

DAHLFELTCONSULTING

CONSULTANT WITHIN QA, QC, QMS, PROCESS SUPPORT,
QA/QC TRAINING AND COMPLIANCE

CONTACT INFORMATION

Name Vicki Holm Ibsen
Nationality Danish
Gender Female
Domicile Denmark

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VICKI HOLM IBSEN - CURRICULUM VITAE

PERSONAL LETTER

Vicki is a Quality Manager who throughout her career, have been taken different roles of all aspects of the Quality management. All from production to build up QMS systems and into operational QA work, combined with QA management and lead role in international variety. Vicki is a quick learner and good at keeping momentum in stressed situations.

She always works with a smile and have good collaborations skills across departments to improve and find solutions. Vicki enjoys the process from the initial phase to the products and lines are in compliance, together as a team or individual.

Vicki is very experienced within giving support and guide the team in the right direction and share her experiences and knowledge.

Structed combined with a professional leadership background, Vicki is good at motivating employees. She has built up a QA team with great success and seen it grow in a very positive way.

STRENGTHS

Vicki is very good at communicating, always with a smile and kindness. She is a positive person. Always act in order to reach the target within deadlines.

She's a strong leader and a good atmosphere among collages strengthens her dedication and commitment in her management style. There must be structure in the team and employees must know their responsibilities and framework. Vicki always listens and work in collaboration with her colleagues to solve tasks, but she can easily also lead, develop, and assign tasks.

EXPERTISE

Vicki has throughout her long career, started in quality in food and candy industry/production. Her roles were responsibility for the laboratory and documentation area, both operational and leading.

Hereafter Vicki joined Pharmaceutical and Medical Device area, where she has been in various roles as Quality Engineer, Quality Manager in different areas, but all of them in QA and documentation, combined with a strong knowledge in overall management and strategic leadership with a high focus for the overall production quality and securing the company were in control. Also managing the project from one stadium to the next level of compliance. Vicki has extensive experience in QMS and general QA work.

- IT SKILLS**
- ∴ MS office (Word, excel, PowerPoint, Teams)
 - ∴ TrackWise
 - ∴ Lotus Notes
 - ∴ PDM

EDUCATION AND DEGREES

Strategic management Education
Management education (grundlæggende lederuddannelse)
Roskilde Slagteriskolen, Roskilde / Food technician / levnedsmiddeltekniker

CERTIFICATIONS AND COURSES

- ∴ Internal lead auditor in ISO 9001 and ISO 13485
- ∴ ISO 13485:2016
- ∴ MDR - EU Medical Device Regulation
- ∴ Medical Device FDA QSR & QSIT
- ∴ Other regulation as Brazil, Canada, Japan and US QSR 21 CFR Part 820

LANGUAGE SKILLS

| | | |
|-----------|--------------------|----------|
| Danish | Written and spoken | Native |
| English | Written and spoken | Fluent |
| Norwegian | | Business |
| Swedish | | Business |

PROFESSIONAL BACKGROUND

2023 – present
[DahlfeltConsulting](#) | **Senior Consultant**
Quality Assurance, Production & Strategic Compliance & Validation, Design & Process management

- ∴ Various Consultancy tasks within Pharma and medical Device business.
- ∴ Full responsible for building a new training and education area in large pharmaceutical company in North Sealand.
- ∴ Process and project support to VP Compliance QA in securing compliance in QA, training and education.
- ∴ Weekly report to stakeholders in top management, performance measuring in affected areas in the company

2022 – 2023
[ConvaTec](#) | **Quality Operation Manager**
Responsible for Quality Operation with 6 employees

- ∴ People management.
- ∴ Production Quality issues with collaboration with production leads
- ∴ QA support to project including implantation in production.
- ∴ QA support to the organization to ensure compliance.
- ∴ Responsible for Value stream team - improvement in production area.
- ∴ Support into the microbiological area.
- ∴ Participation in internal audits from authorities.
- ∴ Internal and Supplier auditor as lead auditor.

2016 – 2022

[ConvaTec | Quality Manager & Site Lead](#)

Responsible for QA department with 10 employees

- ∴ People management.
- ∴ Internal audits as Lead Auditor, Supplier audits, part in MDSAP audits, MDR audit etc.
- ∴ Change Control system (Review, approval)
- ∴ NC/CAPA system (Root Cause, Review, approval)
- ∴ QM systems (approvals, improvement of documentation)
- ∴ Production Quality issues with collaboration with production leads
- ∴ QA support to projects including implementation in production.
- ∴ Participation in cross-functional projects.
- ∴ QA support to the organization to ensure compliance
- ∴ Standards maintenance.

2013 – 2016

[ConvaTec | Quality Engineer](#)

Responsible for NC/CAPA and Change Control system

- ∴ Change Control system (Review, approval, training employees)
- ∴ NC/CAPA system (Root Cause, Review, approval, training employees)

2008 – 2013

[ConvaTec | Manufacturing Quality Engineer](#)

Responsible for quality in production

- ∴ Responsible for training production employees in Quality.
- ∴ Improvement of quality processes
- ∴ Creation and updating of instructions and procedures (SOP)
- ∴ NC/CAPA handling
- ∴ Participation in projects with implementation in production.
- ∴ Trainee in hygiene and GMP
- ∴ Internal auditor
- ∴ Part in Notified Body audits, FDA audits.
- ∴ Drive Change Control process

2002 – 2008

[Malaco Leaf A/S](#) | Quality Technician & TPM / LEAN Coordinator

- ∴ Finish Goods control
- ∴ Handling customer Complaints
- ∴ Control of cleaning in production
- ∴ Pest control
- ∴ Internal auditor
- ∴ Responsibility for TPM/LEAN area
 - ❖ Educated employee in TPM/LEAN
 - ❖ Implementation TPM/LEAN

1998 – 2000

[Blomberg A/S](#) | Laboratorieleder

- ∴ Quality assurance within production lines and finish goods
- ∴ Products development
- ∴ Control of cleaning in production and overall routines
- ∴ General documentation

DAHLFELTCONSULTING

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