



Jens-Kristian Søndergaard

RISK ENGINEER - MEDICAL DEVICE

Details

Bakkedraget 6

Thisted, 7700

Denmark

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NATIONALITY

Danish

DRIVING LICENSE

Car B

DATE / PLACE OF BIRTH

1957-10-09

Rær

Links

[LinkedIn](#)

[JKS Consult](#)

Skills

Ability to Work in a Team

Leadership

Quality Management - Systems
(ISO 9001 and ISO 13485)

Strategic planning

Risk Assessment - ISO14971,
Projects, Product and Processes

Validation of processes and Test
Methods

Lean Six Sigma (PDCA/DMAIC) -
Visual Management

Auditing (ISO 9001, ISO 13485 &
ISO14001)

Innovation - Stage Gate model.
Design Control

Profile

Engineer focusing Quality Management and Auditing. Enabling appropriate Risk Management and Validation within Medical Device for compliance with MDR. Emphatic, straight and realizing all achievements are based on Team Work.

Results:

- Several years of Quality (QEHS) Management experience.
- Systematic and Risk Based approach and mitigation enables optimized action.
- Achieve and maintaining certification of Coloplast Site.
- Timely launch of new innovative MDR compliant products.
- Transfer of matured products and processes to Malaysia, Hungary and China.

Specialist within:

- Auditing (ISO 9001/13485/14001 and MDSAP) focusing objective evidence.
- Risk Management and validation related to Medical Devices (MDR)
- Design Control ref. MDR
- Ensure data provision and analysis, utilizing tools as DMAIC/Six Sigma.
- Management Review
- Stage Gate development of innovative products
- Process optimization and Ramp-up. Transfer to other countries.
- Engineering skills within plastic, steel and energy technologies
- Review and approval of key documents.

Employment History

Head of Quality & EHS, Coloplast, Thisted

AUGUST 2005 – JULY 2020

Ensure that Coloplast Quality System is maintained, developed and implemented with respect to maintain ISO13485 and MDSAP Certification and License to sell Medical Devices. Manager for 10 employees/various organizational level.

Quality Lead Auditor. Risk Management, JKS Consult, Thisted

JANUARY 1991 – PRESENT

Managing and conducting Internal QEHS audits within Coloplast Organisation (MDR). Review and approval of Risk Assessment documents and Process validation. Transportation studies. FAT/SAT Protocol and Reports for new machines.

Mentor in relation to Quality aspects and Risk Management.

Supervisor for implementation of Quality Management Systems

Quality Manager, Alkaline Batteries A/S (Gold Peak Batteries), Thisted

FEBRUARY 1991 – SEPTEMBER 2005

Quality System development, implementation and Certification ref. AQAP and ISO9001 standards. Change Management during close down process.

Supplier Management and auditing. Approval of specifications.

Consultant and Auditor, S&Q Tech (Force Technology), Vejen and Viborg

AUGUST 1985 – FEBRUARY 1991

Consultant enabling Industry to achieve ISO 9001 Certification.

Quality Assurance of Supplier for Natural gas steel components.

Supplier Control, audits and approval.

Inspection of steel (and PEM) pipes, valves, regulators for high pressure parts.

Process Ramp Up and Transfer of Products and Processes

Change Management - i.e. Kotter 8 steps

CAPA, NC, Change Control (ISO 13485 & ISO 9001) and RCA

Presentation and teaching

Office Package, Trackwise and Veeva

Environmental Management ISO 14001

GMP/GLP

MDR for CE marking

Management Review

Languages

Danish

English

German

Scandinavian

Hobbies

Photography, Gardening, Nature, Philosophy, Psychology, Religion, Travel, MTB tours and Trading at the Stock Market.

Education

Design Control Medical Device, Medicoindustrien/Gantus, Hørsholm

SEPTEMBER 2019 – SEPTEMBER 2019

Design Control requirements and methods for Medical Devices ref. MDR.

Implementation of MDR for CE-marking, Medicoindustrien/BSI, Hørsholm

AUGUST 2019 – AUGUST 2019

Preparation for Implementation of MDR for CE marking of existing and new products.

Lean Six Sigma Black Belt Training, MoreSteam University E-Learning, Ohio

FEBRUARY 2011 – FEBRUARY 2012

Utilizing Lean Six Sigma concepts. Based on DMAIC principles.

Bachelor in Environmental Management and Environmental Economy, EUC Thisted, Thisted

JANUARY 1997 – JUNE 1998

Environmental Management related to the governing standards.

Akademiingeniør (B.Sc.), Aalborg University, Aalborg

SEPTEMBER 1978 – JANUARY 1984

Energy line focusing on High Voltage/Electrical Engineering

Electrician, Den Jyske Haandvaerkerskole, Hadsten

JULY 1974 – JULY 1978

Skilled electrician

Courses

Training as Manager , Coloplast

AUGUST 2005 – AUGUST 2020

Remote audit, Bureau Veritas

APRIL 2020 – APRIL 2020

Shaping Behaviour, F5

FEBRUARY 2020 – FEBRUARY 2020

Management by Distance, Mannaz

APRIL 2020 – APRIL 2020

Reporting on Sustainable Development Goals, IDA

MARCH 2020 – MARCH 2020

Change Management, IDA

FEBRUARY 2019 – FEBRUARY 2019

Certified Auditor, Gilbert Associates (Force)

FEBRUARY 1989 – MARCH 1989

Extra-curricular activities

Networking groups: EGN, F5 and local group.

JANUARY 1992 – PRESENT

References

References available upon request