



2026 Annual IVD Regulatory Hybrid Meeting Agenda

WEDNESDAY APRIL 22, 2026

Canopy by Hilton: Outlook Ballroom

Presenter Location

8:00 – 8:50 am	Networking Breakfast	
8:50 – 9:00	Welcome / Opening Remarks <i>Michelle Roeding and Lisa Charter: Event Co-Chairs</i>	Onsite
9:00 – 9:40	U.S. IVD Overview and Update – FDA Perspective <i>Courtney Lias, PhD: FDA Director of OIVD/OHT7</i>	Onsite
9:40 – 10:20	U.S. IVD Overview and Update – Industry Perspective <i>Randy Prebula: Partner, Hogan Lovells</i>	Onsite
10:20 – 10:40	Morning Break	
10:40 – 11:20	Case Study & Mock Trial <i>Jeff Gibbs: Senior Counsel, Hyman Phelps & McNamara, Former Associate Chief Counsel FDA; George Scavdis: Principal, The Scavdis Group, LLC, former FDA Special Agent in Charge; Allyson Mullen: Director, Hyman Phelps & McNamara</i>	Onsite
11:20 – 11:40	Q&A and Panel Discussion <i>Jeff Gibbs, George Scavdis, and Allyson Mullen</i>	Onsite
11:40 – 12:20	Q&A with FDA OHT7 Directors Moderator <i>Brittany Schuck, PhD: Deputy Director OHT7 Mariana Perez-Torres, PhD: Division Director, Chemistry & Toxicology; Soma Ghosh, PhD: Division Director, Molecular Pathology and Genetics; Uwe Scherf, PhD: Deputy Director, Microbiology Devices; Takeesha Taylor-Bell: Deputy Director, Immunology & Hematology</i>	Onsite
12:20 – 1:40	Networking Lunch	
1:40 – 2:20	Truth to Power: Delivering Bad News to Executives <i>Chris Daly: Principal, Ironline Consulting</i>	Onsite
2:20 – 3:00	Managing Difficult News in the Press <i>Angela Calman: CEO, AAN / Diagnosish; Former Director, Office of Communication and Education, FDA</i>	Onsite
3:00 – 3:40	Claims and Consequences Balancing Marketing Ambition with IVD Regulations <i>Laura LaBrie, Esq: Food and Drug Practice Team, Arnall Golden Gregory, LLP</i>	Onsite
3:40 – 4:00	Afternoon Break	
4:00 – 4:40	AI & Digital Pathology and New Wearables Guidance <i>Brendan O'Leary: Consultant, Digital Health; Former Deputy Director, Digital Health Center of Excellence FDA</i>	Onsite
4:40 – 5:00	AMDM Annual Business Meeting <i>Lisa Charter: President, AMDM</i>	Onsite
5:00 – 6:00	Onsite Welcome Reception	



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THURSDAY APRIL 23, 2026

Canopy by Hilton: Outlook Ballroom

Presenter Location

8:00 – 9:00 am	Networking Breakfast	
9:00 – 9:40	Similarities & Differences: EU IVDR vs UK IVD Regulations <i>Kirsten Van Garsse: Business Unit Manager RA IVD, QbD Group</i>	Remote
9:40 – 10:20	Update on UK IVD Regulation Invitation Pending	Pending
10:20 – 10:40	Morning Break	
10:40 – 11:20	Oncology Companion Diagnostics (CDx): Drug & Device Perspective <i>Reena Philip, PhD: Executive Director, Companion Diagnostics IVD, MERCK, former Associate Director of Biomarkers and Precision Oncology</i>	OnSite
11:20 – 12:00	CDx: Alzheimer’s and Non-Oncology Companion Diagnostics <i>Elizabeth Somers: Independent Consultant</i>	OnSite
12:00 – 12:40	Fireside Chat Former FDA OIVD Leaders Q&A Panelists: <i>Estelle Russek-Cohen, PhD; Brendan O’Leary; and Kris Roth, PhD</i>	Onsite
12:40 – 12:45	Closing Remarks <i>Michelle Roeding and Lisa Charter: Event Co-Chairs</i>	Onsite
12:45 - 1:45	Box Lunch	Onsite