MDR TRAINING COURSE - GET READY FOR MDR BY NB2265

Place: Bratislava, Slovak Republic

Day 1	
9.00 – 9.30	Welcome speech, goal of the training course, introduction of participants (K. Srdošová, Ľ. Lysák)
9.30 – 10.30	Legal changes in the field of Medical Devices – New MDR Requirements (Ľ. Lysák)
10.30 – 10.45	Coffee break
10.45 – 11.45	Legal changes in the field of Medical Devices – New MDR Requirements (Ľ. Lysák) cont.
11.45 – 13.00	Lunch
13.00 – 15.00	General Safety Requirements as per Attachment I. MDR (M. Tomin, K. Srdošová)
15.00 – 16.00	Open tasks, issues, evaluation of day.
Day 2	
9.00 – 10.30	NB2265 Conformity assessment process of Medical Devices as per MDR (Ľ. Lysák, N. Achimská)
10.30 – 10.45	Coffee break
10.45 – 11.45	NB2265 Conformity assessment process of Medical Devices as per MDR (Ľ. Lysák, N. Achimská) cont.
11.45 – 13.00	Lunch
13.00 – 14.00	Biocompatibility process (N. Achimská)
14.00 – 14.15	Coffee break
14.15 – 16.00	Audit techniques as per MDR, ISO 13485:2016 and ISO 19011:2018, Introduction of Mandatory Checklist (M. Tomin, K. Srdošová)
16.00 – 17.00	Open tasks, issues, evaluation of day.
Day 3	
9.00 – 10.30	How to proper evaluate the Risk Analysis (M. Tomin)
10.30 – 10.45	Coffee break
10.45 – 12.00	Requirements for the Clinical Evaluation and Post Marketing Surveillance etc. (J. Šalgovič)
12.00 – 13.00	Lunch
13.00 – 14.30	Sterilization Processes (J. Slúka)
14.30 – 14.45	Coffee break
14.45 – 17.00	Open tasks, issue
17.00	Thank you, End of the training, Final Evaluation and feedback