



FDA Industry IVD Roundtable

FDA-Industry IVD Roundtable Meeting

*Hosted by AdvaMedDx
 FDA White Oak Campus Conference Center
 Building 31, Great Room
 10903 New Hampshire Avenue
 Silver Spring, MD 20993*

**AGENDA
 Friday, November 15, 2013
 9:00 AM - 3:00 PM**

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| 9:00 – 9:10 AM | Welcome and Introductions <i>Khatereh Calleja, AdvaMed Runa Musib, FDA/CDRH/OIR Jean Cooper, FDA/CDRH/OIR</i> |
| 9:10 – 10:00 AM | OIR Update <i>Alberto Gutierrez, FDA/CDRH/OIR</i> <ul style="list-style-type: none"> • OIR 2013-2014 Priorities • FDASIA/MDUFA III Implementation Update • Key Issues and Guidances |
| 10:00 – 10:30 AM | CBER Update <i>Sayah Nedjar, FDA/CBER/OBRR</i> <ul style="list-style-type: none"> • CBER 2013-2014 Priorities • FDASIA/MDUFA III Implementation Update • Key Issues and Guidances |
| 10:30 – 10:45 AM | Software and Platforms for Infectious Diseases <i>Sayah Nedjar, FDA/CBER/OBRR</i> |
| 10:45 – 11:15 AM | Mobile Applications <i>Bakul Patel, FDA/CDRH/OC</i> |
| 11:15 – 11:40 AM | Cybersecurity and Medical Devices <i>Bakul Patel, FDA/CDRH/OC</i> |
| 11:40 AM – 12:00 PM | HbA1c Update <i>Carol Benson, FDA/CDRH/OIR</i> |
| 12:00 PM – 1:00 PM | Lunch (may be purchased) |
| 1:00 – 2:00 PM | New IDE Structure: What Does it Mean to Industry? IVD Presubmissions <i>Elizabeth Hillebrenner, FDA/CDRH/OIR</i> |

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| 2:00 – 2:30 PM | Use of Investigational Devices in Therapeutic Trials <i>David Litwack, FDA/CDRH/OIR</i> |
| 2:30 – 2:55 PM | Interactive Discussion Session <i>OIR Management</i> |
| 2:55 – 3:00 PM | New Business and Next Meeting |