Energy Hansen
MSc. Food Science & Technology
KU LIFE, Frederiksberg

Senior QA & Compliance Expert

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Competences

- Audit Process Management
- Inspection Readiness
- Active & Certified Lead Auditor; external/internal audits
- Gap Analyses Expert
- Root Cause & Investigations SME
- Quality Management| QMS elements
- Supplier Quality Management
- Team Management Representative
- Experienced QP & RP
- Expert knowledge in GMP, GDP, & ISO 9001
- Transformational Trainer

Key results

- Performed PAIs which contributed to a successful FDA inspection result
- Improved an entire QMS framework/structure through rebuilding Deviation Management, CAPA, Risk Management
- Developed, organized, and Facilitated workshops on the implementation of compliance initiatives
- Pharma warehouse extension approved
- Successfully trained thousands of GMP/GDP personnel
- Fixing broken stakeholder relationships

Regulations / Standards / Guidance

Extensive knowledge in:

- **EU regulations**: EU GMP: Regulation No. 1252/2014 and Directive 2003/94/EC, applying to active substances and medicines for human use
- **FDA regulations**: CFR 21 Part 211, Part 11, Part 210,
- **Guidelines**: EU Guidelines 2013/C 343/01 Good Distribution Practice (GDP)
- **EU harmonized/internationally recognized**
- **standards**: ISO 9001, 22001

Personal Characteristics

Energy is known to be detailed but at the same time pragmatic. She is structured and is a fantastic communicator (which includes listening skills). Dealing with tricky/difficult stakeholders are a breeze for her.

Energy has 20+ years in QA & Compliance/ Auditing and Inspection within the Pharma, Food, Health, Warehousing & Medical Devices

In her spare time, Energy is currently working on her first novel (low-fantasy), learning to play the cello, doing fitness, & spending time with her 2 sons.

References

Ferring Pharmaceuticals

Associate Director Quality Compliance

- Has direct responsibility for the Manufacturing Sites being in compliance with Ferring QMS and applicable Health Authority regulations
- Take ownership for preparation of manufacturing sites for health authority inspections
- Support sites before during and after health authority inspections
- Perform GMP/GDP Internal Audits & Third-Party critical Manufactures

Agilent Technologies

QA Operations Manager

- Lead, Direct, Guide, and mentor the NCR and QPR personnel
- Ensure department releases product in accordance to country specific regulations

Leman

Head of Group QSHE & QP

- Overall responsible for establishment, maintenance, and continuous improvement of QMS
- Work together with Executive Leadership to develop, manage and monitor the QSHE performance of the company
- Be certified as and maintain the role as Qualified Person

Leo Pharma

Lead Auditor & RP

- Plan and perform Supplier and Internal Audits while acting as the responsible person within GDP for site Denmark
- Communicate findings and risks to management.
- Review external supplier CAPAs and direct them how to close the deviations

Novo Nordisk

Lead Supplier Auditor

- ISO/GMP/GDP - raw materials, excipients, primary & secondary packaging, storage and warehouse, process aids, transport
- Responsible for facilitation of the process which supports mitigation of findings/risks