

Design Control

Day 1:

08.30 – 09.00	Registration and breakfast
09.00 – 09.10	Welcome by Medicoindustrien
09.10 – 10.10	Introduction <ul style="list-style-type: none">- Authority Requirements for development of medical devices- Development Planning, how to define activities- Design Input definition
10.10 – 10.30	Coffee break
10.30 – 11.30	Design Input <ul style="list-style-type: none">- Design Input specification (user, customer & authority requirements)- Authority expectations- Product Requirement Specification- Design Input Review Short break
11.30 – 12.00	Risk Management Process (ISO 14971:2019) <ul style="list-style-type: none">- Use FMECA- Design FMECA- Process FMEV'CA
12.00 – 13.00	Lunch
13.00 – 14.30	Design Output <ul style="list-style-type: none">- Development Process- Design Specification, Hardware Specification & Software Specification- Output documents according to EU MDR
14.30 – 14.50	Coffee break
14.50 – 16.00	Design Output <ul style="list-style-type: none">- Output documents according to EU MDR
16.00 – 16.10	Wrap up and conclusions

Day 2:

08.30 – 09.00	Registration and breakfast
09.00 – 10.10	Design Verification <ul style="list-style-type: none">- Device Functionality Testing (mechanical, electrical, software)- Biocompatibility- Device Aging/lifetime testing
10.10 – 10.30	Coffee break
10.30 – 11.30	Clinical Evaluation & Investigation <ul style="list-style-type: none">- Clinical Evaluation Plan- Clinical Evaluation Report Short break
11.30 – 12.00	Design Validation (Usability) <ul style="list-style-type: none">- IEC 62366 requirements- Practical Performance Introduction
12.00 – 13.00	Lunch
13.00 – 14.30	Design Transfer <ul style="list-style-type: none">- Production Setup incl. Tracability- Supplier management & purchase- Process validation
14.30 – 14.50	Coffee break
14.50 – 15.50	Design Changes & DHF/DHR/DMR <ul style="list-style-type: none">- 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