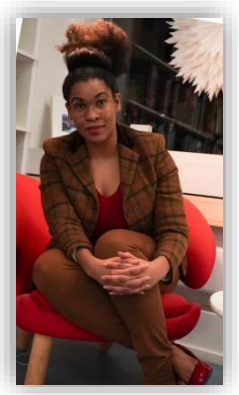
Energy Kristina Hansen



Position	Senior Level
Employment status	Contract
Link for linkedin profile	LinkedIn

Profile

She is/ has been:

- *Leader of Quality Assurance/Compliance teams*
- *Certified Lead Auditor*
- *RCA expert (w/human error aspect)*
- *Creator of the 3BMethod™*
- *GMP and ISO knowledgeable/certified*
- *RP and GDP knowledgeable/certified*
- *ISO 9001, ISO 13485 certified*
- *Change and Nudge implementor!*

As a Quality Expert, with 23+ years of experience in quality assurance and compliance, spanning across food, health, manufacturing, pharmaceutical, and government sectors - I have optimized operations/activities, lead hundreds of audits within GMP, GDP, and ISO, been a RP and QP, and have strengthened processes as well as people.

I am also a passionate speaker of change! My area of specialty is in and around human error in the workplace. As the founder of MILCOR CONSULTING (2016), I have been teaching, and advising organizations and its senior/executive leaders on how to create better incentives and a more emotional safe environment for employees, how to understand why SMART humans make mistakes, and ways to decrease human errors within the workplace.

I am the creator of the 3BMethod and its behavioral root cause analysis (bRCA) tool that helps companies find the true root cause within a human error related deviations (HErD) and in turn reduce recurrence. I am also the author of the book PROBE the HErD (releasing 2024) which is a guidebook for understanding and implementing the 3BMethod and its frameworks. I leverage my knowledge of behavioral sciences and my passion for delivering motivational presentations to train and educate thousands of individuals on the subject over the past 10 years.

**A fun fact: Her first real & legal name is Energy and her middle name is Kristina. She goes by either or.*

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Skills

Competency		Level* (1 – 5)
	Plan, Perform,Execute, Follow-up Audits (cGMP, GDP, ISO 9001, ISO 22000)	5
	Plan, Perform,Execute, Follow-up Audits (ISO 13485)	3
	Review and Approval; Action Plans/CAPAs	5
	Supervision of Implementation & Effectiveness Check	5
	Strengthening & Maintaining company QMS	5
	Root Cause Analysis Investigations	5
	Audit and Inspection Support; GDP/GMP/ISO	5
	Organizational Change Management (Compliance)	5
	Management/Engagement/Influence Employees	4
	Behavioral Organizational Education & Training	5

Industry	Level* (1 – 5)
Pharma	5
Med. Devices	3
Food	5
Health	4
Transport/Warehousing	5

Languages	Level of proficiency
English	Mother Tongue
Danish (understanding/oral / written)	Proficient/ Elementry / Basic

**Note on Level: 1 = Basic knowledge, 2 = Good insight, 3 = Thorough insight, 4 = Masters, 5 = Expert*

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Selected work & project experience

2017-08 – **present**

Creator of 3BMethod™ | Speaker | Teacher | Quality Expert
CEO & Founder
MILCOR CONSULTING
FREELANCE:
Increase organizational compliance with behavior science methods
Key deliverables/responsibilities

- Work with different industry leaders to help them find the true root cause behind human error related deviations
- Advising organizations on:
  - Improving the Quality Culture throughout the company
  - Optimizing processes and procedures
  - Finding the gaps and giving LEAN solutions
  - Ideation and creation on ways to decrease unwanted behaviors
  - How to engage employees
  - How to Increase digestion/output through training
  - Ways to enhance the spread of best practices
    - Education Delivered on her very own: 3BMETHOD™ Framework (behavioral RCA for getting to the true root cause)
    - Training Specialists on her HOW2NUDGETHEM™ Framework (behavioral corrective and preventative actions based off validated behavioral strategies)
- Brilliant Orator/Presenter/Lecturer/Keynote Speaker/Course Director for several certified training organizations (i.e., *Key 2 Compliance*, *Concept Heidelberg*, *R3Nordic*, *University of Copenhagen*)

