2022 Annual IVD Regulatory Hybrid Meeting Agenda

Wednesday April 27th
Room: White Flint Amphitheater and Common Area

9:00 – 9:50 am EST	**Networking Breakfast**	
9:50 – 10:00	**Welcome / Power of AMDM Membership** Tiffany Levin, AMDM President	*Onsite*
10:00 – 10:45	**IVDR Update / Hot Topics** Maurizio Suppo, PhD, Principal Consultant, Qarad	*Onsite*
10:45 – 11:30	**United Kingdom Policy Updates** Toby Hannam, Director, Incisive Health	*Onsite*
11:30 – 12:15	**United States Regulatory Updates** Jonathan Kahan, Partner, Hogan Lovells US LLP	*Onsite*
12:15 – 1:15	**Break / Lunch**	
1:15 – 2:00	**IVDR Technical Documentation – Notified Body Expectations and Lessons Learned** Stefan Burde, PhD, BSI	*Onsite*
2:00 – 2:45	**Compliance Hot Topics** Allyson Mullen, Director, Hyman, Phelps & McNamara, P.C.	*Onsite*
2:45 – 3:30	**Clinical Evidences – Study or Not Study, That is the Question** Julien Senac, Global Director, IVD Focus Team, TÜV SÜD	*Virtual*
3:30 – 3:45	**AMDM Annual Business Meeting**	
3:45 – 4:45	**Welcome Reception**	

Meeting Materials are posted online at https://www.amdm.org/april-am-dashboard.html
Password: AMDM2022

2022 Annual IVD Regulatory Hybrid Meeting Agenda

Thursday April 28th
Room: White Flint Amphitheater and Common Area

9:00 – 9:50 am EST	**Networking Breakfast**	
10:00 – 10:45	**Software AI Best Practices for QMS and Regulatory Submissions** Taranjit Samra, Expert Consultant, NDA Partners	*Onsite*
10:45 – 11:30	**Data Privacy - New and Upcoming Legislation/ Compliance strategies for Diagnostics Companies** Kate Black, Partner, Hintze Law	*Onsite*
11:30 – 12:15	**FDA Regulatory Considerations for AI-ML based Software as Medical Devices** Vivek Thakkar, Regulatory Program Director, Personalized Healthcare - Digital Health, Genentech/Roche	*Virtual*
12:15 – 1:15	**Break / Lunch**	
1:15 – 2:00	**Best Practices for LDT Companies with Assays Developed Under CLIA to Work Towards Medical Device** Annette Clark, CLS, MT (ASCP), QA Consulting	*Onsite*
2:00 – 2:45	**Covid DTC Test** Marisa Cruz, M.D., EVP of Regulatory and Clinical Affairs, Everly Health Bio	*Virtual*
2:45 – 3:30	**The 3 Rs to a COVID-19 At-Home Test Authorization** Kelli Turner, Sr. Program Manager, Regulatory Affairs, Roche Gail Radcliffe, President, Radcliffe Consulting, Inc. & Regulatory Consultant, RADx	*Onsite*
3:30	**Adjourn**	

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