FDA Industry IVD Roundtable

FDA-Industry IVD Roundtable Meeting

Hosted by CBER
FDA White Oak Campus
Building 2, Room 2031
10903 New Hampshire Avenue
Silver Spring, MD 20993

AGENDA
Friday, June 10, 2011
8:00 AM - 3:30 PM

8:00 – 8:15 AM	**Welcome and Introductions** *Jean Cooper, FDA/CDRH/OIVD* *Sheri Hall, IVD Roundtable Liaison*
8:15 – 9:00 AM	**OIVD Update** *Alberto Gutierrez, FDA/CDRH/OIVD*
9:00 – 9:15 AM	**CBER Update** *Sayah Nedjar, FDA/CBER/OBRR*
9:15 – 9:45 AM	**A Statistician's Perspective on Multiplex Assays** *Estelle Russek-Cohen, FDA/CBER/OBE*
9:45 – 10:00 AM	**Break**
10:00 AM – 12:30 PM	**CLIA Waiver Working Session*** **Introduction of Presenters (10:00-10:05 AM)** *Betty Stephenson, BD* **Industry Case Examples—Presentation of Challenging Test Case Examples (10:05 to 11:45 AM)** *Ken Kupfer, Alere* *Bob Sarber, Sekisui Diagnostics* **Audience Discussion** --- **FDA Case Example—Quality Waiver Submission; Test Case Characteristics and Overall Performance (11:45 to 12:30 PM)** *Ann Chappie, FDA, CDRH, OIVD* **Audience Discussion** ***Case examples to be provided in advance of the meeting**
12:30 – 1:30 PM	**Lunch** (may be purchased in FDA Cafeteria)

1:30 – 2:00 PM	**Personalized Medicine Update** *Elizabeth Mansfield, FDA, CDRH, OIVD*
2:00 PM – 2:30 PM	**Blood Glucose Meter Disinfection** *Alan Cariski, AdvaMed BGM Working Group, LifeScan* *Leslie Landree, FDA, CDRH, OIVD*
2:30 – 2:45 PM	**Break**
2:45– 3:15 PM	**Research Use Only** *Katherine Serrano, FDA, CDRH, OIVD* .
3:15 – 3:30 PM	**New Business and Next Meeting**