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, November 9, 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 – 10:30 AM	**Update from New OIR Director** *Tim Stenzel, FDA/CDRH/OIR*
10:30 – 11:00 AM	**Antimicrobial Susceptibility Test Disk Update** *Ribhi Shawar, FDA/CDRH/OIR/DMD*
11:00 – 11:30 AM	**Special 510(k): OIR Perspective and What Diagnostic Companies Need to Know** – *(QUiK, OIR SMART Template)* *Marjorie Shulman, Director, 510(k) and 513(g) Programs* *FDA/CDRH/ODE*
11:30 AM– 12:00 PM	**Personalized Medicine Update** *Stayce Beck, Laura Koontz, & Zivana Tezak, FDA/CDRH/OIR*
12:00 PM – 1:00 PM	**Lunch** (Sandwiches and other food will be available for purchase onsite)
1:00 – 1:30 PM	**MDIC Somatic Reference Samples Project** *J.D. Alvarez, Janssen, MDIC*
1:30 – 1:50 PM	**Cybersecurity: Update and Considerations for Dx Innovators** *Aftin Ross, FDA/CDRH/OCD*
1:50 – 2:55 PM	**Interactive Discussion with CDRH: Roundtable Question and Answer Session** *FDA Staff*
2:55 – 3:00 PM	**New Business and Next Meeting**