MEDICO INDUSTRIEN
MEDTECH DENMARK

# Program

# Clinical Evaluation for Medical Devices in Europe and International approach

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| **Dates:** 5 - 6 November 2024<br>**Location:** Medicoindustrien, Bøge Allé 5, 2970 Hørsholm<br>**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<br>Pre-requisites to clinical evaluation – new approach from WI of ISO 18969<br>Clinical Evaluation/performance Plan<br>• MDR requirements and main differences for IVD devices<br>• Scope<br>• Define standard of care<br>• Clinical development plan<br>• Define relevant data sets<br>Clinical evaluation report<br>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<br>• Broad strategy<br>• Define objectives and endpoints<br>• How to reach meaningful conclusions<br>• Study design types<br>Clinical investigation planning, conduct and close down – MDR vs ISO 14155 |
| 13:30 – 15:30 | PMCF plan<br>Is an international strategy feasible? |
| 12:30 – 13:30 | Lunch |