Curriculum vitae

Name	Gitte Fuglsang-Fog
Nationality	Danish
Gender	She/Her
Domicil	Ballerup, Denmark

Contact Information

Name	CEO and owner Torben Dahlfelt
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Personal Letter

The red thread throughout my +25 years in the pharmacuetical industry is Quality Control and Quality Assurance where I have applied my skills to plan, implement and set targets.

I have many years of experience with stakeholder and change management across an international organisation. These have been important tools to obtain a common understanding of process direction, and to ensure that goals and process changes are commonly accepted to secure a smooth implementation.

Meeting and implementing regulatory requirements has been a big part of my responsibilities and which have given me a solid knowledge within GMP, ISO-13485, FDA 21CFR and MDR. The regulatory knowledge have been gained within below mentioned experiences and during close collaboaration with various stakeholders.

Expertise within the last 10 years:

- Quality Management Systems (QMS)
- Quality Risk Management within area of responsibility
- Value stream mapping of quality processes (flow charts)
- Process owner delegate for global quality processes (Customer Complaints and External requirements)
- Process optimization of global quality processes to comply with regulatory requirements
- Process monitoring to identify challenges and improve the user experience
- Drive quality projects (ex. alignment of data quality and process review)
- Core member in implementation of new systems and projects
- Participant during continuous improvement to IT systems, Power BI ect.
- Manage Process groups and provide training during new implementations
- Manage quality issues via Deviations, Change Controls, CAPAs etc.
- Document management (Maintain SOP, WI, ENC and training documentation)
- Presenter of global quality processes during audits and inspections
- Analyze data, visualize and communicate adverse trends and KPIs

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Strengths:

I am a very outgoing person with a positive mindset, who is keen to make my colleagues and stakeholders even better by building a great team spirit and an open atmosphere. I am a quick learner with a great overview and can adapt to a complex and dynamic business model. I am persistent and willing to go the extra mile to deliver solutions of high quality.

IT Skills :

- Veeva Vault (QualityDocs and Quality vault)
- Microsoft office
- Microsoft Visio
- Outlook
- TEAMS/SharePoint
- TrackWise

Education and degrees

1989 – 1990 Laboratory Technician, Laborantskolen (The laboratory school)

Certifications and courses (most relevant)

- Prosci - Certification in Change Management (planned for June 2023)
- Lean Six Sigma, yellow belt (2023)
- Annual GMP Update, Different providers
- Project Manager training, Implement (2021)
- Profit realization, LEO Pharma (2021)
- Author course, "Write good instructions", LEO Pharma (2020)
- Introduction to Change Management, LEO Pharma (2020)
- Test Center, Test Execution (Veeva Vault), LEO Pharma (2019)

Language skills — Level

Danish – written and spoken	Native
English – written and spoken	Fluent

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Professional background

Dahlfeltconsulting
Apr 2023 – now, Senior Consultant Quality Assurance
Consultancy tasks within Pharma

LEO Pharma
2015 – 2023, Process owner delegate, LEO Pharma
Process Owner delegate for the Customer Complaint Process - globally

Key Responsibilities

- Accountable for designing an effective process
- Responsible for meeting regulatory requirements
- Define the process objectives and mission
- Plan and manage process improvement
- Optimize the process design
- Engage stakeholders to ensure alignment with their requirements and expectations
- Define and monitor performance targets
- Perform data analysis
- Communicate performance

Achievements:

- Implemented a global approach and minimized local processes
- Develop relations to stakeholders and ensured a global interaction
- Ensured processes in compliance and inspection ready

LEO Pharma A/S
2013 – 2015, Complaint Coordinator, Finished Goods Denmark Quality, LEO Pharma
Handling customer complaints for LEO Pharma Denmark

Key Responsibilities

- Handling Customer Complaints for products manufactured by LEO Pharma Denmark
- Create globally trend reports for Customer Complaints
- Participate in updates, testing and validating the quality IT system
- Document management
- Present customer complaints during audits and inspections
- Support during recalls (administrative tasks)
- Deliver data for KPI boards, QMR and PQR
- Support with input to Quality Agreements
- Parcipate in relevant project work

Achievements:

- An effective complaint handling and an updated IT system
- Ensure that documents are inspection ready
- Provide trending of customer complaint data

LEO Pharma A/S
2005 – 2013, Responsible person for LEO Reference Substances, QC Laboratories

Key Responsibilities

- Purchase and life cycle management of references substances used in the QC Lab

Achievements:

- Ensures that reference substances of the right quality are available for the daily analysis in the QC lab.

LEO Pharma A/S
1999 – 2005, QC Technician in Non-sterile process steam and Quality Control R&D

Key Responsibilities

- Sampling of raw materials and finished products
- Review of batch documentation
- Issue export certificates
- Document management

Achievements:

- Handover a complete record of the manufacturing process to the releasing QP, and confirms that that the products has been manufactured according to standards.

LEO Pharma A/S
1996 – 1999, QC Laboratories, Secretary

LEO Pharma A/S
1990 – 1996, QC Laboratories, Laboratory Technician
