MDS DENMARK × SPARK DENMARK

Webinar: Why the Clinical Evaluation Plan & Report is Your Gateway to Market Entry

📅 September 3rd, 2025 | 🕓 16:00 – 17:00 | Online via Zoom

Launching an AI-powered medical device in the European Union is a high-stakes journey where regulatory strategy and clinical evidence can make or break success. This exclusive session will reveal why the Clinical Evaluation Plan (CEP) and Clinical Evaluation Report (CER) are not just paperwork — they are the foundation of your MDR/IVDR market approval.

What You'll Learn

💡 **Regulatory Roadmap for AI Medical Devices**
- CE Marking, MDR/IVDR essentials, and AI-specific challenges like adaptive algorithms, bias mitigation, and data integrity
- Role of Quality Management Systems

💡 **Budgeting for Success**
- Cost drivers from prototyping to post-market surveillance, and how early regulatory decisions affect long-term budgets

💡 **Clinical Trials 101**
- When trials are needed, their key stages, and AI-specific challenges such as dataset representativeness and performance drift

💡 **CEP & CER – Your Clinical Evidence Backbone**
- Purpose, structure, evidence sources, and strategies to meet MDR safety, performance, and benefit-risk requirements

💡 **Case Study: From Concept to Market**
- A condensed example of an AI device journey from classification to market, highlighting budget and evidence development

A robust CEP and CER can accelerate market entry, reduce costs, and prevent regulatory delays. Gain practical insights and first-hand advice from an experienced MedTech founder with a track record in AI-powered devices, and take advantage of the Q&A session to get practical answers and tailored pointers for your own market journey!

Sign up today by scanning the QR-code!