FDA-Industry IVD Roundtable Meeting

Hosted by AdvaMed
701 Pennsylvania Ave, NW
Suite 800
Washington, DC 20004

DRAFT AGENDA
Thursday, June 7, 2012
9:00 AM - 3:30 PM

9:00 – 9:10 AM	**Welcome and Introductions** *Khatereh Calleja, AdvaMed* *Sheri Hall, IVD Roundtable Liaison*
9:10 – 10:00	**OIVD Update** *Don St. Pierre, FDA/CDRH/OIVD* • **OIVD 2012 Priorities** • **510(k) Reform Implementation Update** • **Key Guidances** • **Class I/II IVD Exemptions** • **Special 510(k)s in OIVD: Status Update**
10:00 – 10:10 AM	**Break**
10:10 – 11:00 AM	**CBER Update** *Sayah Nedjar, FDA/CBER/OBRR* • **CBER 2012 Priorities and Updates** • **Key Guidances**
11:00 – 11:45 PM	**OIVD Triage Pilot: Overview and Developments** *Don St. Pierre, FDA/CDRH/OIVD*
11:45 AM – 12:30 PM	**Discussion Session: Challenges and Opportunities in Next Generation Sequencing** **Introduction** *Melina Cimler, Illumina* ***Industry Presenter*** *Bill Pignato, AdvaMed Personalized Medicine and Molecular Diagnostics Working Group* ***FDA Presenter*** *Elizabeth Mansfield, FDA/CDRH/OIVD*

12:30 – 1:30 PM	**Lunch**
1:30 – 2:00 PM	**Personalized Medicine Update** *Elizabeth Mansfield, FDA/CDRH, OIVD*
2:00 – 2:30 PM	**OIVD Reorg – What's Important for You to Know** **Introduction** *Don St. Pierre, FDA/CDRH/OIVD* **Feedback Session with Attendees**
2:30 – 3:00 PM	**Companion Diagnostics** *Andy Dayton, FDA/CBER/OBRR*
3:00 – 3:30 PM	**New Business and Next Meeting**