

# 2012 OIVD Submissions Workshop

## Meeting Agenda

Tuesday

April 17, 2012

9:00 a.m. – 5:15 p.m.

		Room
8:00 – 9:00 a.m.	<b>Registration / Breakfast</b>	White Flint
9:00 – 9:45	<b>Welcome and Introduction</b> Alberto Gutierrez, Ph.D., Director, OIVD Judi Smith, AMDM President	
9:45 – 10:15	<b>Small Manufacturers Assistance (DSMICA)</b> Elias Mallis, OIVD	
10:15 – 10:45	<b>Registration and Listing</b> David Gartner, OIVD	
10:45 – 11:00	<b>Break</b>	
11:00 – 11:30	<b>510(k) Program</b> Marjorie Shulman, OIVD	
11:30 – 12:00	<b>Special and Abbreviated 510ks</b> Douglas Rheinheimer, OIVD	
12:00 – 1:15	<b>Networking Lunch with FDA</b>	
1:15 – 1:45	<b>DeNovo 510k</b> Kate Simon, OIVD	
1:45 – 2:15	<b>Part 1 - 510k Case Study - Molecular Diagnostics</b> Donna Roscoe, OIVD	
2:15 – 3:00	<b>Part 2 - 510k Case Study - Software in an IVD World</b> Andrew Grove, OIVD	
3:00 – 3:15	<b>Break</b>	
3:15 – 4:15	<b>RUO and IUO</b> Karen Bijwaard, OIVD	
4:15 – 5:15	<b>PMA Process</b> Kelly Wilkicki and Bill Shackelford, OIVD	

# 2012 OIVD Submissions Workshop

## Meeting Agenda

Wednesday

April 18, 2012

9:00 a.m. – 4:30 p.m.

		Room
8:00 – 9:00 a.m.	<b>Registration / Breakfast</b>	White Flint
9:00 – 9:30	<b>Bioresearch Monitoring</b> Veronica Calvin, OIVD	
9:30 – 10:30	<b>Quality System Regs and Compliance Interactions</b> David Kalins & Rebecca Keenan, OIVD	
10:30 – 10:45	<b>Break</b>	
10:45 – 11:15	<b>Health Hazard Evaluation</b> Than Nguyen, OIVD	
11:15 – 11:45	<b>Import-Export</b> Tanisha Adams, OIVD	
11:45 – 1:00	<b>Networking Lunch w/FDA</b>	
1:00 – 1:45	<b>e-MDR Reporting</b> Eugene Reilly, OIVD	
1:45 – 2:15	<b>IDE</b> Nina Hunter, OIVD	
2:15 – 3:00	<b>CLIA Waiver</b> Ann Chappie, OIVD	
3:00 – 3:15	<b>Break</b>	
3:15 – 4:15	<b>Ask the FDA</b> FDA Panel	
4:15 – 4:30	<b>Review &amp; Wrap Up</b> Alberto Gutierrez, OIVD	