2021 AMDM Annual Virtual IVD Regulatory Meeting Agenda

Day 1 Agenda: Friday, April 16
All times are PDT

Topic	Time	Speaker
Open Online Portal Welcome	8:45 ***PDT***	**Meeting Chairs***
Industry Perspective IVDR • The most important things to consider when getting started with the IVDR • Intended Purpose • Performance Evaluation • Maintaining compliance • Common mistakes and top tips for compliance	9:00-9:45	**Sue Spencer,** IVD Lead & Principal Consultant Qserve Group, United Kingdom
The UKCA Mark and Impacts for IVD Manufacturers	9:45-10:30	**Richard Saunders** Technical Director, International Regulatory Affairs Ortho Clinical Diagnostics
IVDR Update – State of Play	10:30-11:00	**Julien Senac,** Global Director-IVD Focus Team TÜV SÜD
BREAK 11:00 - 11:15		
Challenges and Opportunities for (non-COVID) Diagnostics in the Time of COVID-19	11:15-11:45	**Allyson B. Mullen**, Director Hyman, Phelps & McNamara, PC
Global COVID-19 Submission Pathways	11:45-12:30	**Kelli Tanzella, Ph.D**. Senior Director, Global Regulatory Affairs, Clinical & Compliance Thermo Fisher Scientific
CLOSING REMARKS		

2021 AMDM Annual Virtual IVD Regulatory Meeting Agenda

Day 2 Agenda: Friday, April 23
All times are PDT

Topic	Time	Speaker
Open Online Portal Welcome	8:45 ***PDT***	**Meeting Chair***
China New MDR and Companion Diagnostic Requirements	9:00-9:45	**Ms. Jing Nie** Director of Regulatory Affairs, ASPAC **Ms. Xiaofang Zhuo** Assoc. Director Regulatory Affairs, ASPAC Johnson & Johnson
Artificial Intelligence and Machine Learning in Diagnostics - From a CMO's Perspective	9:45-10:15	**Dr. Richard Frank, MD, PhD,** Chief Medical Officer Siemens
Snapshot of Key IVD Policy Issues	10:15-11:00	**Jamie Wolszon,** Associate Vice President Technology & Regulatory Affairs AdvaMed Dx
BREAK 11:00 - 11:15		
COVID-Related Healthcare Compliance Topics • Presentation / Case Study • Breakout Discussions of Compliance Issues • Discussion of Findings/Conclusions	11:15-12:25	**Professor Jacob Elberg** Associate Professor of Law, Associate Director of the Center for Health & Pharmaceutical Law **Professor Jennifer Oliva** Associate Professor of Law, Director of the Center for Health & Pharmaceutical Law Seton Hall University Law School
Wrap-up	12:25-12:45	
CLOSING REMARKS		

**Special thanks to our 2021 Meeting Co-Chairs*

Ann M. Quinn, BSMT (ASCP), RAC, Director, Regulatory Affairs, Ortho Clinical Diagnostics
Gaozhen Hang, Senior Regulatory Strategy & Policy Specialist, Siemens Healthcare Diagnostics, Inc
Donna Link, Director Regulatory & Compliance, TechLab
Karin Hughes, Ph.D., Senior Vice President Regulatory & Quality, Beaufort CRO