MEDICO INDUSTRIEN
MEDTECH DENMARK

Program

U.S. Quality System Regulation and other US Regulations for medical devices – Concepts and Application

MedicoIndustrien, Bøge Allé 5, 2970 Hørsholm

Instructor: Vincenzo Passalia, DONAWA LIFESCIENCE CONSULTING Srl

Day 1: 08.30 – 16.30 (*optional 17:30*)	
08.30 – 09.00	Registration – Breakfast buffet
09.00 – 10.15	Introduction, General information and QSR Subpart A
10.15 – 10.30	Coffee/tea break
10.30 – 12.30	MDSAP Chapters 1 and 2
12.30 – 13.15	Lunch break
13.15 – 14.30	MDSAP Chapters 3 and 4
14.30 – 14.45	Coffee/tea break
14.45 – 16.30	Continuation of MDSAP Chapter 4
16.30 – 17.30	*Optional*: *One-to-one discussion and review of your documents/SOPs*
Day 2: 09.00 – 15.00 (*optional 17:30*)	
09.00 – 10.15	Workshop on Medical Device Reporting and conclusion of MDSAP Chapter 4
10.15 – 10.30	Coffee/tea break
10.30 – 12.30	MDSAP Chapters 5 and 6
12.30 – 13.15	Lunch break
13.15 – 14.30	Conclusion of MDSAP Chapter 6 and other U.S. regulations
14.30 – 15.00	Wrap-up