MEDICO INDUSTRIEN
MEDTECH DENMARK

Program

Clinical Evaluation for Medical Devices in Europe and International approach

Dates: 12 - 13 December 2024 **Location:** Medicoindustrien, Bøge Allé 5, 2970 Hørsholm **Instructor:** Danielle Giroud, CEO, WMDO and CEO MD-CLINICALS	
Day 1: 09.00 – 16.00	
08:30 – 09:00	Breakfast buffet
09:00 – 16:00	Clinical Evaluation Regulatory background Pre-requisites to clinical evaluation – new approach from WI of ISO 18969 Clinical Evaluation/performance Plan • MDR requirements and main differences for IVD devices • Scope • Define standard of care • Clinical development plan • Define relevant data sets Clinical evaluation report Close the loop with risk management and PMS/PMCF/PMPF
12:30 – 13:30	Lunch
Day 2: 09.00 – 15.30	
08:30 – 09:00	Breakfast buffet
09:00 – 12:30	Formulating clinical investigation objectives and endpoints for medical devices • Broad strategy • Define objectives and endpoints • How to reach meaningful conclusions • Study design types Clinical investigation planning, conduct and close down – MDR vs ISO 14155
13:30 – 15:30	PMCF plan Is an international strategy feasible?
12:30 – 13:30	Lunch