

2024 FDA IVD Submissions Workshop

Hosted by AMDM

Monday April 22, 2024

10:00 am – 5:00 pm

		<i>Location</i>
10:00 – 10:40	Welcome and OIVD Update Karin Hughes, President, AMDM Courtney Lias, Acting Office Director, CDRH/OPEQ/OHT7	<i>On-Site</i> <i>On-Site</i>
10:40 – 11:10	510(k) Program LCDR Charles Chiang, Senior Program Management Officer Consultant, CDRH/OPEQ/ORP/DRP1	<i>On-Site</i>
11:10 – 11:30	De Novo Joseph Cleveland, Senior Staff Fellow, CDRH/OPEQ/OHT7/DCTD	<i>Remote</i>
11:30 – 11:45	Break	
11:45 – 12:15	Breakthrough /STeP Jade Noble, Interdisciplinary General Engineer, CDRH/OPEQ/OCEA/DCEA1	<i>Remote</i>
12:15 – 12:45	Pre-Submissions and Q-Subs LCDR Nam To, Policy Analyst, CDRH/OPEQ/ORP.DRP1	<i>On-Site</i>
12:45 – 1:15	Q&A Session	
1:15 – 2:15	Lunch	
2:15 – 2:45	Diagnostic Data Program: Digital Diagnostics - Sara Brenner, Chief Medical Officer and Associate Director for Medical Affairs, CDRH/OPEQ/OHT7	<i>On-Site</i>
	SHIELD - Keith Campbell, FDA Shield Program Director, CDRH/OPEQ/OHT7	<i>Remote</i>
2:45 – 3:15	Predetermined Change Control Plans Brittany Schuck, Deputy Office Director, CDRH/OPEQ/OHT7	<i>On-Site</i>
3:15 – 3:30	Break	
3:30 – 4:00	Consensus Standards Konstantinos Makrodimitris, CDRH/OST/ORR/DSCA	<i>On-Site</i>
4:00 – 4:30	Medical Device Cybersecurity James Graves, Biomedical Engineer, CDRH/OPEQ/OHT8/DHT8B	<i>Remote</i>
4:30 – 5:00	Q&A Session	

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10:00 – 10:15	Division of Industry and Consumer Education (DICE) Eva Ellsworth, Consumer Safety Officer, CDRH/OCE/DICE	<i>On-Site</i>
10:15 – 10:45	FDA Role in CLIA: Categorizations, Waivers and Dual Submissions Tamara Pinkney, CLIA Program Lead/Policy Analyst, CDRH/OPEQ/OHT7/DPOM	<i>On-Site</i>
10:45 – 11:15	Study Design Considerations to Support CLIA Waiver Marina Kondratovich, Mathematical Statistician, CDRH/OPEQ/OHT7	<i>On-Site</i>
11:15 – 11:30	Break	
11:30 – 12:00	Investigational Device Exemption Brittany Aguila, Lead Biologist, CDRH/OPEQ/OHT7/DMGP	<i>On-Site</i>
12:00 – 12:30	Bioresearch Monitoring Adaliz Santaliz-Cruz, Consumer Safety Officer, CDRH/OPEQ/OCEA/DCEA1	<i>Remote</i>
12:30 – 1:00	Q&A Session	
1:00 – 2:00	Lunch	
2:00 – 2:30	eSTAR Lili Duan, Chemist, CDRH/OPEQ/ORP/DRP4	<i>On-Site</i>
2:30 – 2:45	CDRH Portal Nels Anderson, Policy Analyst, CDRH/OPEQ/ORP/DRP4	<i>Remote</i>
2:45 – 3:15	Registration and Listing Lisa King, Consumer Safety Officer, CDRH/OPEQ/ORP/DRP2	<i>Remote</i>
3:15 – 3:30	Break	
3:30 – 4:00	Quality System Regulations, Compliance Interactions, and QMS Rule Eric Horowitz, Lead Consumer Safety Officer, CDRH/OPEQ/ORP/DRP2	<i>On-Site</i>
4:00 – 4:30	eMDR Michelle Rios, Supervisory Consumer Safety Officer, CDRH/OPEQ/ORP/DRP3 Fariba Maramkhah, Consumer Safety Officer, CDRH/OPEQ/ORP/DRP3	<i>Remote</i> <i>Remote</i>
4:30 – 5:00	Q&A Session	