2013-09 – **present**

Guest Lecturer and Sensor
KU (LIFE, Frederiksberg)
MILCOR CONSULTING
Key deliverables/responsibilities

- Present annual lectures on how to change undesirable behaviors in the workplace. Teaching students 3BMethod™
- Prerequisite course for Bachelor and Master Science students at the Copenhagen, KU.
- Periodically act as a sensor for Master Thesis defenses

2021-11 – 2023-10

Associate Director Operational Excellence -DK(Hybrid)
Ferring Pharmaceuticals (Remote/Switzerland - Denmark)
Key deliverables/responsibilities
- Global Lead for Global optimization project (SQM creation/change) for GMP goods with Ferring (aligning Q, Procurement, Manufacturing, and Supply chain)
- Focus group member for Audit Management optimization for Ferring sites
- Has direct responsibility for the manufacturing Sites being in compliance with Ferring QMS and applicable Health Authority

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regulations
- Take ownership for preparation of manufacturing sites for health authority inspections
- Support sites before during and after health authority inspections
- Lead the Inspection Review Board process
- Monitor/ensure cGMP/regulatory compliance of local organizations

2021-02 – 2021-09

- Develop class room GMP/ GDP training modules
- Perform classroom GMP/ GDP training
- Provide had hoc support and technical expertise to Product Supply projects
- Carry out QA due diligence and propose recommendation- Monitor/ensure cGMP/regulatory compliance of local organizations

QA Operations Manager-DK
Agilent Technologies (Glostrup)
Key deliverables/responsibilities

- Lead, Direct, Guide, and mentor the NCR and QPR personnel
- Ensure Compliance (in accordance to IVD-directive, ISO13485, 21CFR and EU GMP) and timely review and approval of controlled documents that are within scope of the Quality Management System
- Ensure department releases product in accordance to country specific regulations
- Ensure department has timely QA Support on Non-Conformance Reports, Deviations, Change Orders, and CAPAs
- Ensure QA Support to stakeholders in daily operations
- Actively participate in the management team for the QA/RA area.
- Report to leadership on operational goals for the department.

2019-09 – 2021-01 **Head of Group QSHE & QP**

HQ LEMAN A/S (Greve)
Lead/Create/Framework anchoring for QSHE Organization
Key deliverables/responsibilities

- Global Head of quality, safety, health, environment areas within LEMAN
- Overall responsible for establishment, maintenance, and continuous improvement of Leman's QMS. This is to include implementation of compliance within EU/DK GDP/GMP legislation in LEMAN's quality management system (QMS)
- Responsible of the proper execution of annual QMRs
- Work together with Executive Leadership to develop, manage and monitor the QSHE performance of the company.
- Monitor and advise on all QSHE matters, issues and concerns to ensure LEMAN compliance with statutory requirements, LEMAN and contractual requirements and good industry practice.
- Responsible for managing QSHE representatives assigned to work within department
    - Training & mentoring,
    - motivating,

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        - and directing employees to optimize workplace productivity and promote professional & personal growth.
    - Also responsible for creating, defining, and managing programs and activities as listed:
        - Authority controls and customer audits
        - internal and external audits (conducting audits when needed)
        - Document Management
        - Change control/ Change Management
        - Deviation & CAPA Management
        - Risk Management
        - Providing/Ensuring relevant training and education is given to staff within Quality, Health, Safety, Environmental, GMP/GDP
        - Ensure that QSHE documentation, procedures and processes are maintained in compliance with industry and regulatory standards
    - Be certified as and maintain the role as Qualified Person according to GMP authorization from DMA, including API registration and storage

2018-01 – 2018-10 **Lead Auditor & RP**
LEO Pharma
Plan and perform Audits while acting as the responsible person within GDP for site Denmark
Key deliverables/responsibilities

- Perform quality audits of external suppliers to LEO Pharma globally
- Communicate findings and risks to management.
- review external supplier CAPAs and direct them how to close the deviations
- GDP, Transport/Storage, Raw materials (GMP), primary/secondary packaging (GMP/ ISO 15378), Quality systems (ISO 9001), process aides/consumables (as needed) and co-audit the internal processes at LEO.
- ADHOC and internal processes (e.g., Quality agreements, procedures, create and deliver training for departments)
- Acting Responsible Person (GDP) for Ballerup and Esbjerg sites.

