FDA-Industry IVD Roundtable Meeting

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

AGENDA
Friday, November 20, 2015
9:00 AM - 3:00 PM

9:00 – 9:15 AM	**Welcome and Introductions** *Sam Rua, IVD Roundtable Liaison* *Allen Webb Jr, FDA/CDRH/OIR*
9:15 – 10:00 AM	**OIR Update** *Alberto Gutierrez, FDA/CDRH/OIR*
10:00 – 10:30 AM	**CLIA Waiver: Processes and Submission Update** *Peter Tobin, FDA/CDRH/OIR* • MDUFA III/Performance • Dual Submission Program and CLIA Waivers
10:30 – 10:50 AM	**CLIA Waiver Accuracy and Concepts in Study Design** *Robert DiTullio, AdvaMed CLIA Working Group*
10:50 – 11:50 AM	**Precision Medicine: Priority Initiatives and What it Means for Diagnostics Now and Into the Future** ***Industry Presenter*** *Debra Rasmussen, Co-Chair, AdvaMed Personalized Medicine and Molecular Diagnostics Working Group* ***FDA Presenter*** *Elizabeth Mansfield, FDA/CDRH/OIR*
11:50 AM – 1:00 PM	**Lunch** (may be purchased at onsite expanded kiosk)
1:00 – 1:45 PM	**Statistical Approaches to Follow-on Companion Diagnostics** ***Industry Presenter-KRAS Example*** *Abha Sharma, Roche Diagnostics* ***FDA Presenter*** *Meijaun Li, FDA/CDRH/OSB*

1:45 – 2:15 PM	**Nov. 12 and 13 Next Generation Sequencing Workshops on Standards-Based and Database-Driven Approaches for IVDs** *David Litwack, FDA/CDRH/OIR*
2:15 – 2:55 PM	**Interactive Discussion: Roundtable Question and Answer Session** *CDRH/CBER*
2:55 – 3:00 PM	**New Business and Next Meeting**