

37th AMDM Annual Meeting
Thursday, April 22 - Friday, April 23, 2010

White Flint Amphitheater
Bethesda North Marriott Hotel and Conference Center
5701 Marinelli Road
N. Bethesda, Maryland

Day 1 – April 22, 2010 (Thursday)

8:00 - 9:00 AM **Registration and Breakfast Buffet**

9:00 - 9:15

Welcome and Introduction

- Judi Smith, President, AMDM
- Karin Hughes, Biosite & Donna Link, TechLab, Program Co-Chairs

9:15 – 10:15

OIVD Roundtable Discussion

- Karin Hughes, Biosite & Donna Link, TechLab, Moderators
- Alberto Gutierrez, Director, OIVD

10:15 – 10:30 **Break**

10:30 – 11:15

How to Prepare and File for CLIA Waiver

- Carol Benson, Associate Director, DCTD

11:15 – 12:00

IVD Industry Overview

- Jonathan Kahan, JD, Hogan & Hartson LLP

12:00 - 1:00 PM **Networking Lunch**

1:00 – 1:45

PMA Applications: Perspectives from an IVD Manufacturer

- James Kelly, Sr Director Regulatory Affairs, Roche Molecular Systems

1:45 – 2:30

The Past, Present and Future of Good Reprint Practices

- Bradley Thompson, JD, Epstein, Becker & Green

2:30– 2:45 **Break**

2:45 – 3:30

FDA Regulatory Considerations in Transfer of Ownership of Diagnostic Technology

- Janice Hogan, Partner, Hogan & Hartson, LLP

3:30 – 4:15

IVD General Classification as Proposed by the GHTF SGI

- Connie O’Conner, Project Manager, KEMA Quality BV
- Gary Barrett, PhD, KEMA Quality BV

4:15 – 4:30 **Break**

4:30 – 5:00

AMDM Annual Business Meeting (All AMDM Members Welcome)

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Day 2 – April 23, 2010 (Friday)

8:00-9:00 AM ***Registration and Breakfast Buffet***

9:00 – 9:45 ***Legislative & Policy Landscape Under New Congress & New Administration***

- Rick Naples, VP, Corporate Regulatory Affairs, Becton Dickinson

9:45 - 10:30 ***Companion Diagnostics in Personalized Medicine Worldwide***

- Eric Lawson, Project Director, Voisin Consulting, Inc.

10:30 - 10:45 ***Break***

10:45 – 11:30 ***Integrating Risk Management into Quality Systems***

- Nathan Conover, Sr Partner, PathWise Inc.

11:30 – 12:00 ***Medical Device Reporting, Part 803:eMDR***

- Sharon Kapsch, Supervisor Consumer Safety Office, RSMB

12:00- 1:00 PM ***Networking Lunch***

1:00 – 1:30 ***Veterinary Diagnostics: Concept to Market***

- Gary A Anderson, DVM, PhD, Director, Kansas State University Veterinary Diagnostic Laboratory

1:30 – 2:00 ***Risk-Based Regulations of Emerging Diagnostics: An Update on AdvaMed's Tier Triage Proposal***

- Sam Rua, Global Regulatory, Clinical, and Government Affairs, Beckman Coulter

2:00 – 2:45 ***Current Policy Topics in OIVD***

- Elizabeth Mansfield, PhD, Director Personalized Medicine, OIVD

2:45 – 3:00 ***Review and Wrap-up***

- Karin Hughes, Biosite & Donna Link, TechLab, Program Co-Chairs

Please travel safely. We hope to see you again next year!