



NN
Cand.Scient. Health Informatics, KU

Senior RA/QA SaMD Specialist

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Medical Device Development

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Competences

- Medical devices regulatory compliance
- MDSW/SaMD Life-cycle management
 - Regulatory Strategy and Submission
 - Digital Therapeutics (DTx)
 - AI/ML Enabled Medical Devices
- Project Management
- Quality Assurance and Design Assurance
- Design Control
 - Risk Management
 - Requirements Engineering / mngt.
 - Usability Engineering
 - Design Verification and Validation
- Technical Writer
 - Design Input/output deliverables
 - Test Protocols and reports

Software/Standards

- MDR
- FDA regulation

- ISO 13485
- ISO 14971 (+ISO/TR 24971:2020)
- IEC 62304
- IEC 82304
- IEC 62366-1 and 62366-2

- eDMS/eQMS Knowledge:
 - GreenLight Guru,
 - Veeva Vault,
 - MasterControl

- Methods: Agile, SCRUM, SAFe5 and V-model,

References

Medicologic A/S (present)

Senior Consultant

RA/QA Specialist

Ensuring regulatory compliance and product market access.

Dawn Health (2018 - 2023)

Various Positions

I worked primarily for the following clients from 2018 to 2023: Novo Nordisk, Coloplast, Novartis, Lundbeck. 20+ digital health projects in various phases of the product life-cycle.

Managed and maintained the ISO13485 certificate from 2019 to present, and MDSAP and ISO2701 program from 2023 to present.

Key results

I'm specialised in medical devices regulatory compliance and market access. I cover several aspects/phases of Class I, Class IIa and Class IIb product development and maintenance with an enhanced focus on Medical Device Software (Stand-alone, embedded or as an accessory).

I have extensive knowledge of the regulatory landscape and market access requirements for medical devices in key markets such as: EU, US, Japan and Canada. This includes ensuring compliance with various industry standards, including but not limited to: ISO13485, ISO14971, IEC62304 and IEC82304.

Key results:

- MDR Class I and MDR Class IIa from concept to product registration/submission (incl. Clinical Evaluation)

Personal Characteristics

I consider myself to be an open and highly collaborative team member. I truly value the importance of teamwork and believe that collective efforts bring the best results. I enjoy engaging in open and honest discussions on how to solve tasks or address and fix issues at hand, as I believe that diverse perspectives lead to better outcomes.

Furthermore, I'm not just motivated by the assignment itself, but rather by the opportunity to find effective solutions and deliver outstanding results. I thrive on challenges and enjoy thinking outside the box to come up with innovative approaches.

In addition to my collaborative skills and problem-solving mindset, I am also excellent in managing my own time and tasks. I am highly organized and efficient, which allows me to prioritize effectively and meet deadlines with ease.