

Curriculum vitae for Hanne Holmbom

Quality mind-set • Compliance • Audit • Change Management • Facilitation • Optimisation • Training

Profile:

Senior Quality and Compliance Consultant with more than 25 years of successfully leading and supporting quality transformation initiatives, audit and inspection readiness programs, training and process optimization projects, and change management activities within the pharmaceutical and life sciences sectors.

I help organizations strengthen quality performance, compliance maturity and operational excellence by simplifying complexity and translating regulatory expectations into fit-for-purpose processes that create value for both the organization and its end users.

I bring a unique combination of deep GMP expertise, business understanding and strong stakeholder management capabilities. I am particularly passionate about strengthening quality culture and driving behavioral changes. By creating engagement, ownership, and clarity of purpose, I help implement changes that are not only compliant but also anchored and sustained over time.

As an experienced facilitator, trainer, and presenter, I build trust quickly and communicate effectively across all organizational levels in both Danish and English. I am known for creating engagement, facilitating decision-making, and ensuring that strategies and decisions are translated into tangible actions and sustainable results.

I hold a degree in Pharmacy and have further qualifications in facilitation, change management, project management, Lean, and as a Lead Auditor. I am currently completing certification as a Transformative Coach through Mindjuice Academy®.

My experience includes roles with Novo, NNE, FOSS, Lundbeck, and Pharmakon.

Understanding your unique challenges and objectives is my top priority, ensuring that my support is tailored to your specific needs.



Core competencies

- GMP Compliance
- Quality Culture and Quality Mindset
- Lead Auditor (GMP, ISO 9001, ISO 14001, ISO 45001)
- Internal and Supplier Audits
- Quality Management Systems
- Training Strategy and Learning Design
- Facilitation and Workshops
- Change Management
- Process Improvement and Simplification
- LEAN and Continuous Improvement
- Transformative Coaching

Education and Certifications

- Mindjuice® Transformative Coach (expected 2026)
- Change Management Foundation, APMG certification (2025)
- Lean Green Belt (2022)
- Facilitation and Process Design (2013)
- Project Management (2008)
- Lead Auditor Certification (2007)
- MSc (Pharm.) (1997)

Languages

- Danish (native)
 - English as primary working language for 20+ years
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Key experiences and selected achievements:

Novo Various roles within Quality, Training and Process Management:
Senior Project Manager / Quality Process Manager / Training and Compliance Consultant / Standardization Partner / GMP responsible chemist

- Corporate process manager for the GxP Training process
- Internal auditor (GMP)
- Training strategy and capability development
- Change management and implementation projects
- Conference planning and facilitation
- Quality and compliance consulting
- Training in GMP and compliance

NNE **Senior Quality Specialist / Principal Consultant**

- QMS ownership and optimisation
- Lead auditor of internal audits (ISO 9001)
- Training of internal auditors
- Handling of external audits and inspections (ISO 9001, ISO 14001, ISO 45001)
- GMP consultancy
- Training in GMP, Good Documentation Practice and compliance

FOSS **Quality Assurance Specialist**

- Lead auditor of internal audits (ISO 9001)
- Training of internal auditors
- Internal audit programme
- QMS and QMR optimisation
- Process governance
- Handling external audits and inspections (ISO 9001, ISO 14001, ISO 45001)

Lundbeck **Compliance Manager / Pharmacist**

- Lead auditor at supplier and internal audits (GMP)
- Establishment of GMP training programmes
- Courses and training development and delivery
- Facilitation of workshops
- Quality systems optimisation

Pharmakon **Consultant for pharmaceutical industry**

- GMP consulting, including as internal auditor
 - Training and course development
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