Kristoffer Schou Madsen
Cand.Scient. Health Informatics, KU

Senior RA/QA SaMD Specialist

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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

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)

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,

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.

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.

DELTA (2015 - 2018)

Senior Medico Specialist
Worked primarily with different start-ups from 2015-2018: Helping companies develop medical-grade software throughout every phase, starting from initial regulatory strategy to ensuring compliance with the following industrial standards: ISO 14971, IEC 62304, IEC 82304-1, IEC/TR 80002-1, IEC 62366-1, and ISO 13485.