FDA-Industry IVD Roundtable Meeting

Hosted by AMDM
Hogan Lovells
555 Thirteenth St. NW
Washington, DC 20004

Thursday, December 8, 2011
9:00 AM - 3:30 PM

AGENDA

9:00 – 9:10 AM	**Welcome and Introductions** *Sheri Hall, IVD Roundtable Liaison, BD*
9:10 – 9:30 AM	**Introductory Remarks: "Perspective Amidst Changing Times"** *Jonathon Kahan, Hogan and Lovells*
9:30 – 10:10 AM	**OIVD Update** *Alberto Gutierrez, FDA/CDRH/OIVD* • **OIVD 2012 Priorities and Updates** • **510(k) Reform Implementation Update [e.g., 510(k) Modifications]** • **Class I/II IVD Exemptions** • **Regulation of Lab Developed Tests** • **October 13 Public Meeting re. Highly Multiplexed Microbiology/MCM Devices** • **Key Guidances**
10:10 – 10:20 AM	**Break**
10:20 – 11:10 AM	**DeNovo Classification Process Guidance: What's New/How It Works and a Case Example** **Introduction of Presenters** *Sheri Hall, BD* **Presenters** *April Veoukas, Abbott* *Melissa Burns, FDA/CDRH/ODE*

11:10 AM – 12:00 PM	**Panel Session: Developments in Personalized Medicine: In Vitro Companion Diagnostics Guidance** **Introduction of Presenters** *Robert DiTullio, Alere* **Panel Discussion** *Eric Lawson, Voison Consulting, AMDM Companion Diagnostics Working Group* *William Pignato, AdvaMed Personalized Medicine and Molecular Diagnostics Working Group, Novartis* *Andrew Dayton, FDA/CBER/OBRR* *Elizabeth Mansfield, FDA/CDRH/OIVD/FDA*
12:00 – 1:00 PM	**Lunch**
1:00 – 1:45 PM	**Research Use Only** *James Kelly, AdvaMed Diagnostics Task Force, Affymetrix* *Katherine Serrano, FDA/CDRH/OIVD*
1:45 – 2:30 PM	**CBER Update** *Sayah Nedjar, FDA/CBER/OBRR* • **CBER 2012 Priorities and Updates** • **Key Guidances**
2:30 – 3:15 PM	**Regulatory Considerations for HLA Test Kits** *Annette Ragosta, FDA/CBER/OBRR*
3:15 – 3:30 PM	**New Business and Next Meeting**