MEDICO INDUSTRIEN
MEDTECH DENMARK

Programme

Clinical Evaluation for Medical Devices in Europe and International approach

Instructor: Danielle Giroud, WMDO	
Day 1: 09.00 – 16.00	
08.30 – 09.00	Breakfast buffet
09:00 – 16.00	Regulatory background of clinical evaluation. Clinical evaluation through review of existing data • What are your pre-requisites • The literature review process – what needs to be included • Consistent approach – link with risk management • Formulating meaningful conclusions • Case study Formulating the objectives and endpoints of a clinical investigation and identify the right study design pre-and post CE-mark
12:30 – 13:30	Lunch
Day 2: 09.00 – 16.00	
08:30 – 09:00	Breakfast buffet
09:00 – 16:00	Globalization of clinical data – how to optimize the use of clinical data internationally (including case studies). EU-MDR a review for clinical professionals Full review of FDIS ISO 14155:2019 – what all clinical professionals should know to ensure compliance starting now!
12:00 – 12:45	Lunch