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	*Onsite*
9:00 – 9:40	**U.S. IVD Overview and Update** Jeff Gibbs, Director, Hyman Phelps & McNamara	*Onsite*
9:40 – 10:20	**Recent FDA Proposals & Actions: Draft LDT Rule, Harmonization of QSR & ISO 13485, Potential Down Classification of Some CDx Assays, & More** Tim Stenzel, MD, PhD, Former FDA Director of OIVD at FDA	*Remote*
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	*Onsite*
11:20 – 12:00	**Strategic and Tactical Application of PCCP to AI and Beyond** Brendan O'Leary, Digital Health, Tech., Reg. & Policy Consultant	*Onsite*
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	*Onsite*
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	*Onsite*
2:20 – 2:40	**Afternoon Break**	
2:40 – 3:20	**National Science Foundation / Small Business Innovation Research Related to In Vitro Diagnostics** Henry Ahn, Program Director, SBIR/STTR National Science Foundation	*Remote*
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	*Onsite*
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.	*Onsite*
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	*Remote*
9:00 – 9:40	**Establishing the Right Level of Clinical Evidence Under IVDR** Peter Bogaert, PhD, Senior Consultant IVD - Regulatory Affairs, Qarad	*Onsite*
9:40 – 10:20	**What's Hot and What's Not in CDx in Asia-Pac. + India** Ames Gross, President, Pacific Bridge Medical	*Onsite*
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	*Onsite*
11:20 – 12:00	**EU/IVDR Updates** Stefan Burde, Director, Global Focus Team IVD, TÜV SÜD	*Onsite*
12:00	**Adjourn / Lunch to Go**	