# 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 G51410903 New Hampshire Avenue Silver Spring, MD 20993

**AGENDA**

Friday, December 2, 20169:00 AM - 3:00 PM

9:00 – 9:15 AM Welcome and Introductions
Sam Rua, IVD Roundtable Liaison Allen Webb Jr, FDA/CDRH/OIR/DPOM

9:15 – 10:00 AM OIR Update
Alberto Gutierrez, FDA/CDRH/OIR

- Organizational/Staffing Update
- OIR 2017 Priorities—CDRH Priorities
- FDASIA/MDUFA III Implementation Update
  - 21st Cures Initiative/Dx Reform
  - Risk Based Framework for LDTs
    - Key Issues and Guidances
  - Software as a Medical Device: Clinical Evaluation
  - Deciding When to Submit a 510(k) for a Change to an Existing Device
  - Deciding When to Submit a 510(k) for a Software Change to an Existing Device
  - 510(k) Third Party Review Program
  - Personalized Medicine Guidances—NGS and Codevelopment

10:00 – 10:35 AM Blood Glucose Monitoring Test Systems Guidances—Perspectives and Key Issues Looking Ahead
Jamie Wolszon, AdvaMedm / Courtney Lias, FDA/CDRH/OIR

10:35 – 11:00 AM POC Diagnostics: Role, Regulation, and Issues for Innovators
Leanne Kiviharju , AdvaMed POC Subteam

11:00 – 11:45 AM Culture-Independent Diagnostic Initiative & Molecular Multi-Analyte Gastrointestinal Detection Panels Update — Public Health and Industry Efforts
Brad Spring, Becton DickinsonJohn Besser, CDC/DFWED/NCEZID/ EDLKim Sconce, FDA/CDRH/OIR/DMD

11:45 AM – 12:45 PM
Lunch (Sandwiches and other food will be available for purchase onsite)

12:45 – 1:15 PM Use of Real World Evidence to Support Device Regulatory Decision making TBD, FDA

1:15 – 1:40 PM Interoperability—Workshop Update and Next Steps
Steve Gitterman, FDA/CDRH/OIR/DMD Michael Waters, FDA/CDRH/OIR/DMD
Danelle Miller, AdvaMed Diagnostics Task Force

1:40 – 2:15 PM Update on Liquid Biopsy
Reena Phillips, FDA/CDRH/OIR/DMGP Leslie Farrington, Roche Molecular

2:15 – 2:55 PM Interactive Discussion: Roundtable Question and Answer Session

FDA Staff

2:55 – 3:00 PM New Business and Next Meeting