NN
B.Sc. Business

Senior Consultant Audit and Validation

ID1025

Direct (+45)
nn@medicologic.com

medicologic®

Medical Device Development

Competences

- Qualified Lead auditor with notified body experience for:
- Medical Device Regulation 2017/745 (MDR)
- MDSAP
- Medical Device Directive 93/42/EEC
- ISO 13485:2016
- ISO 9001:2015
- 3 years of international audit experience within Quality Management Systems
- Expert in process validation

Key results

- Conducted + 100 international MDSAP/ISO 13485/CE audits for notified body and accredited organization.

- Key responsible for validation activities (process and software) for international FDA compliance projects.

Regulations/Standards/Guidance

- Medical Device Directive MDD 93/42/EEC,
- Medical Device Regulation MDR 2017/745
- ISO 13485:2016
- ISO 9001:2015
- MDSAP
- Harmonized/Internationally recognized standards i.e. ISO13485, ISO14971, EN62366, EN62304
- MEDDEV 2.7.1/4

Extensive knowledge in:
- MDD 93/42/EC
- ISO13485:2016
- FDA regulation [CFR part 820]
- MDSAP

Personal Characteristics

He is a thorough and dedicated person, who believes that results are best achieved in a straightforward open minded dialogue between the parties.

His spare time is used watching films, theater, football or art exhibitions. What time is left is allocated for music, food, books and travelling.

References

Medicologic A/S (2019 – present)

Audit Consultant
Audits within the medical device industry

Presafe Denmark A/S

Lead auditor and Quality Manager
International assignments as MDD/MDSAP/ISO 13485 auditor
Responsible for accreditation of Presafe to ISO 17021

NNIT A/S

Principal Consultant
IT compliance and IT security consulting

AL Engineering A/S

Senior Consultant
FDA compliance consulting
Validation expert – process and SW.

WIDEX A/S

RA Specialist
FDA-specialist
Software validation
Implementation of EN62304

AMBU A/S

Quality Systems Coordinator
Global implementation of quality systems and QMS software solutions.

Angiotech A/S

Validation responsible

Process and software validation

Unomedical

Quality Technician

Quality systems maintenance, development of QMS databases