



2024 Annual IVD Regulatory Hybrid Meeting Agenda

Wednesday April 24th

Room: White Flint Amphitheater and Common Area

Presenter Location

8:00 – 8:50 am	Networking Breakfast	
8:50 – 9:00	Welcome / Opening Remarks Lisa Charter / Michelle Roeding, Event Co-Chairs	<i>Onsite</i>
9:00 – 9:40	U.S. IVD Overview and Update Jeff Gibbs, Director, Hyman Phelps & McNamara	<i>Onsite</i>
9:40 – 10:20	The LDT Regulatory Landscape & Final Rule - Quality System Regulation Tim Stenzel, MD, PhD, Former FDA Director of OIVD at FDA	<i>Remote</i>
10:20 – 10:40	Morning Break	
10:40 – 11:20	Laboratorian View on LDTs and Q & A Jonathan Genzen MD, PhD, Chief Medical Officer, ARUP Laboratories Professor, University of Utah Department of Pathology Eric Konnick, M.D., M.S., FCAP Associate Professor, Associate Director - Genetics & Solid Tumor Laboratory, Dept of Lab. Medicine & Pathology Jeff Gibbs, Director, Hyman Phelps & McNamara	<i>Onsite</i>
11:20 – 12:00	Strategic and Tactical Application of PCCP to AI and Beyond Brendan O’Leary, Digital Health, Tech., Reg. & Policy Consultant	<i>Onsite</i>
12:00 – 1:00	Networking Luncheon	
1:00 – 1:40	Global Regulatory Toolbox for Clinical Trial Assays Banu Saritas-Yildirim, PhD, Sr. Director, Regulatory Affairs, Natera	<i>Onsite</i>
1:40 – 2:20	Global Clinical Pharma – Device Partnerships What Device Manufacturers Need to Know to Support Pharma Claudia Dollins, VP, Precision Medicines, Global Reg. Affairs, GSK	<i>Onsite</i>
2:20 – 2:40	Afternoon Break	
2:40 – 3:20	IVD Development: Partnering w/ BARDA & Regulatory Considerations Danielle M. Turley, PhD, Chief, Regulatory Affairs Branch, HHS	<i>Onsite</i>
3:20 – 4:00	IVD Development: a DOD Perspective Chandar Thakur, PHD, RAC, Branch Chief Medical Devices & Diagnostics, ORA, U.S. Army Medical Research & Dev. Command	<i>Onsite</i>
4:00 – 4:40	The Effect of COVID-19 on the Regulatory Landscape Maureen Garner, President, New World Regulatory Solutions, Inc. Glenn Neumann, Director, Scientific Affairs, NWRS, Inc.	<i>Onsite</i>
4:40 – 5:00	AMDM Annual Business Meeting	
5:00 – 6:00	Onsite Welcome Reception	



Thursday April 25th

Room: White Flint Amphitheater and Common Area

Presenter Location

7:30 – 8:10 am	Networking Breakfast	
8:10 – 8:20	Opening Remarks Lisa Charter / Michelle Roeding, Event Co-Chairs	
8:20 – 9:00	China Regulatory Updates Dr. Yun-Fu Hu, Chief Medical Officer, Genetron Health	<i>Remote</i>
9:00 – 9:40	Establishing the Right Level of Clinical Evidence Under IVDR Peter Bogaert, PhD, Senior Consultant IVD - Regulatory Affairs, Qarad	<i>Onsite</i>
9:40 – 10:20	What's Hot and What's Not in CDx in Asia-Pac. + India Ames Gross, President, Pacific Bridge Medical	<i>Onsite</i>
10:20 – 10:40	Morning Break	
10:40 – 11:20	GDPR - General Data Protection Regulation / Privacy/ Cybersecurity Landscape & Compliance Stephen Ferrell, VP IT Governance & Software Assurance CompliancePath Limited	<i>Onsite</i>
11:20 – 12:00	EU/IVDR Updates Stefan Burde, Director, Global Focus Team IVD, TÜV SÜD	<i>Onsite</i>
12:00	Adjourn / Lunch to Go	

