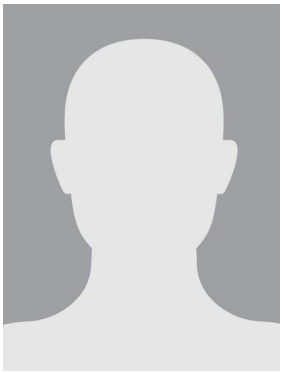

NN
M.Sc. Nanoscience, Aarhus University

Regulatory Affairs & Project Management

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Medical Device Development

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DK-2300 Copenhagen
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contact@medicologic.dk
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Competences

- Project Management, R&D
- Design Controls, R&D
- FDA approval process (PMA, De-Novo)
- Technical/regulatory writing incl. gap analysis
- Implants
- Biocompatibility
- Sterile barrier systems incl. sterilization
- Stability (shelf life) / Transportation
- Audit SME (Design control)
- Regulatory inquiries
- Manufacturing problem solving and optimization

Key results

Continuous delivery of projects in accordance with agreed quality, budget and timeline

Numerous successful regulatory approvals achieved (Class 1s-III), incl. PMA approval in US (class III)

Numerous audits from FDA, Europe and rest of world completed with no observations

Continuous ability to address and close technical inquiries from competent authorities

Software/Standards

Regulations
- MDD, MDR, CFR 21 part 820

Standards
- ISO 13485 (Quality Standard)
- ISO 14708-1 / EN 45502-1 (Active implantable medical devices)
- ISO 14971 (Risk Management)
- ISO 10993 (Biocompatibility)
- IEC 62366-1 (Usability)
- IEC 60601 (Electrical safety)
- ISO 11135 (ETO Sterilization)
- ISO 11607-1 (Sterile Barrier System)
- ASTM D4169 (Transportation)

Personal Characteristics

He is known for his goal-oriented way of working, effortlessly mixing a forward-looking attitude with a special blend of humor and dedication.

His great skill in connecting with team members through strong social abilities creates a team-oriented and pleasant atmosphere at work.

This balance between being professional and light-hearted, together with his focus on good results, clearly marks him as a highly valued and respected team member.

Moreover, his approach to work shows the Danish values of practical thinking, teamwork, and a friendly, personal way of interacting, making him an essential part of any collaborative project.

References

Medicologic A/S (present)

Senior Consultant

UNEEG Medical (2021 – 2023)

Project Manager

Project Manager for technical activities related to US registration. Project team consisting of 8-12 persons involving QA, RA, Hardware, Electronics, System Engineering, Consultants, CMOs, external specialists etc.

Contura International A/S (2016-2021)

Project Manager

Project Manager for design control activities related to US registration (PMA). Lead author on numerous technical documentations. Project manager on numerous development projects related to product extensions, market expansions, change in accessories manufacturing changes etc.

Contura International A/S (2014-2016)

Process Engineer

Production process execution, development and optimization.
QMS activities (NC, CAPA, CR and update of QMS procedures)
Design control activities (Author)

Teknologisk Institut (2011-2014)

Consultant

Project participant in European medical device research projects. Research into new materials intended for urinary catheters. Lab scale process set-up, development, and operation. Coordination of preclinical testing. Material characterization by analytical techniques (Chemical, physical, mechanical test etc.)