

## WEEKLY TRAINING MODULE 1

	<b>Monday</b>	<b>When</b>	<b>Who</b>
<b>27-Nov</b>	Opening message launched in the Forum (asynchronous activity)	10:00	
	<b>Live opening event</b>	14:00 - 15:30	
<b>28-Nov</b>	<b>Tuesday</b>	<b>When</b>	<b>Who</b>
	Independent asynchronous study		
<b>29-Nov</b>	<b>Wednesday</b>	<b>When</b>	<b>Who</b>
	Synchronous live session on <b>Overlaps between SoHO, ATMPs and Medical Devices frameworks</b>	14:00 - 15:30	
<b>30-Nov</b>	<b>Thursday</b>	<b>When</b>	<b>Who</b>
	Independent asynchronous study		
<b>01-Dec</b>	<b>Friday</b>	<b>When</b>	<b>Who</b>
	Forum	14:00 - 16:00	
<b>02-Dec</b>	<b>Saturday</b>	<b>When</b>	<b>Who</b>
	Independent asynchronous study		
<b>03-Dec</b>	<b>Sunday</b>	<b>When</b>	<b>Who</b>
	Independent asynchronous study		

WEEK 1 27/11/23 - 01/12/23	TOPIC EU LEGAL PROVISIONS			LEAD TUTOR/S S. Pupella - H. Kurz
SUB-TOPIC	METHODOLOGY	TIMING	TEACHER EXTERNAL EXPERT INVOLVED	
EU current directives	Pre-recorded presentation and reading of selected parts of the directives followed by discussion in the <b>Forum</b>	Available on the platform	H. Kurz	
Intro to the new regulation	Pre-recorded presentation	Available on the platform	DG SANTE	
Basic info on current Medical Device Regulations relevant for BTC establishments defining the borderlines for novel BTC with other regulatory frameworks, in particular where medicinal products and medical devices are concerned	Pre-recorded presentations	Available on the platform	External Experts	
Overlaps between SoHO, ATMPs and Medical Devices frameworks	Discussion (Q&A session, breakout rooms) in synchronous <b>live session</b>	29/11/2023	H. Kurz, S. Pupella	
<p><b>LEARNING OBJECTIVES</b></p> <p>To facilitate a harmonised interpretation of the EU legislative framework</p> <p>To deepen awareness of the connection and interaction of SoHO legal provisions with medical devices and ATMP regulations as well as Regulation and Directive of medicinal products and their impact on inspections and authorisation of novel processes</p>				
<p><b>BIBLIOGRAPHY</b></p> <p>EU BTC Directives; Regulation EU 2017/746 Invitro diagnostic medical devices; Regulation EU 2017/745 on medical devices amending Directive 2001/83/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 on medicinal products; Regulation (EC) No 1394/2007 on advanced therapy medicinal products</p>				