Energy Kristina Hansen

Position	Senior/Executive Level
Employment status	Full-Time
Link for linkedin profile	LinkedIn

Profile

As a leader, Energy is known to be/have:

- *Flexible but firm*
- *Detailed but pragmatic*
- *Very structured*
- *Knows how to delegate, and trust others*
- *Fantastic communication skills*
- *Courageous change agent*
- *Great listening skills*
- *Very energetic and motivating*
- *Great stakeholder management skills*
- *Works well under high pressure environments*

She is also:

- *Leader of Quality Assurance/Compliance teams*
- *Certified Lead Auditor*
- *QP at LEMAN, Greve*
- *GMP and ISO knowledgeable/certified*
- *RP and GDP knowledgeable/certified*
- *ISO 9001, ISO 13485 certified*
- *Knowledgeable in performing a behavioural root cause analysis*
- *Change and Nudge implementor*

She has 19+ years in current measures towards internal and external audit and inspection within Life Sciences, HealthCare, and Warehousing. She is also strong within project management, promotion of motivating education and training, dealing with stakeholders in an above satisfactory way. Tasks where she needs to enhance personnel performance by using influence and behavioural science to increase compliance is also where she shines.

She is a Jamaican and Cherokee American who has a brilliant 18-year-old son and awesome almost 4-year-old son. As a single mom - Business travel is not a problem, but Energy would love to minimize it to < 40days a year. She has taken 6 months of Danish courses and can understand 70% of what is being said in conversation. Speaking great Danish is the tricky part, but she is continuing to try.

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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
	Handling/Creating Procedures	5
	Audit and Inspection Support; GDP/GMP/ISO	5
	Organizational Change Management (Compliance)	4
	Management/Engagement/Influence Employees	5
	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** **Behavioral Compliance Orator|CEO &Founder**
MILCOR CONSULTING
Increase organizational compliance with behavior science methods
Key deliverables/responsibilities

- Work with different industry leaders to help them find the true root cause to behavior related deviations
- Advising organizations on:
  - how to find 'hidden' barriers that inhibit desired practices
  - decreasing human error related issues
  - how to create better habits within workplace
  - ways to decrease unwanted behaviors
  - how to engage employees
  - how to Increase digestion/output through training
  - ways to enhance the spread of best practices
    - Educated and Delivered through my very own: B4UNUDGETHEM™ Framework & HOW2NUDGETHEM™ Framework
- Brilliant Orator/Presenter/Lecturer/Keynote Speaker/Course Director for several certified training organizations (i.e., *Key 2 Compliance*, *Concept Heidelberg*, *R3Nordic*, *GRC*, *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.
- Prerequisite course for Bachelor and Master Science students at the Copenhagen, KU.
- Periodically act as a sensor for Master Thesis defenses

2021-02 - **present** **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.

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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,
    - 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

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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

- 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

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- 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

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

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