

DAHLFELTCONSULTING

SENIOR CONSULTANT CV WITHIN QC, PRODUCTION & PROCESS EQUIPMENT

CONTACT INFORMATION

Name Anne Damm
Nationality Danish
Gender Female
Domicile Denmark

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ANNE DAMM - CURRICULUM VITAE

PERSONAL LETTER

Anne is a dedicated and experienced engineer with extensive experiences and knowledge of Quality Assurance & Control, Validation, Risk management & project management. Anne have gained a deep understanding and insights to process Methods in production, Standards and Lean Process Improvement methods for production and validation of equipment and IT throughout her career.

She has more than 20 years' experience with execution of projects including implementation of quality management systems and LEAN methodologies including boards, internal audit programs, non-conformance and CAPA handling systems.

Anne thrives in management of compliance projects and her great communication skills makes her excel in a multilingual and multi-cultural work environment bridging the gap between the technical and commercial.

STRENGTHS

- ❖ Result oriented
- ❖ Self-driven and proactive
- ❖ Problem solving personality
- ❖ Dedicated, Focused and Structured
- ❖ Supervising
- ❖ Team player
- ❖ Excellent interpersonal skills

EXPERTISE

- ❖ 10 years' experience with QA and QC
- ❖ 20 years' + engineering experience
- ❖ Project management
- ❖ Risk Management
- ❖ Process optimization
- ❖ Validation in QA, IT & production equipment
- ❖ Implementation of standard operating procedures and change control
- ❖ 8D Process and "root cause analysis" methodology
- ❖ EHS management, chemical risk assessment, and WPA incl. ATEX
- ❖ Auditor, internal & external supplier audit under following standards:
ISO9001, FSC-STD-40-003, and SMETA
- ❖ GMP, GXP

IT SKILLS

- ❖ Microsoft Office / Outlook / Excel / Word /Power Point / Projects
- ❖ Microsoft 365 / SharePoint / Teams / Forms
- ❖ Microsoft AX Dynamics – user
- ❖ Software validation, methods, techniques, processes, changes

EDUCATION AND DEGREES

- 2017 Internal Auditor v. Lasse Ahm Consult
- 2010 Lean Six Sigma Green Belt v. Unipart Expert Practices
- 2008 Diploma Graduate in Management v. University College of Engineering
- 1999 B.Sc. Export Engineering v. University College of Engineering

CERTIFICATIONS AND COURSES

- 2017 Lasse Ahm Consult - Internal Auditor certification
- 2010 Unipart Expert Practices - Lean Six Sigma Green Belt certification
- 2008 University College of Engineering - Diploma Graduate in Management
- 1999 University College of Engineering - Masters, Export Engineering

LANGUAGE SKILLS

- | | | |
|---------|------------------|------------|
| Danish | Written & spoken | Native |
| English | Written & spoken | Fluent |
| German | Written & spoken | Proficient |

PROFESSIONAL BACKGROUND

Dec. 2023 - Present

[Dahlfelt Consulting](#) | Senior Consultant within QA, QC, Risk management, Validation in Production and Process equipment

On-site consultancy

Dec. 2020 – Nov. 2023

[Paboco - The Paper Bottle Company A/S](#) | Quality Assurance Manager & Head of PMO

Head of PMO responsibilities:

Develop the strategy for and implementation of the PMO. Deliverables include but are not limited to:

- ❖ Developing and implementing standardized project management methodologies, tools, and templates, resulting in improved project delivery efficiency and quality.
- ❖ Collaboration with senior stakeholders to align project objectives with the organization's strategic goals and ensure effective communication throughout the project lifecycle.
- ❖ Introduction to and training of all Project Managers in the methodologies, tools, and templates.
- ❖ Review of project progress across the organization to ensure project completion according to agreed cost, quality, and delivery.

