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, Room G512 and G514
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Thursday, June 2, 2016
9:00 AM - 3:00 PM

9:00 – 9:15 AM

Welcome and Introductions
Khatereh Calleja, AdvaMed
Cathy Craft, IVD Roundtable Liaison
Allen Webb Jr, FDA/CDRH/OIR/DPOM

9:15 – 10:00 AM

OIR Update
Don St. Pierre, FDA/CDRH/OIR

- **Organizational/Staffing Update**
- **OIR 2016 Priorities**
- **FDASIA/MDUFA III Implementation Update**
- **21st Cures Initiative/Dx Reform**
- **Risk Based Framework for LDTs**
- **CLIA Waiver**
- **Key Issues and Guidances**
  - Leftover De-Identified Specimens
  - Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling
  - Emerging Postmarket Medical Device Signals
  - Emergency Use Authorization of Medical Products and Related Authorities

10:00 – 10:30 AM

Clinical Chemistry Analyzer MDRs (JJE Product Code)
Courtney Lias, FDA/CDRH/OIR/DCTD

OIR MDR analysts often must reassign MDRs inappropriately submitted as analyzer/instrument injuries/malfunctions when they should be submitted under specific assay product codes. OIR will introduce this topic as the start of an interactive discussion.

10:30 – 11:00 AM

PrecisionFDA Platform: What You Need to Know and How It Works
Taha Kass-Hout FDA /OCS/OHI

PrecisionFDA is an online, cloud-based, virtual research space to allow scientists from academia, industry, health care organizations, and government to work together on creating tools to evaluate a method of "reading" DNA known as next generation sequencing (or NGS). The goal of precisionFDA is to foster innovation and develop regulatory science around NGS tests, which are essential to achieving the promise of President Obama's Precision Medicine

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	Initiative.
11:00 – 11:30 AM	**Research Roadmap for Next-Generation Sequencing Informatics** *Katherine Donigan, FDA/CDRH/OIR* The Precision Medicine Initiative (PMI) is a U.S. national effort "to enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care". One goal is to bring about the routine use of next-generation precision diagnostics to benefit individuals and public health. As part of its PMI effort, FDA seeks to undertake and support regulatory science research that will enhance our understanding of NGS test products and their development and validation, as well as how the results of such tests are best communicated in an evolving health care environment.
11:30 AM – 12:30 PM	**Lunch** (Sandwiches and other food will be available for purchase at the kiosk in the Building 66 Atrium.)
12:30 – 1:00 PM	**Emergency Use Authorization Program: Zika Virus Update** *Uwe Scherf, FDA/CDRH/OIR/DMD* Will describe FDA's Emergency Use Authorization templates for nucleic acid based and serological assays, clinical sample opportunities and challenges, NAT reference materials and serological reference panels.
1:00 – 1:15 PM	**Piloting of Transitional Approach (EmergingDx)—Update and Looking Ahead** *Don St. Pierre, FDA/CDRH/OIR* Will describe FDA's experience with this pilot so far, now that FDA has hit the 1.5 year mark.
1:15 – 1:45 PM	**Cybersecurity and Interoperability Update** *Dharmesh Patel, FDA/CDRH/OIR/DPOM* *Steve Gitterman, FDA/CDRH/OIR/DMD* Overview of recent draft guidances for Postmarket Cybersecurity Management and Interoperability. In addition, FDA will discuss laboratory semantic interoperability.
1:45 – 2:00 PM	**eCopy Program Update** *Jerry Logue, FDA/CDRH/OIR/DPOM* Recent developments in the eCopy program as well as common eCopy issues and how to avoid them.
2:00 – 2:10 PM	**Quality Management Update** *Nick Pastelak, FDA/CDRH/OIR/DPOM* Recent progress implementing ISO 9001:2015, next steps for FY17, and need for stakeholder input on process improvement priorities.
2:10 – 2:55 PM	**Interactive Discussion: Roundtable Question and Answer Session** *FDA Staff*
2:55 – 3:00 PM	**New Business and Next Meeting**