FDA Industry IVD Roundtable

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
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Friday, May 11, 2018
9:00 AM - 3:00 PM

9:00 – 9:15 AM	**Welcome and Introductions** *Khatereh Calleja, AdvaMed* *Tiffany Levin, IVD Roundtable Liaison* *Nick Pastelak, FDA/CDRH/OIR/DPOM*
9:15 – 10:00 AM	**OIR Update** *TBD, FDA/CDRH/OIR* ○ Organizational Changes/New TPLC Model ○ Current and Future Priorities ○ Implementation of Recent Legislation ○ 21st Century Cures ○ FDARA and MDUFA IV ○ Key Issues and Guidances
10:00 – 11:00 AM	**Implementing Least Burdensome & Recent Flexible Device Clearance/Approvals** *Opening Remarks, FDA/CDRH/OIR/DPOM* *Presentations from each of Divisions: DCTD, DIHD, DMGP, and DMD*
11:00 – 11:30 AM	**Replacement Reagent Policy Update** *Avis Danishefsky, FDA/CDRH/OIR/DPOM*
11:30 AM – 12:00 PM	**What's New in Digital Health: Update on Precertification Pilot and Other Developments** *Opening Remarks, Shami Feinglass, Co-Chair, AdvaMed Diagnostics Task Force* *TBD, FDA/CDRH*
12:00 PM – 1:00 PM	**Lunch** (Sandwiches and other food will be available for purchase onsite)

1:00 – 1:30 PM	**IVD Real World Evidence Project Update** *Lesley Maloney, Roche, MDIC*
1:30 – 2:00 PM	**Reducing False Positives with Molecular Blood Culture ID Tests** *TBD, FDA/CDRH/OIR/DMD*
2:00 – 2:55 PM	**Interactive Discussion with FDA Management: Roundtable Question and Answer Session** *FDA Staff*
2:55 – 3:00 PM	**New Business and Next Meeting**