DAHLFELTCONSULTING

CONSULTANT WITHIN QA, QC, RISK, QMS AND VEEVA

Name	Gitte Fuglsang-Fog
Nationality	Danish
Gender	Female
Domicile	Denmark

CONTACT INFORMATION

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GITTE FUGLSANG FOG - CURRICULUM VITAE

PERSONAL LETTER

The red thread throughout her +25 years in the pharmaceutical industry is Quality Control and Quality Assurance where she has applied her skills to plan, implement and set targets.

Gitte has many years of experience with stakeholder and change management across an international organization. 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 have been a big part of her responsibilities and which have given Gitte a solid knowledge within GMP, ISO-13485, FDA 21CFR and MDR. The regulatory knowledge has been gained within below mentioned experiences and during close collaboration with various stakeholders.

STRENGTHS

Gitte is a very outgoing person with a positive mindset, who is keen to make her colleagues and stakeholders even better by building a great team spirit and an open atmosphere.

She is a quick learner with a great overview and can adapt to a complex and dynamic business model.

Persistent and willing to go the extra mile to deliver solutions of high quality.

EXPERTISE

- Combination Products/Medical Device – Technical Writer (Design documentation and Design Verification)
- Document Management (training, procedures and supplier documentation)
- Quality Management Systems (QMS)
- Quality Risk Management within area of responsibility
- Supplier Management
- Drive quality projects (ex. alignment of data quality and process review)
- Value stream mapping of quality processes (flow charts)
- Process optimization of global quality processes to comply with regulatory requirements

- Core member in implementation of new systems and projects
- Participant during continuous improvement to IT systems, Power BI etc.
- Analyze data, visualize and communicate adverse trends and PIs
- Manage quality issues via Deviations, Change Controls, CAPAs etc.
- Process owner delegate for global quality processes (Customer Complaints and External requirements)
- Process monitoring to identify challenges and improve the user experience
- Manage Process groups and provide training during new implementations
- Presenter of global quality processes during audits and inspections

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

2024	Design Control and Risk Management for Combination Products
2023	Prosci - Certification in Change Management
Annual	GMP Update, Different providers
2023	Lean Six Sigma, yellow belt
2021	Project Manager training, Implement
2021	Profit realization, LEO Pharma
2020	Author course, "Write good instructions", LEO Pharma
2020	Introduction to Change Management, LEO Pharma
2019	Test Center, Test Execution (Veeva Vault), LEO Pharma (2019)

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent

PROFESSIONAL BACKGROUND

2023 – Present

DahlfeltConsulting | Quality Assurance Specialist and Senior Consultant

- Consultancy tasks within Pharma

2015 - 2023

LEO Pharma | 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

2013 - 2015

LEO Pharma A/S | Complaint Coordinator, Finished Goods Denmark Quality

Handling customer complaints for LEO Pharma Denmark

Key Responsibilities:

- Handling Customer Complaints for products manufactured by LEO Pharma DK
- 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
- Participant in project work

Achievements:

- An effective complaint handling and an updated IT system

- Ensure that documents are inspection ready
- Provide trending of customer complaint data

2005 - 2013

LEO Pharma A/S | 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.

1999 - 2005

LEO Pharma A/S | 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 have been manufactured according to standards.

1996 - 1999

LEO Pharma A/S | QC Laboratories, Secretary

1990 - 1996

LEO Pharma A/S | QC Laboratories, Laboratory Technician