MDR TRAINING COURSE - GET READY FOR MDR BY NB2265

May 4th – 6th, 2022

Place: online course

Day 1	
9.00 – 9.30	Welcome speech, goal of the training course, introduction of participants (K. Srdošová, Ľ. Lysák)
9.30 – 11.00	Legal changes in the field of Medical Devices – New MDR Requirements (Ľ. Lysák)
11.00 – 11.10	Break
11.10 – 12.00	Classification of MD according to MDR (J. Slúka)
12.00 – 13.00	Lunch
13.00 – 14.30	General Safety Requirements as per Attachment I. MDR (I. Poláček)
14.30 – 14.40	Break
14:40 – 16.00	Introduction to the differences between ISO 13485 and MDR quality management system requirements (N. Achimská)
16:00 – 16:30	Open tasks, issues, evaluation of day
Day 2	
9.00 – 10.30	Risk Management of MD as per ISO 14971 and MDR (I. Poláček)
10.30 – 10.40	Break
10.40 – 12.00	Requirements for the Clinical Evaluation and Post Marketing Surveillance etc. (J. Šalgovič)
12.00 – 13.00	Lunch
13.00 – 14.30	Requirements for the Clinical Evaluation and Post Marketing Surveillance etc. (J. Šalgovič) cont.
14.30 – 14.40	Break
14.40 – 16.00	Requirements for the Clinical Evaluation and Post Marketing Surveillance etc. (J. Šalgovič) cont.
16.00 – 16.30	Open tasks, issues, evaluation of day.
Day 3	
9.00 – 9.50	Requirements for technical documentation according to MDR (J. Slúka)
9.50 – 10.00	Break
10.00 – 12.00	Unique device identification system - "UDI system" (N. Achimská)
12.00 – 13.00	Lunch
13.00 – 14.30	NB2265 Conformity assessment process of Medical Devices as per MDR (Ľ. Lysák)
14.30 – 14.40	Break
14.40 – 15.40	EU declaration of conformity, instructions for use and labeling of the medical device (J. Slúka)
15.40 – 16.30	Thank you, End of the training, Final Evaluation and feedback