

- Introduction
- The GxP mindset:
  - Why GxP is important to know and follow.
  - The long road to developing a new drug.
  - Control of the Life Science sector.
  - Why control is necessary.
- NNIT and Life Sciences industry:
  - NNIT and Life Science customers.
  - What is GxP.
  - Validation.
  - Data Integrity.
- Regulation – General knowledge of the regulations in the Life Sciences industry:
  - The regulations you need to know.
  - 21 CFR part 11.
- NNIT Specifics:
  - What does GxP mean for NNIT.
  - What GxP means for your daily work.
  - QMS/QMIT ensures compliance with GxP.
  - How to identify if system is GxP or not?

(1 hour)(Interactive web based training)(NNIT HQ)

2018 *GxP Change Management in NNIT covering.*

- Introduction:
  - Change management and GxP.
  - Roles and Responsibility.
- GxP change handling in NNIT:
  - Normal GxP Change in NNIT.
  - STD113 instructions.
  - Making sure to work in compliance.

(1 hour)(Interactive web based training)(NNIT HQ)

2018 *GMP Audit & Inspection.*

- Basis for Audit & Inspection from Health Authorities.
- A Global view on inspections.

(2 hours) (Inge-Lise Rønnow)(Alfa Nordic) & (Henrik Friese)(Novo Nordisk)

2018 Risk Assessment in Life Sciences industry according to ICH Q9 (Quality Risk Management)
(1½ hours) (Frank Winther-Hinge) (AlfaNordic Herlev)

2017 *Measuring and Calibration according to cGMP.*
An inspiration meeting from a practical approach, for Metrology & Measuring equipment qualification in Life Science industry.
(1½ hours) (Peter S. Anthonisen) (AlfaNordic Herlev)

2017 Risk assessment for GxP systems according to NNIT QMS Processes and Procedures.
(3½ hours) (Anders Vidstrup/AVID) (NNIT HQ)

2017 *SOP Inspiration/topics meeting.*

- Defining framework and limitation of SOP.
- Purpose of SOP.
- When is a SOP good? Language use and barriers.
- SOP that works – focused, readable (lix number) and intentions.

(1½ hour)(Mai-Britt Olafsson)(AlfaNordic Herlev)

2017 *NC3 – National Cyber Crime Center in Denmark.*

- NC3 talk insights into NC3's work and achievements.
- Peak into the authorities work.
- Hear what kind of Cyber Crime NC3 experience.

(2 hours)(Lars Egholm Blomgaard)(NNIT HQ)

2017 *EMA Annex 15 (Qualification & Validation) walkthrough.*

- Comparison with FDA Process and Validation Guide.
- Examples of new thinking within Qualification and Validation.
- Incl. focus on time, money and complexity of Qualification & Validation projects.

(2½ hour)(Gert Mølgaard)(AlfaNordic Herlev)

2017	Data Integrity/Compliance in Pharma & Medico (FDA & ISO13485) + Challenges in Validation of software & Cloud solutions. (1½ hour)(Tom Andersen)(AlfaNordic Herlev)
2016	LEAN & Operational Excellence (Case: Radiometer / Mads Friis)(NNIT Oestmarken).
2016	Training in SOP-writing (NN Hilleroed).
2016	Global ITQ Forum: Inspection setup of Corporate IT, Introducing System Architecture.
2015	On-The-Job Training for CR case (NN Bagsvaerd) (5 hours).
2015	Good Documentation Practice (NN Bagsvaerd) (2 hours).
2015	Mandatory Yearly GMP Training (Scope: Data Integrity, Quality Metrics, Risk Based Approach, Quality oversight, Facility upgrades, GMP Trends, non-conformity). (NN Bagsvaerd – Webinar/Online training) (3 hours)
2015	IT compliance, Regulatory req., GAMP5, Data Integrity, Cloud Computing (NN Bagsvaerd)
2015	PS eTIMS (HP QC 9.2) 2-day Workflow Course - beginner (NN Bagsvaerd).
2015	Agile System Development and GxP Systems (ISPE/GAMP) (NN Bagsvaerd).
2015	eTIMS (HP QC 9.2) – 1/2 day Introduction Course (NNE Pharmaplan Gentofte).
2015	Product Supply - CR NovoGloW Change Owner & QA approver training (NN Bagsvaerd).
2015	IT Project Management Methodology (NN Bagsvaerd).
2015	Training in Validation approach (QBIQ: 169742) (NN Bagsvaerd) (3 hours).
2014	Validation in Product Supply (NN Bagsvaerd).
2014	Introduction to the IT Processes and the IT Quality portal (NN Bagsvaerd).
2013	Good Test practice (NN Bagsvaerd).
2012	VMware – vSphere: Fast Track [V5.0] (Arrow ECS – Ballerup).
2012	CA ARCserve R16, D2D, replication and High Availability (Arrow ECS – Ballerup).
2011	Do's and don'ts at FDA inspections (NN Gentofte).
2011	Security of IT Systems (NN Bagsvaerd).
2011	Regulatory Requirements for Computer Systems (intro) (NN Bagsvaerd).
2011	GMP-2 Walkthrough of EU-GMP (NN Bagsvaerd).
2011	QA and System Manager for GxP critical IT Systems (NN Bagsvaerd).
2010	Introduction to GAMP5 (NN Bagsvaerd).
2010	VMware VMWORLD2010 (Bella Center).
2010	Test of Computer Systems (NN Bagsvaerd).
2010	Introduction to Periodic System Evaluation (NN Bagsvaerd).
2009	Master Service Agreement Training (NN / NNIT Soeborg).
2009	Computer Validation (NN Bagsvaerd).
2009	Writing and approving local SOP (NN Bagsvaerd).
2009	Inspection readiness of Computer Systems (NN Bagsvaerd).
2009	Information security (Olympia hall, central London) www.infosec.co.uk
2009	Risk assessment of Computer Systems (NN Bagsvaerd).
2009	Regulatory Requirements for Computer Systems (intro) (NN Bagsvaerd).
2007	IT Customer Consultant – Module 1 (NNIT Skodsborg).
2007	Information security (Olympia hall, central London) www.infosec.co.uk
2007	Business Continuity Expo 2007 (Excel Exhibition Centre, London) (2 days).
2006	Novo Nordisk Global Service Desk (NNIT Bagsvaerd).
2006	Pharma Days, Understanding the basics of R&D within the Bio and Pharmaceutical sector (2 days) (NN & NNIT Skodsborg).

Personal & Professional skills

Language skills

	Oral	**Reading**	**Written**
Danish	Native	Native	Native
English (American)	Native-like	Native-like	Native-like

Social skills and competencies	-Through my studies and work related assignments, I've learned to work together with different groups of people. Which in return has developed me as a person and my communication skills.
Personality	Positive. Down to earth/Realistic/Pragmatic. Committed. Detail oriented. Practical.
Computer skills	Active Directory, Domain controller. Citrix (Desktop). VMware (Workstation & ESXi) Microsoft Office 2000/2003/2007/2010/2013/2016/Office 365. Microsoft Windows 95, 98, 98 SE, 2000, XP, Vista, 7, 10, 11.
References	Contact ISKH
Driver license	Category B.