2014 OIR Submissions Workshop Meeting Agenda

Online evaluation at: amdm.org/510kevaluation.html

Monday / April 7, 2014

9:00 a.m. – 5:00 p.m.

		Room
8:00 – 9:00 a.m.	**Registration / Breakfast**	White Flint
9:00 – 9:30	**Welcome and Introduction** Don St. Pierre, Deputy Director, OIR Judi Smith, AMDM President	
9:30 – 9:45	**Ecopy** / **Samie Allen-Niver, OIR**	
9:45 – 10:00	**Small Manufacturers Assistance (DSMICA)** William Sutton, OIR	
10:00 – 10:30	**Registration and Listing** / David Gartner, OIR	
10:30 – 10:45	**Break**	
10:45 – 11:15	**Pre-Submissions** / Fatameh Razjouyan, OIR	
11:15 – 11:45	**510(k) Program, IVD and Overview of MDUFA III** Marjorie Shulman, ODE	
11:45 – 12:15	**Special 510(k), Triage** / Douglas Rheinheimer, OIR	
12:15 – 1:30	**Networking Lunch with FDA**	White Oak
1:30 – 2:00	**DeNovo 510(k)** / Yvonne Shea, OIR	
2:00 – 3:00	**Submissions for Molecular Devices** / Donna Roscoe, OIR	
3:00 – 3:15	**Break**	
3:15 – 3:30	**Mobile Medical Apps** / Bakul Patel, OIR	
3:30 – 3:45	**CyberSecurity** / Seth Caramody, OIR	
3:45 – 4:00	**RTA** / Fatameh Razjouyan, OIR	
4:00 – 4:15	**UDI** / Steve Gitterman, OIR	
4:15 – 4:30	**Companion Diagnostics** / David Litwack, OIR	
4:30 – 5:00	**Q&A**	

2014 OIR Submissions Workshop Meeting Agenda

Online evaluation at: amdm.org/510k evaluation.html

Tuesday / April 8, 2014

9:00 a.m. – 5:00 p.m.

		Room
8:00 –9:00 a.m.	**Registration / Breakfast**	White Flint
9:00 – 9:30	**CLIA Processes and Categorizations** / Ann Chappie, OIR	
9:30 – 10:00	**Bioresearch Monitoring** Veronica Calvin, Office of Compliance	
10:00– 11:00	**Quality System Regs and Compliance Interactions** Tonya Wilbon, OIR	
11:00 – 11:15	**Break**	
11:15 – 11:45	**IDE** / Stayce Beck, OIR	
11:45 – 12:15	**MDR** / Isaac Chang, OIR	
12:15 – 1:30	**Networking Lunch w/FDA**	White Oak
1:30 –2:15	**Clinical Trials /** Sally Hojvat, OIR	
2:15 – 3:00	**CLIA Waiver Study Design** / Marina Kondratovich, OIR	
3:00 – 3:30	**Health Hazard Evaluation** / Steve Gitterman, OIR	
3:30 – 3:45	**Break**	
3:45 – 4:45	**Ask the FDA** / FDA Panel	
4:45 – 5:00	**Review & Wrap Up** / Alberto Gutierrez, OIR	