

2019 OIR Submissions Workshop

Meeting Agenda

Monday / April 8, 2019

9:00 a.m. – 5:00 p.m.

		Room
8:00 – 9:00 a.m.	Registration / Breakfast	White Flint
9:00 – 9:45	Welcome and Guidance Highlights Timothy Stenzel, Director, OIR Ann Quinn, AMDM	
9:45 – 10:00	Division of Industry and Consumer Education (DICE) Anike Freeman, OCE	
10:00 – 10:30	Registration and Listing / Speaker To Be Announced, OC	
10:30 – 10:45	Break	
10:45 – 11:15	MDR / Eveline Arnold, OIR	
11:15 – 11:45	510(k) Program Speaker To Be Announced	
11:45 – 12:15	Precision Medicine / Kate Donigan, OIR	
12:15 – 1:30	Networking Lunch with FDA	Brookside A
1:30 – 2:00	CLSI: Overview / Marina Kondratovich, OIR	
2:00 - 2:30	Third Party / Greg Pishko, OIR	
2:30 - 2:45	Break	
2:45 - 3:00	DeNovo / Josh Balsam, OIR	
3:00 – 3:15	Pre- and Post-Market Cybersecurity for Medical Devices Speaker To Be Announced, OCD	
3:15 – 3:45	Submissions for Molecular Devices / Speaker To Be Announced, OIR	
3:45 - 4:30	Companion Diagnostics / Speaker To Be Announced, OIR	
4:30 – 5:00	Q&A	

2019 OIR Submissions Workshop

Meeting Agenda

Tuesday / April 9, 2019

9:00 a.m. – 5:00 p.m.

		Room
8:00 – 9:00 a.m.	Registration / Breakfast	White Flint
9:00 – 9:30	Pre-Submissions and Q-Subs / Majda Haznadar, OIR	
9:30 – 10:00	Bioresearch Monitoring / Tamika Allen, OC	
10:00– 11:00	Quality System Regs and Compliance Interactions Rick Mallonee, OIR	
11:00 – 11:15	Break	
11:15 – 11:45	IDE / Kate Donigan, OIR	
11:45 – 12:15	Health Hazard Evaluation / Ian Pilcher, OIR	
12:15 – 1:30	Networking Lunch w/FDA	Brookside A
1:30 – 2:00	CLIA Processes and Evaluation / Peter Tobin, OIR	
2:00 – 2:45	CLIA Waiver Study Design and Dual Submission Marina Kondratovich, OIR	
2:45 – 3:15	OIR Update / Don St. Pierre, Deputy Director, OIR	
3:15 – 3:30	Break	
3:30 – 4:45	Ask the FDA / FDA Panel	
4:45 – 5:00	Review & Wrap Up / OIR Staff	