

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 Type 1 Diabetes Screening | 10:45-11:15 | Francisco Leon Co-founder / CSO ProventionBio | Review of diabetes biology and current methods and paradigms for diagnosis of disease. |
| | Regulatory Considerations in Type 1 Diabetes | 11:15-11:45 | Marjana Marinac, Sr. Director, Regulatory Affairs JDRF | |
| 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 | |