FDA-Industry IVD Roundtable Meeting

Hosted by CDRH OIR
FDA White Oak Campus
Building 66, Room G512 and G514
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Tuesday, November 18, 2014
9:00 AM - 3:00 PM

9:00 – 9:15 AM	**Welcome and Introductions** *Khatereh Calleja, AdvaMed* *Sam Rua, IVD Roundtable Liaison* *Allen Webb Jr, FDA/CDRH/OIR*
9:15 – 10:00 AM	**OIR/Guidance Update** *Alberto Gutierrez, FDA/CDRH/OIR* • **OIR 2014-2015 Priorities** • **FDASIA/MDUFA III Implementation** • **CLIA Waiver Update** • **CMS/FDA Parallel Review** • **Key Issues and Guidances** o Balancing Premarket and Postmarket Data Collection o Benefit-Risk Factors to Consider When Determining Substantial Equivalence in 510(k)s with Different Technological Characteristics o Highly Multiplexed Microbiological/Medical Countermeasure IVD NAT Based Diagnostic Devices
10:00 – 10:30 AM	**Laboratory Developed Tests & Risk Based Regulatory Framework** *Elizabeth Mansfield, FDA/CDRH/OIR*
10:30 – 10:50 AM	**Personalized Medicine Update** *Elizabeth Mansfield, FDA/CDRH/OIR* • *In Vitro* Companion Diagnostic Devices Guidance • Reorganization and Other Activities
10:50 – 11:20 AM	**New Cybersecurity Guidance—What it Means for Industry** *Bakul Patel, FDA/CDRH/OC*
11:20 – 11:45 AM	**Industry Perspective—Key Considerations in Study Design for Glucose and Beyond** *Nate Carrington, Roche, AdvaMed BGM Working Group*
11:45 AM – 1:00 PM	**Lunch** (may be purchased)

1:00 – 1:30 PM	**Recent Experiences in Submissions—Replacement Reagent and Instrument Family Policy** *Mark Del Vecchio, BD, AdvaMed Diagnostics Task Force*
1:30 – 2:00 PM	**Flu Antigen Detection Test Systems Reclassification** *Sally Hoyvat, FDA/CDRH/OIR*
2:00 – 2:50 PM	**Interactive Discussion: Roundtable Question and Answer Session** *CDRH OIR and CBER OBRR*
2:50 – 3:00 PM	**New Business and Next Meeting**