Morten Sørensen
MD, University of Copenhagen

Clinical evaluations and compliance

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Competences

- Project management
- Clinical evaluations.
- Clinical compliance (MDR/IVDR)
- Clinical trials and GCP
- Clinical investigations and GCP
- Expert insight within the healthcare sector
- Business innovation on the basis of science and research
- Fundraising
- R&D development and launch within MedTech.
- Literature and vigilance
- ISO 14155, 13485 and 14791
- Startup and early-stage project scoping

Key results

- Clinical Trials and clinical investigation execution for private companies and start-ups
- Peer-reviewed publications
- Development of solutions and products within the healthcare space
- Attraction of +4 million SEK in angel funding
- Clinical experience, +5 years
- Creation and review of clinical documentation packages including CIPs, CIRs, CEPs. CERs and PMCF plans and reports for medical devices.
- Development of execution plans and strategic approach for medical device projects
- Clinical and technical reviews to Notified Bodies as part of transition from MDD to MDR

Standards

- Clinical evaluation according to MDR regulations and MEDDEV 2.7.1 rev. 4: author and evaluator of Clinical Evaluation Plans and Reports
- ISO 14155
- ISO 13485
- ISO 14791
- GCP
- GDP
- IMFDR

Personal Characteristics

Morten has vast experience across the healthcare sector within the clinical development area – ranging from medical devices to pharmaceutical trials.

Morten has a personal trait that makes people feel safe and empowered through his calm nature and optimistic view on things. He truly believes there is always a way to move forward.

His values are excellence, integrity and innovation

References

Medicological A/S

Consultant, Clinical evaluations, and compliance

Novo Nordisk A/S

International Medical Manager
Clinical evaluations of medical devices and combination products. Risk class 2.

AMBU A/S

Clinical Innovation Specialist
Clinical evaluations of medical devices and post market updates. Risk class 1-2

Sanos Clinic A/S

Principal Investigator

Execution of trials from greenlight to close-out. Phase 1-3, and risk class 1.

MTLS Group ApS

CEO
Consultancy in MedTech, biotech and Healthtech, product development and early-stage investment

Medflow ApS

CEO
Software development for medical device project management and QMS including AI through Large Language Model development