FDA-Industry IVD Roundtable Meeting

Hosted by CDRH (OIR)
FDA White Oak Campus
Building 66, Rooms G512/G514
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Thursday, November 29, 2012
9:00 AM - 2:00 PM

9:00 – 9:10 AM	**Welcome and Introductions** *Jean Cooper, FDA/CDRH/OIR*
9:10 – 9:40 AM	**OIR Update** *Don St. Pierre, FDA/CDRH/OIR*
9:40 – 10:05 AM	**CBER Update** *Sayah Nedjar, FDA/CBER/OBRR*
10:05 – 10:20 AM	**CBER Direct Recall Classification Program** *Laura Hieronymus, FDA/CBER/OC*
10:20 – 10:50 AM	**Personalized Medicine Update** *Elizabeth Mansfield, FDA/CDRH/OIR*
10:50 – 11:20 AM	**Cybersecurity** *John Murray, FDA/CDRH/OC*
11:20 AM – 12:00 PM	**OIR Possible Topics of Interest—Session I Interactive Discussion** • **OIR Reorganization** • **OIR Triage Pilot** • **Sponsor Request for Consults**
12:00 – 1:00 PM	**Lunch** (may be purchased in FDA Cafeteria)
1:00 – 1:40 PM	**OIR Possible Topics of Interest—Session II Interactive Discussion** • **Status of CLIA Categorization** • **FDA Replacement and Instrument Family Policy—Use and Considerations** • **Other Issues of Interest**
1:40 – 2:00 PM	**New Business and Next Meeting**