MEDICO INDUSTRIEN

Design Control

Day 1:

08.30 – 09.00	**Registration and breakfast**
09.00 – 09.10	**Welcome by Medicoindustrien**
09.10 – 10.10	**Introduction** - Authority Requirements for development of medical devices - Development Planning, how to define activities - Design Input definition
10.10 – 10.30	**Coffee break**
10.30 – 11.40	**Design Input** - Design Input specification (user, customer & authority requirements) - Authority expectations - Product Requirement Specification - Design Input Review
	Short break
11.40 – 12.20	**Risk Management Process (ISO 14971:2019)** - Use FMECA - Design FMECA - Process FMECA
12.20 – 13.20	**Lunch**
13.20 – 14.30	**Design Output** - Development Process - Design Specification, Hardware Specification & Software Specification - Output documents according to EU MDR
14.40 – 14.50	**Coffee break**
14.50 – 16.00	**Design Output** - Output documents according to EU MDR
16.00 – 16.10	**Questionnaire and conclusions**

Day 2:

08.30 – 09.00	**Registration and breakfast**
09.00 – 10.10	**Design Verification** - Device Functionality Testing (mechanical, electrical, software) - Biocompatibility - Device Aging/lifetime testing
10.10 – 10.30	**Coffee break**
10.30 – 11.30	**Clinical Evaluation & Investigation** - Clinical Evaluation Plan - Clinical Evaluation Report - Clinical Investigation process
	Short break
11.30 – 12.20	**Design Validation (Usability)** - IEC 62366 requirements - Practical Performance Introduction - Moderator Guide & Observation form
12.20 – 13.20	**Lunch**
13.00 – 14.30	**Design Transfer** - Production Setup incl. Traceability - Supplier management & purchase - Process validation
14.30 – 14.50	**Coffee break**
14.50 – 15.50	**Design Changes & DHF/DHR/DMR** - Change Management Process - Design History File (DHF) – Document Order - Device History Record (DHR) - Device Master Record content (DMR)
15.50 – 16.00	**Wrap up and conclusions**