



**MEDICAL DEVICE
REGULATIONS CONFERENCE**



September 21-23, 2021

Virtual

UGA Athens

Day 3 Agenda – MDR/IVDR Workshop: September 23, 2021 Moderated by: Kimberly Walker		
8:00-8:15 AM	Welcome and Workshop Overview	Ms. Kim Walker
8:15-9:15 AM	Economic operators role <ul style="list-style-type: none"> • Distributors • Importers • EC-REP 	Seppe de Gelas
9:15-10:00 AM	PRRC expectations and implementation; how to select / prepare your PRRC	Philippe Etter (Medidee)
10:00-10:15 AM	Morning Break	
10:15-10:45 AM	From ER to GSPR	Anthony Rizzo (BSI)
10:45-11:15 AM	Typical gaps – Biological safety	Thor Rollins (Nelson)
11:15-11:45 AM	Typical gaps – Clinical Evaluation, PMCF	Dr. Richard Curno (Medidee)
11:45-12:15 PM	QMS changes for MDR / IVDR	Anthony Rizzo (BSI)
12:15-12:45 PM	Brexit - SwissXit	Michael Maier (Medidee)
12:45-1:15 PM	Lunch Break	
1:15-2:45	Technical Documentation upgrade planning exercise – <i>review of a sample anonymized Tech Doc to find gaps and plan changes</i>	Philippe Etter (Medidee)
2:35-3:00 PM	Closing Remarks	