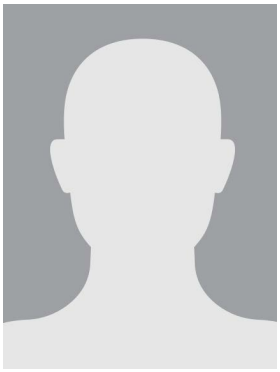

NN
B.Sc. IT & Electronics, DTU
M.Sc Telecommunications, DTU

Senior RA/QA Software Specialist

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Medical Device Development

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Competences

- Medical devices regulatory compliance (MDR)
- In vitro devices regulatory compliance (IVDR)
- Software
  - Software for medical devices
  - Software as a medical device (SAMD)
- Project management (Prince2 / SCRUM Master)
- Product management (SCRUM Product Owner)
- Design control
  - Requirements Management
  - Usability engineering
  - Verification and Validation
  - Post Market Surveillance (PMS)
- Cyber security
  - Cyber security for companies
  - Cyber security for products
- Medical device certification
  - Technical file for CE marking
  - FDA 510(k) submission
- Risk Management
  - Product risk & Software risk
  - CAPA
- Internal and External Auditor

Key results

20+ career as project manager and consultant within software development for medical devices and as QA responsible.

A solid track record within project planning, coordination and deliverance.

Extensive knowledge of the regulatory landscape and market access requirements for medical devices in EU and US.

Built and certified several ISO 13485 quality management systems with focus on quality and maintainability.

Certified several products with the CE mark and FDA approval.

Focus on software development for medical devices and cybersecurity for companies and products.

Strong experience as technical writer for regulatory and quality standards with startup companies and within upgrading from MDD to MDR for existing medical products.

Project manager and director for interdisciplinary groups within software, mechanics and chemistry.

Software/Standards

- ISO 13485 - Medical devices - Quality Management Systems
- ISO 14971, ISO 24971 - Medical devices - Risk management
- EU Directives: Medical Device Directive MDD 93/42/EC, in vitro diagnostic directive IVDD 98/79/EC, AIMDD 90/385
- EU regulations: Medical device regulation 2017/745, In vitro diagnostic medical devices 2017/746
- FDA regulations: CFR 21 Part 820, Part 11
- IEC 62304, IEC 82304 - Medical device software and SAMD
- IEC 62366 - Usability engineering
- ISO/TR 20416 - Post Market Surveillance
- ISO 27001 - Information security, cybersecurity
- IEC 81001 - Health software and health IT systems safety
- ISO 15223-1 Labelling of medical devices
- Prince2, Professional Scrum Master & Product owner, SAFe
- Windows, Linux, Embedded Linux, Git, Jira, Confluence
- C++, Python, C#, Web API
- PyTest, PyCharm, Unit Test and Integration test

Personal Characteristics

Strong technical competences and communication abilities. Deep business understanding allows the consultant to cooperate on all levels. Excels within working processes, project planning, the technical development, managing contracts, and the ability to challenge technical solutions.

Hands-on experience with every aspect of quality management and Regulatory Affairs from startup companies and management experience for large international corporations. Good in creating target and directions for project teams and departments. Motivated to create effective and innovative solutions.

Focus on collaboration and effective solutions, organised and efficient to maintain milestones.

Knowledgeable regarding GMP solutions within QA, software development and medical device validation.

References

Medicologic A/S (present)

Senior Consultant

Robotics Company

Cybersecurity consultant with focus on software and cybersecurity for a medical device, EU and US.

Convatec **Project manager** for MDD to MDR transition.

Qlife A/S **Software QA manager** for IVD detection of Covid.

Spiromagic and Lina Medical

QA Manager for creation of QMS regarding lung measurements and menstruation equipment.

Unisense Fertilitech

Software QA manager medical device for embryo development.

Dako Denmark / Agilent Technologies

Software director medical device for cancer detection.