



MEDICAL DEVICE
REGULATIONS CONFERENCE



September 21-23, 2021

Virtual

UGA Athens

Day 3 Agenda – MDR/IVDR Workshop: September 23, 2021* Moderated by: Kim Walker		
8:00 - 8:15 AM	Welcome and Workshop Overview	Kim Walker, Global Regulatory, Quality & Clinical Consultant
8:15 - 9:15 AM	Economic Operators Role <ul style="list-style-type: none"> • Distributors • Importers • EC-REP 	Seppe de Gelas, UGA
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	MDR Technical Documentation Submissions – Lessons Learned	Anthony Rizzo, BSI
10:45 - 11:15 AM	Typical Gaps – Biological Safety	Thor Rollins, Nelson Labs
11:15 - 11:45 AM	Typical Gaps – Clinical Evaluation, PMCF	Richard Curno, Medidee
11:45 - 12:15 PM	How to Manage MDR/IVDR Quality System Changes	Anthony Rizzo, BSI
12:15 - 12:45 PM	Brexit – SwissXit	Michael Maier, Medidee
12:45 - 1:15 PM	Lunch Break	
1:15 - 2:45 PM	Technical Documentation Upgrade Planning Exercise – <i>Review of a sample anonymized Tech Doc to find gaps and plan changes</i>	Philippe Etter, Medidee
2:45 - 3:00 PM	Closing Remarks - Philippe Etter, Medidee	

*Workshop is Solely Sponsored by UGA