

DAHLFELTCONSULTING

CONSULTANT CV WITHIN QA/QC, LEAD AUDITOR

Name Lil Orsini
Nationality Danish
Gender Female
Domicile Denmark

CONTACT INFORMATION

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LIL ORSINI - CURRICULUM VITAE

PERSONAL LETTER

Lil has 23 years of experience in QA whereof 7 years in QC within production and distribution of pharmaceuticals, food supplements, medical devices and IVDR as Quality Coordinator/Assistant/Responsible and furthermore ECA Certified QA Manager.

From Lil's role in QA, she has gained an extensive understanding of the relations between daily operations and quality management, which has given her a pragmatic approach to solve tasks. By auditing, preparation and approval of SOPs her work, has been performed in accordance with applicable legal requirements and guidelines. Therefore, it is natural for her to read, assess and implement requirements.

To organize and maintain quality tasks is an exciting challenge for Lil. As Lil finds it natural to think of improvements and optimization, she has participated in several quality improvement projects.

Presentation, education and training, has been a natural conclusion of tasks and has been carried out at all levels of the organization. Lil thrives in an environment with a high level of quality mindset and dynamics.

As a person she is structured, proactive and involved. It is important to Lil to be authentic and obliging. Flexibility and service are a fundamental part of her personality. Analytically she is quick and sharp. And then she is cheerful and has a positive attitude and thereby contributing with good energy to the group.

Lil takes interest in peoples wellbeing and has therefore for several years performed voluntary social work, as a mentor for young people with challenges. In this connection, Lil has completed courses in; Crisis-Psychology, The difficult conversation and From Victim to Human being. Beside that Lil is a board member in a newly established homeowner association of 192 apartments.

STRENGTHS

- ❖ The ability to plan a strategy, goals, a project, tasks, resources and reach these in cooperation with colleagues and management
- ❖ Great overview and an eye for details
- ❖ Go to work with the mindset of working hard and having a good time
- ❖ Goal oriented and perseverant

EXPERTISE

- ❖ Development, maintenance and approval of quality systems (QMS)
- ❖ Lead auditor - planning, conducting, reporting and follow up on internal audits

- ❖ Review of Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) protocols and reports
- ❖ Batch Review
- ❖ Complaint handling, NC / Documentation
- ❖ Investigation report & Trending
- ❖ Coordinating and conducting recalls – contact to health authorities
- ❖ Change Control
- ❖ Deviation management and CAPA
- ❖ GAP assessments
- ❖ Quality Agreements
- ❖ Optimization of quality systems
- ❖ Writing and approval of SOPs
- ❖ Education, training and presentation
- ❖ Specialist working in ISO 13485, Eudralex vol 4, GDP, ISO 13485, FDA 21 CFR Part 210 & 820 and food legislation

IT SKILLS

- ❖ Vault QualityDocs
- ❖ novoDocs
- ❖ novoGlow
- ❖ ISOtrain
- ❖ TrackWise
- ❖ Microsoft Office
- ❖ Microsoft Visio etc.

EDUCATION AND DEGREES

1986-1989 B.Sc. in Medical Laboratory Technology, Frederiksberg Hospital

CERTIFICATIONS AND COURSES

2025 Certified QA Manager-ECA

2025 Quality Culture. ECA 2 days

2024 Lean GMP Systems. ECA 2 days

2022 Personal Leadership Program – PLPPM II - Acuity World, Education ongoing

2020 Personal Leadership Program – PLPPM I - Acuity World, 14 days

2019 Data Integrity and Good Documentation Practice. ECA, 2½ days

2018 Introduction to Management– Mannaz, 3 days

2017 The Validation Manager in the Pharmaceutical Industry – ECA, 3 days

2017 Quality Risk Management (ICH Q9) – ECA, 2 days

2017 Deviation Management and CAPA. ECA, 2 days

2016 Complaint Handling and Recall Management. ECA, 2 days

2015 ISO 9001/13485 Auditor/Lead Auditor. IRCA Approved (examined), 5 days

- 2014 Quality Risk Management. Pharmakon, 1 day
- 2013 GDP 2 – Quality Management. Pharmakon, 1 day
- 2013 GDP- rules-requirements-interpretation (examined). Pharmakon, 2 days
- 2012 GDP 1- Basic. Pharmakon, 1 day
- 2008 Anatomy. William Cook Europe, 4 days
- 2008 DS/EN ISO 13485:2003 Compliance – a strategic decision. DK standard, 2 days
- 2008 Introduction to clinical drug trials. Handling of test drugs. Chp.Uni.Hosp., 1 day
- 2007 Self Inspections and Audits. Pharmakon, 3 days
- 2005 Workshop: SOP-writing. Pharmakon, 1 day
- 2005 Workshop: Handling of deviations. Pharmakon, 1 day
- 2003 GMP for Packaging. Pharmakon, 1 day
- 2003 GMP and dissemination. Pharmakon, 3 day
- 2002 Review of batch records. Pharmakon, 1 day

