

ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS

2021 FOCUS MEETING OCTOBER 1ST AND 8TH

TWO HALF DAYS, 100% REMOTE

Day 1: October 1, 2021				
Session	Topic	Time (PST)	Speaker	Overview
Welcome	Open Portal - Welcome	8:20	Tiffany D. Levin, AMDM President / 55 th Parallel Lesley Farrington / Janssen Dx	
FDA Updates	FDA/OHT7 Office Updates	8:30-9:00	Don St. Pierre Office Deputy Director FDA/OHT7	Latest OHT7 Updates / Hot Topics
Legislative Update	VALID Act: What's next?	9:00-9:30	Jeffrey N. Gibbs Director Hyman, Phelps & McNamara	VALID Act: short- and long-term impacts
IVDD/R Update	IVDR Hot Topics	9:30-10:10	Stefan Burde IVD Product Expert BSI Group	Updates on IVDR status and implementation
	Successful Implementation of IVDR: Industry Perspective	10:10-10:40	Casey Fox Regulatory Affairs Project Manager Becton Dickinson Biosciences	Presentation from the first company to achieve IVDR certification
	IVDR Panel Discussion	10:40-11:00	Stefan Burde,/Casey Fox	Open panel discussion for registered attendees
Break 11:00-11:15				
Companion Diagnostic Updates	Group Labeling in Practice	11:15-11:45	Sarah Parsons Director Regulatory Affairs Janssen Dx	Review of how the 'Class Claims' guidance is used in practice
	PET imaging as a Companion Diagnostic	11:45-12:15	Megan Doyle Director, Global Regulatory and R&D Policy Amgen	Review of strengths and limitations, and current FDA regulatory landscape (ref, FR Doc. 2021-16944, pub 8/9/2021).
CLOSING	Announcements/Closing	12:15-12:30	AMDM Board Representative/Conference Co-Chairs	

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Day 2: October 8, 2021				
Session	Topic	Time (PST)	Speaker	Overview
	Open Portal - Welcome	8:50	Lesley Farrington / Janssen Dx Tiffany D. Levin / AMDM President Karin Hughes / AMDM Vice President	
COVID-19 Updates	EUA Experience for COVID-19	9:00-9:30	Rita Hoady Sr. Manager Regulatory Affairs Roche Diagnostics	
	COVID-19: US Testing and Data Trending	9:30-10:00	Harvey Kaufman Senior Medical Director Quest Diagnostics	Review of current National trending and data collected by Quest
	EUA → Pre-market Authorization	10:00-10:30	Alberto Gutierrez Partner NDA Partners	
BREAK 10:30-10:45				
Diabetes Testing	Current Landscape in Testing and Diagnosis Paradigms	10:45-11:15	Francisco Leon Co-founder / CSO ProventionBio	Review of diabetes biology and current methods and paradigms for diagnosis of disease.
	Diabetes Testing and Monitoring	11:15-11:45	Speaker TBD	
Hot Topic	ISO 13485/CFR 820 Harmonization Efforts	11:45-12:15	Allyson B. Mullen Director Hyman, Phelps, McNamara	Summarize latest discussions, benefits, and potential limitations for industry
Annual Meeting	AMDM Annual Meeting/Closing	12:15-12:30	AMDM Board Representative / Conference Co-Chairs	