ASSOCIATION OF MEDICAL DIAGNOSTICS MANUFACTURERS

2018 FOCUS MEETING OCTOBER 11TH AND 12TH

LOS GATOS, CALIFORNIA

Day 1: October 11, 2018				
Session	**Topic**	**Time**	**Speaker**	**Overview**
Intro and Industry Updates	Registration / Continental Breakfast Welcome	8:00-8:30	Meeting Chair: Tiffany D. Levin, 55th Parallel (tiffany@55thparallel.com) Meeting Co-Chair: Lesley Farrington/Janssen Dx (lfarring@its.jnj.com)	
	Industry Update / FDA Perspective	8:30-9:00	Brendan O'Leary *Div. Director* Tim Stenzel *Office Director*	OIR will introduce the new Office Director, as well as provide a general industry update and review any upcoming changes.
	IVD Industry Update / Industry Perspective	09:00-09:30	Allyson Mullen *Hyman, Phelps*	The focus of this talk will be an overview of what is working and discuss new challenges facing our industry
Software	Software Pre-Certification Pilot Program	9:30-10:00	Deb Rasmussen *Janssen Diagnostics*	This discussion is intended to provide insights to the development and progress of the Software Pre Certification Program
Third Party Review	Third Party Review: FDA Perspective	10:10-10:30	Elizabeth Hillebrenner *Div. Director*	This talk will provide FDA perspectives on the third-party review process and the MSK IMPACT approval
	Third Party Review: Panel Discussion	10:30-10:45	Reena Philip *Div. Director* Brendan O'Leary *Div. Director* Elizabeth Hillebrenner	Q&A Session
BREAK 10:45-11:00				
Companion Diagnostics	Considerations for Streamlined Significant Risk Determination	11:00-11:30	Yun-Fu Hu *FDA/OIR* *Deputy Div. Director*	FDA to provide perspective on the practical application of implementation of the FDA guidance Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination Guidance for Industry
	New Approval - cobas® EGFR Mutation Test v2 CDx label expansion Dx Manufacturer Perspective	11:30-11:50	Helen Wu *Roche*	This discussion will focus on the Dx Manufacturer's perspective for the label expansion to add Tagrisso
	New Approval - cobas® EGFR Mutation Test v2 CDx label expansion Rx Manufacturer Perspective	11:50-12:15	Helen Wu *(on behalf of Astra Zeneca)*	We will continue discussion on the label expansion from the Rx Manufacturer's perspective

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LUNCH 12:15-1:15				
Global Registrations	China IVD Registrations	1:15-1:45	Grace Fu Palma *China Med Device*	Review of some of the changing landscape of China IVD registration process
	Supporting Global Market Access: Aligning Regulatory and Clinical Deliverables	1:45-2:30	Sarah Parsons *Janssen Diagnostics*	This talk will review current strategies to align clinical and regulatory deliverables in support of global market access.
	Update on IVDR	2:30-3:00	Stefan Burde *BSI*	Discussion to focus on the latest updates for the practical application of the new IVDR
BREAK 3:00-3:15				
Women's Health	Prenatal Testing	3:15-3:45	Michelle Roeding *Natera*	Discussion to focus on prenatal testing and the advances in the space.
	HPV	3:45-4:15	Sam Rua *HTG Molecular*	This presentation will cover a brief history of cervical cancer testing, current guidelines, recent submissions, market/regulatory considerations for new/improved products, including a brief discussion on the impact of HPV vaccines on cervical disease.
	POC Testing	4:15-4:45	Erika Ammirati *Ammirati Regulatory Consulting*	Discussion to cover general regulatory aspects regarding the various types of POC environments, and CLIA categorization consideration and also describe POC IVDs related to Women's health, primarily in the fields of STDs and hormonal infertility.
End of Day 1				

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Day 2: October 12, 2018				
	Topic	**Time**	**Potential Speakers & Titles**	**Overview**
New Guidance/ Hot Topics	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics	8:30-9:00	Laura Koontz *FDA/OIR Staff Fellow*	FDA will share perspective on new guidance and considerations for using databases to support clinical validation for genetic tests, as well as how they may aid in supporting less frequently occurring genetic variations
	Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)–Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases	9:00-9:30	Zivana Tezak *FDA/OIR Assoc. Director*	FDA will share perspective on new guidance and highlight special considerations for development and analytical validation of NGS assays used to aid in the diagnosis of suspected germline disease.
	Case Study: Breakthrough Devices Program for De Novo application	9:30-10:00	Douglas Jeffery *FDA/OIR Branch Chief*	FDA will share perspective on new guidance using the recently approved De Novo for Banyan Biomarkers, as an example of the process.
Break: 10:00 – 10:30				
NGS/Liquid Biopsy	Myriad BRCA Single-site approval	10:30-11:15	Jolette Franco *Myriad*	Discussion to focus on transforming a CLIA lab to additionally comply with 21CFR820
	Liquid Biopsy – Current Practices and Considerations	11:15-11:45	Jennifer Dickey *PGDx*	This talk to review considerations for registration of liquid biopsy applications
	NGS Regulatory and Reimbursement Update	11:45-12:15	Lynne McBride *Thermo Fisher Scientific*	This talk will focus on the evolving registration requirements including supporting label claims, tumor profiling and reimbursement.
Box Lunch: 12:15 pm				
End of Day 2				