- ❖ Reporting strategic progress to BoD.
- ❖ Validation of system, software, methods & equipment acc. to GAMP5

QA Manager responsibilities:

Develop the strategy for and the Implementation of a Quality Management System in compliance with ISO9001:2015, SMETA compliance, FSC compliance, and B Corp compliance. Deliverables include but are not limited to:

- ❖ Ensure a risk-based approach and verify effectiveness of mitigating actions.
- ❖ Plan and execute internal audits.
- ❖ Plan and host Management Review of the Quality Management System and FSC certification.
- ❖ Change management of entire organization in understanding and embracing the Quality Management System.
- ❖ Validation of processes

EHS representative for Management - Responsibilities:

Develop the strategy for and implementation of the environmental, health, and safety programs to ensure compliance with regulations, minimize risks, and promote a safe and sustainable work environment. Deliverables include but are not limited to:

- ❖ Plan and host yearly EHS discussions and other HSE meetings.
- ❖ Lead implementation of identified areas of improvements.
- ❖ Complete chemical risk assessments and workplace assessments.
- ❖ Create and update relevant procedures and instructions.

May. 2016 – Dec. 2020

C & H System | Quality Assurance and Documentation Manager

Responsibilities:

Development and implementation of a quality management system in compliance with ISO9001:2015, SMETA and Machinery Directive.

- ❖ Leading the customer documentation department enabling successful delivery of customer documents, manuals, and CE Marking.

Deliverables:

- ❖ Initial ISO9001:2015 certification without any non-conformances.
- ❖ ISO9001:2015 re-certification without any non-conformances.
- ❖ SMETA audit completed and corrective actions to non-conformances implemented and approved.
- ❖ 15% improvement of efficiency in Documentation

Feb. 2015 – Apr. 2016

Cook Medical Europe | CAPA Specialist

Responsibilities:

- ❖ Development of a strategy for and establishment of a CAPA (Corrective and Preventive Actions) team.
- ❖ Develop and standardize a creative problem-solving approach for CAPA resolution in compliance with 21 CFR Part 820 and EN ISO 9001:2015.

- ❖ Train and educate CAPA team in appropriate tools and techniques to investigate problem and cause and identify root cause and countermeasure of the non-conformances.
- ❖ Coach and mentor CAPA team in rules, guidelines, and best practices to continuously improve quality of CAPA resolution.

Deliverables:

- ❖ Implementation of a CAPA team for handling of all CAPAs including root cause analysis through implementation of corrective and preventive actions.

Dec. 2007 – Jan. 2015

[Howden Denmark | Variable positions over the years](#)

Jan. 2013 – Jan. 2015 Manager, Customer Documentation & Manuals:

Leading the technical documentation department with BAU and business process improvement projects through the LEAN philosophy.

Responsibilities:

- ❖ Develop and implement a new organizational department of 11 employees responsible for on time delivery of customer related documentation.
- ❖ Daily management

Deliverables:

- ❖ 30% yearly improvement on quality against department metrics through standardization and continuous improvement.
- ❖ 30% yearly improvement on delivery performance against department metrics through process optimization and continuous improvement.
- ❖ 30% yearly cost reduction against department budget through standardization, process optimization, and continuous improvements.

Nov. 2010 – Dec. 2012 Colfax Business System and LEAN facilitator:

Responsibilities:

- ❖ Implementation of Lean and Colfax Business System as management philosophy.
- ❖ Strategic, tactical, and operational support of management.
- ❖ Coaching Management in Development of Strategy Deployment.
- ❖ Support management in fulfilling strategy.
- ❖ Facilitate major Kaizen activities.
- ❖ Introduction of the Lean and Colfax Business System philosophy to all new employees.
- ❖ Train all employees in Lean and Colfax Business System philosophy, tools, and techniques.

Deliverables:

- ❖ 30% cost reduction against yearly company budget.

Dec. 2007 – Nov. 2010 Project Manager

- ❖ Handling OEM contracts from PO to final hand over to customer. Responsible for quality, cost, and delivery of assigned projects.
- ❖ Internal tasks include definition of scope and key metrics for the projects, planning of tasks, assigning of resources, tracking progress, and reporting to management.
- ❖ External tasks include all customer communication, preparing progress reports, visit suppliers and customers in connection with FAT and SAT.

Jan. 2006 – Dec. 2007

[SELCO | Marketing Coordinator](#)

Jan. 2005 – Jan. 2006

[SIEMENS A/S | Account Manager](#)

Jan. 2003 – Jan. 2005

[SIEMENS A/S | Bid Manager](#)

Jan. 2000 – Jan. 2003

[SIEMENS AG München, Germany | Bid- and Business Development Manager](#)

DAHLFELTCONSULTING

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