



JKS Consult By Jens-Kristian K. Søndergaard

CONSULTANT

Details

Bakkedraget 6

Thisted, 7700

Denmark

20653625

jks@io.dk

NATIONALITY

Danish

DRIVING LICENSE

Car B

DATE / PLACE OF BIRTH

1957-10-09

Rær

Links

[LinkedIn](#)

[JKS Consult](#)

Skills

QEHS Management -
Systems & Auditing (ISO
9001/14001/45001/13485)

Risk Assessment - ISO14971,
Projects, Product and Processes

Lean Six Sigma (PDCA/DMAIC) -
Visual Management

Office Package, Trackwise and
Veeva

GMP/GLP/GDP

MDR for CE marking

Management Review

Profile

QEHS Management and Audit Services.

Mission: *Enable growth of people and organizations.*

Values: *Respectful understanding of people with intention of guiding*

Vision: *Listen and respond*

Tasks - results

Quality Management

FEBRUARY 1991 – PRESENT

Quality (QEHS) Management and Services

- Achieve and maintaining AQAP/MDSAP/ISO9001/ISO 13485 certification.
- Timely launch of innovative products.
- Transfer of products and processes to Malaysia, Hungary and China.
- Change Management during factory close down process.
- Supplier Audit and approval of Suppliers.
- Internal Audit System development, planning and execution.
- Transportation studies
- Approvals achieved by key Customers
- FAT/SAT Protocol and Reports for new machines.
- Approval of validations

Skills

FEBRUARY 1991 – PRESENT

Qualifications and experiences:

- Auditing (ISO 9001/13485/14001/45001/MDSAP).
- PDCA/DMAIC/Six Sigma.
- Stage Gate development of innovative products
- Engineering skills within plastics, steel and energy technologies
- Analyses and utilization of data.
- Complaint analysis and improvement
- Risk Assessment, mitigation and validation.
- Creation of Control plans.
- CAPA, RCA, Change Control and NC
- Design of Management Review
- Review and approval of key documents.
- Supplier selection and making agreements

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

Languages

Danish

English

German

Utilizing Lean Six Sigma concepts. Based on DMAIC principles.

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

SEPTEMBER 1978 – JANUARY 1984

Energy line focusing on High Voltage/Electrical Engineering

Courses - updating

Management Training, Coloplast

AUGUST 2005 – AUGUST 2020

Remote audit, Bureau Veritas (North America)

APRIL 2020 – APRIL 2020

Shaping Behaviour, F5

FEBRUARY 2020 – FEBRUARY 2020

Managemant 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