FDA-Industry IVD Roundtable Meeting

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

AGENDA
Friday, May 30 2014
9:00 AM - 3:00 PM

9:00 – 9:15 AM	**Welcome and Introductions** *Allen Webb Jr, FDA/CDRH/OIR* *Sheri Hall, IVD Roundtable Liaison*
9:15 – 9:45 AM	**OIR Premarket/Compliance Update** *Don St. Pierre, FDA/CDRH/OIR*
9:45 – 10:15 AM	**BNP** *Courtney Lias, FDA/CDRH/OIR*
10:15 – 10:45 AM	**Glucose Guidance** *Leslie Landree, FDA/CDRH/OIR*
10:45 – 11:00 AM	**Break** (may be purchased)
11:00 AM – 11:30 AM	**Proposed IMDRF IVD Market Authorization Table of Contents** *Danelle Miller, AdvaMed Diagnostics Task Force*
11:30 – 12:00 PM	**Personalized Medicine and Reorganization Update** *Elizabeth Mansfield, FDA/CDRH/OIR*
12:00 – 1:00 PM	**Lunch** (may be purchased)
1:00 – 1:30 PM	**Premarket and Postmarket Device Data Collection Subject to Premarket Approval Guidance** *Don St. Pierre, FDA/CDRH/OIR*
1:30 – 2:00 PM	**High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers Workshop** **Introduction** *Mark Del Vecchio, BD*

	FDA Presenter *Peyton Hobson, FDA/CDRH/OIR*
2:00 - 2:15 PM	**CBER Update** *Sheryl Kochman, FDA/CBER/OMPT/OD/ADRM*
2:15 – 2:45 PM	**Roundtable Question and Answer Session** *Don St. Pierre, FDA/CDRH/OIR* *Sheryl Kochman, FDA/CBER/OMPT/OD/ADRM*
2:45 – 3:00 PM	**New Business and Next Meeting**