2015-02 – 2018-01 **Lead Auditor**
NOVO NORDISK
Plan and perform audits
Key deliverables/responsibilities

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- Performed quality audits of external suppliers to Novo Nordisk globally
- Communicated findings/risks to Novo Nordisk supplier responsible/owners.
- raw materials, excipients, primary & secondary packaging, storage and warehouse, process aids, transport
- Responsible for facilitation of the process which supports mitigation of findings/risks.

2013-08 – 2015-02 **Change Implementation, Compliance Project Management**
NOVO NORDISK
Global Business Process Optimization
Key deliverables/responsibilities

- Optimized complex business processes across quality, manufacturing development, and production in DFP and Product Supply.
- Drove various projects that sought to continuously optimize compliance level,
- Developed, organized, and Facilitated workshops on the implementation of compliance initiatives for the DFP sites (Denmark, U.S., Brazil, France, and China).
- Secured alignment with stakeholders at all levels – from Operators to Vice Presidents

2009-09 – 2010-05 **Operations Quality, Supervisor**
Land'OLakes
Implemented Quality Oversight on shop floor
Key deliverables/responsibilities

- Performed general and GMP inspections/audits in Butter, Cheese, Powder and Fluid Plants.
- Conducted HACCP, GMP and food safety related trainings for all departments in all plants.
- GMP Compliance and Inspection Support (inspectors and auditors)
- Elevate production without interrupting quality of the product being produced.
- Supervision of sanitation to ensure proper protocols are met
- Supervision of employees working night shift on shop floor
- Safety Coach

2008-10 – 2010-05 **Food Auditor Specialist**
National Everclean Services
Improve food retail environments
Key deliverables/responsibilities

- Strengthen retail food facilities Food Safety activities, including in - process quality control and facility GxPs and sanitation practices.
- Utilized behavioral change management strategies to change their undesirable behavior and improve compliance.
- Conducted mock audits and Developed technical reports

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2005-05 – 2006-11 **Meat/Poultry Slaughter Inspector**
U.S.D.A Food Safety & Inspection Service
Inspector
Key deliverables/responsibilities

- Ante-mortem inspection of livestock and poultry
- Post-mortem inspection of red meat and or poultry
- Ensure the safety and quality of consumable meat products.

2001-06– 2005-05 **Environmental Health and Safety, Project/People Manager**
USAF
Oversaw 41 facilities attaining zero discrepancies within scheduling, planning, and execution. Trained and supervised airmen under my ranking within Public Health office
Key deliverables/responsibilities

- Managed and performed public health activities and programs:
    - occupational safety, food inspection, sanitation, entomology programs, vector borne/communicable disease prevention and control
- Promoted and provided health education and safety training daily.
- Interacted daily with stakeholders and senior staff to perform needs analysis
- Developed, scheduled, and performed preventive training/briefings, quality assurance inspections (GxP), and safety observations with minimal impact to daily routine.

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Certifications and Education

Education	University of Copenhagen, KU
Area	M.Sc. in Food Science & Technology (Food Safety option) with a Behavior Science Approach
Date of certification	2013
Certification	IRCA
Area	QMS/Lead Auditor Training Course ISO 9001
Date of certification	2015
Certification	ECA
Area	GDP Responsible Person
Date of certification	2018
Certification	Key2Compliance Certificate
Area	ISO 13485,MDD and CMDCAS
Date of certification	2015
Certification	ECA
Area	QP Certification Course
Date of certification	2019