MEDICO INDUSTRIEN
MEDTECH DENMARK

Programme

ISO 13485 and Quality Management for Medical Devices / Internal Auditing

Day 1 - ISO 13485 and Quality Management for Medical Devices	
08.30 - 09.00	Breakfast and registration
09.00 - 09.30	Introduction and presentations
09.30 - 12.00	Regulatory framework Introduction to ISO 13485 (Ch. 1-3) Morning break(s)
12.00 - 13.00	Lunch
13.00 - 16.45	Documents and records (Ch. 4) Management responsibility (Ch. 5) Resource management (Ch. 6) Introduction to risk and usability Product realization (Ch. 7) - Design Afternoon break(s)
16.45 - 17.00	Wrap up for the day

Day 2 - ISO 13485 and Quality Management for Medical Devices	
08.30 - 09.00	Breakfast
09.00 - 09.15	Recap from Day 1
09.15 - 12.00	Product realization (Ch. 7) - continued - Design - Change management - Supplier control Morning break(s)
12.00 - 13.00	Lunch
13.00 - 16.45	Product realization (Ch.7) - continued - Production Technical documentation Measurement, analysis and improvement (Ch. 8) Afternoon break(s)
16.45 - 17.00	Wrap up for the day

Day 3 - Auditing	
08.30 - 09.00	Breakfast
09.00 - 12.00	Audit fundamentals (EN ISO 19011) - Principles - Planning - Activities Agenda and preparing the audit How to conduct an audit - Observations, non-conformities and recommendations Morning break(s)
12.00 - 13.00	Lunch
13.00 - 13.45	How to conduct an audit – continued - Observations, non-conformities and recommendations Audit report and follow-up Auditor behavior Do’s and don’ts
13.45 - 14.00	Break
14.00 - 16.00	Test