LANGUAGE SKILLS	Danish	Written & spoken	Native
	English	Written & spoken	Fluent

PROFESSIONAL BACKGROUND

2023 - Present
[DahlfeltConsulting](#) | **Senior Consultant**
 Consultancy tasks within Pharma, IVDR and medical Device, hereby QA & QC

2020 – 2023
[Sigma Connectivity Denmark](#) | **Senior Consultant**

Worked for clients within:

- ❖ Review of pharmaceutical batches
- ❖ Deviation management - handling and investigation of deviations
- ❖ Mentoring, Training & education
- ❖ Eudralex vol 4, GMP, GDP
- ❖ Change request support
- ❖ Updating raw material specifications

2014 – 2020
[AlfaNordic](#) | **Senior QA Consultant**

- ❖ Bavarian Nordic Pharma | Production Support: Batch Review, Investigation of deviations, Supplier complaints, Change Notifications from suppliers, Change Request, Aseptic Process Simulation Reports, SOP & specification updates.
- ❖ Biogen Pharma | QA LSM Cell Culture and Purification: Batch Review, Deviation trending, Compliance adherence project. Batch Review optimization project.

- ❖ **Widex Medical Device** | Global Quality System: Handling of deviations.
- ❖ **Agilent IVDR** | FDA Remediation Program and QA: Training, Change Control review, GAP Assessments | Batch Reports evaluation, QA support, QMS, Complaint handling, Review of validation protocols and reports (IQ/OQ/PQ/IPV), Change Management.
- ❖ **Biogen** | Label & Packaging: Investigation of deviations, support, PQR.

2012 – 2014

[Teva Pharmaceuticals](#) | QA Officer

- ❖ Quality Responsible according to GDP
- ❖ Optimizing the Quality System, including writing SOPs and training the organization
- ❖ Implementation of the new GDP guideline
- ❖ Final release to market of finished products
- ❖ Handling of complaints, recalls, deviations, CAPA and Change Control

2009 – 2012

[Sandoz A/S](#) | QA/QC Coordinator

- ❖ Final release to market of finished products
- ❖ Maintenance of SOPs within my responsibility area
- ❖ Performing Internal audits as Lead Auditor

2008 - 2009

[William Cook Europe](#) | Quality System Coordinator

- ❖ Approval of SOPs
- ❖ Performing Internal audits as Lead Auditor
- ❖ Responsible for the ISO-Standard System
- ❖ Participating in projects

2007 – 2008

[Nomeco](#) | QA Assistant

- ❖ Quality control of incoming APIs
- ❖ Batch review for bulk production, finished products and packaging of clinical trials
- ❖ Performing Internal audits as Lead Auditor

2004 – 2007

[Axellus](#) | QA Assistant

- ❖ Approval and handling of deviation reports
- ❖ Optimizing of SOPs
- ❖ Performing Internal audits as Lead Auditor
- ❖ Batch review for bulk production, QC and packaging for pharmaceuticals and food supplements
- ❖ Participating in projects

2002 – 2004

[ALK-Abelló A/S | QA Assistant](#)

- ❖ Batch review for bulk production (sterile) and packaging

2000 – 2002

[Novo Nordisk A/S | QC Laboratory Assistant](#)

- ❖ Conducting analysis of SDS-page and ELISA
- ❖ Maintenance, control, evaluation, qualification and purchasing of laboratory equipment

1999 – 2000

[Københavns Praktiserende Lægers Laboratorium | Medical Laboratory Technologist](#)

- ❖ Performing medical laboratory tests

1998 – 1999

[Frederiksberg Hospital | Medical Laboratory Technologist](#)

- ❖ Performing medical laboratory tests

ACHIEVEMENTS

- ❖ Optimized an existing inadequate quality system in a year to comply in parallel with the management of operational tasks. Subsequent audit from the head office gave the lowest number of observations at European level among Commercial Units.
- ❖ Added additional value to the traditional conformity audit by also looking at goals, strategies and opportunities for improvement in interaction with existing systems.
- ❖ Developed a system for deviation management for the purpose of documentation recording, monitoring and trending.
- ❖ Made extensive changes to the batch documentation for optimizing workflows and building quality into the processes.

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