FDA-Industry IVD Roundtable Meeting

Hosted by the Office of In Vitro Diagnostics and Radiological Health (OIR)
Of the FDA's Center for Devices and Radiological Health
FDA White Oak Campus
Building 66, Room G512 and G514
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Wednesday, November 29, 2017
8:00 AM - 2:00 PM

8:00 – 8:15 AM	**Welcome and Introductions** *Khatereh Calleja, AdvaMed* *Sam Rua, IVD Roundtable Liaison* *Allen Webb Jr, FDA/CDRH/OIR/DPOM*
8:15 – 9:00 AM	**OIR Update** *Elizabeth Hillbrenner, FDA/CDRH/OIR* ○ Organizational Changes ○ Implementation of Recent Legislation ○ 21st Century Cures ○ FDARA and MDUFA IV ○ CLIA Waiver Program ○ Recent Authorizations
9:00 – 9:30 AM	**Surrogate Sample Framework** *April Veoukas, Abbott, MDIC*
9:30 – 10:00 AM	**Least Burdensome: Training and Update on Responding to Deficiencies in Accordance with the Least Burdensome Provisions** *Robert Sauer, FDA/CDRH/OIR/DPOM*
10:00 – 10:20 AM	**FDA Perspectives on Point-of-Care Testing** *Kelly Oliner, FDA/CDRH/OIR/DIHD*
10:20 – 10:40 AM	**Program for FDA-CMS Parallel Review: What You Need to Know** *Rochelle Fink, FDA/CDRH/OCD*
10:40 – 11:00 AM	**Patient Preference Initiative and Considerations for Dx Developers** *Shami Feinglass, Co-Chair, AdvaMed Dx Task Force* *Heather Benz, FDA/CDRH/OCD*
11:00 – 11:40 AM	**Antimicrobial Susceptibility and Resistance and Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices** *Sandy Perreand, Co-Chair, AdvaMed Dx Task Force* *Rihbi Shawar, FDA/CDRH/OIR/DMD*

11:40 AM – 12:30 PM	**Lunch** (Sandwiches and other food will be available for purchase onsite)
12:30 – 1:00 PM	**IVD Real World Evidence Project** *Amy Ghering, Abbott, MDIC and Mike Waters, FDA/CDRH/OIR/DMD*
1:00 – 1:55 PM	**Interactive Discussion with CDRH and CBER: Roundtable Question and Answer Session** *FDA Staff*
1:55 – 2:00 PM	**New Business and Next Meeting**