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Association of
Medical
Diagnostics
Manufacturers

and

Food and Drug
Administration

37th Annual Meeting & OIVD Submissions Workshop



*Educating industry
for over 30 years.*

April 19-23, 2010

Bethesda North Marriott
Hotel & Conference
Center
5701 Marinelli Road
N. Bethesda, MD

April 20, 2010 (Tuesday) **OIVD Submissions Workshop**

8:00-9:00 AM Registration & Breakfast Buffet

9:00-9:15 AM Welcome and Introduction

- Judi Smith, President, AMDM

9:15-10:00 AM Introduction to OIVD

- Don St Pierre, Deputy Director, OIVD

10:00-10:15 AM Break

10:15-10:45 AM Small Mfrs Assistance

- Joe Tartal, DSMICA Branch Chief

10:45-11:15 AM Registration and Listing

- David Gartner, Program Analyst, OC

**11:15-12:15 PM When to Submit (or not) a
510(k), that is the Question!**

- Heather Rosecrans, Director, ODE

**12:15-1:30 PM Networking Lunch with the FDA
Staff**

**1:30-2:00 PM Special & Abbreviated 510(k) and
Add-to-Files**

- Doug Rheinheimer, Sci Reviewer, DCTD

**2:00-3:30 PM 510(k) Review Part 1 Decision
Summaries:**

A Reviewer's Perspective with Case Studies

- Stephanie Akselrod, Reviewer, DMD

Software in the World of IVDs

- Andrew Grove, PhD, Sci Reviewer, DMD
- Eugene Reilly, Sci Reviewer, DCTD

3:30-3:45 PM Break

**3:45-4:15 PM 510(k) Review Part II:
Molecular Diagnostics**

- Kellie Kelm, Sci Reviewer, DCTD

4:15-4:45 PM De Novo

- Donna Roscoe, PhD, Sci Reviewer, DMD

**4:45-5:15 PM 510(k) Combination Product &
Companion Diagnostics**

- Joseph Milone, PhD, Biologist, OCP

5:15- 5:30 PM Strategies for Working with FDA

- Judi Smith, President, AMDM

April 21, 2010 (Wednesday) **OIVD Submissions Workshop**

8:00-9:00 AM Registration & Breakfast Buffet

9:00-9:30 AM PMA Process

- Zivana Tezak, Assoc Dir for Science and Technology
- Kate Simon, Sci Reviewer, DMD
- Sally Hojvat, Director, DMD

9:30-10:00 AM Bioresearch Monitoring (BIMO)

- Veronica Calvin, MA, Biologist Division of Bioresearch Monitoring, OC

10:00-10:15 AM Break

10:15-10:45 AM Health Hazard Evaluation / Recalls

- Murray Malin, MD, Medical Officer, DOEA, OC

**10:45-11:15 AM Interacting with Compliance / Case
Management**

- Tara Goldman, Biologist, Consumer Safety Officer, OIVD

11:15-11:45 AM Quality System Regulations

- Tonya Wilbon, BS, M(ASCP), Compliance Reviewer, OIVD

11:45-12:15 PM Import / Export

- Laurence Spears, Dep Dir Reg Aff, OC

12:15-1:30 PM Networking Lunch with FDA Staff

**1:30-2:45 PM Frequently Asked Questions Submitted
by the Audience**

- FDA Staff
(Submit questions in advance to
amdm_secretary@sbcglobal.net)

2:45-3:00 PM Break

**3:00-4:15 PM FDA's New Statistical Guidance Docu-
ment: An Interactive Session**

- Kristen Meier, PhD, OSB

**4:15-4:45 PM Hematology: Premarket & Postmarket
Findings for Home-Use PT/INR Devices**

- Leonthena Carrington, Assoc Dir, HPD

4:45-5:00 PM Wrap-Up

April 22, 2010 (Thursday)
AMDM 37th Annual Meeting

- 8:00-9:00 AM Registration/Breakfast Buffet**
- 9:00-9:15 AM Welcome and Introductions**
- Judi Smith, President AMDM
 - Karin Hughes, Biosite & Donna Link, TechLab, Program Co-Chairs
- 9:15-10:15 AM OIVD Roundtable Discussion**
- Karin Hughes & Donna Link, Moderators
 - Alberto Gutierrez, Director, OIVD
- 10:15-10:30 AM Break**
- 10:30-11:15 AM How to Prepare and File for CLIA Waiver**
- Carol Benson, Associate Dir, DCTD
- 11:15-12:00 PM IVD Industry Overview**
- Jonathan Kahan, JD, Hogan & Hartson LLP
- 12:00-1:00 PM Networking Lunch**
- 1:00-1:45 PM PMA Applications: Perspectives from an IVD Manufacturer**
- James Kelly, Sr Dir RA, Roche Molecular Systems
- 1:45-2:30 PM The Past, Present and Future of Good Reprint Practices**
- Bradley Thompson, JD, Epstein, Becker & Green
- 2:30-2:45 PM Break**
- 2:45-3:30 PM FDA Regulatory Considerations in Transfer of Ownership of Diagnostic Technology**
- Janice Hogan, Partner, Hogan & Hartson LLP
- 3:30-4:15 PM IVD General Classification as Proposed by the GHTF SG1**
- Connie O'Conner, Project Manager, KEMA Quality BV
 - Gary Barrett, PhD, KEMA Quality BV
- 4:15-4:30 PM Break**
- 4:30 - 5:00 PM AMDM Annual Business Meeting (All AMDM Members Welcome)**

April 23, 2010 (Friday)
AMDM 37th Annual Meeting

- 8:00-9:00 AM Registration/Breakfast Buffet**
- 9:00-9:45 AM Legislative & Policy Landscape Under New Congress & New Administration**
- Rick Naples, VP Corp RA, Becton Dickinson
- 9:45-10:30 AM Companion Diagnostics in Personalized Medicine Worldwide**
- Eric Lawson, Project Dir, Voisin Consulting, Inc
- 10:30-10:45 AM Break**
- 10:45-11:30 AM Integrating Risk Management into Quality System**
- Nathan Conover, Sr Partner, PathWise Inc
- 11:30-12:00 PM Medical Device Reporting: eMDR**
- Sharon Kapsch, Supervisor, CSO, RSMB
- 12:00- 1:00 PM Networking Lunch**
- 1:00-1:30 PM Veterinary Diagnostics: Concept to Market**
- Gary A Anderson, DVM, PhD, Dir, Kansas State University Veterinary Diagnostic Lab
- 1:30-2:00 PM Risk-Based Regulation of Emerging Diagnostics: An Update on AdvaMed's Tier Triage Proposal**
- Sam Rua, Global Reg, Clin, & Govt Aff, Beckman Coulter
- 2:00-2:45 PM Current Policy Topics in OIVD**
- Elizabeth Mansfield, Dir, Personalized Med
- 2:45-3:00 PM Review and Wrap-up**
- Karin Hughes & Donna Link, Co-Chairs

Hotel Information

The conference will be held at:

Bethesda North Marriott Hotel & Conference Center
 5701 Marinelli Road
 North Bethesda, MD 20852

Individual guest reservations can be made by calling the hotel directly at **301-822-9200** or at **Marriott reservations 1-800-228-9290**.

A block of rooms has been reserved under “**AMDM Conference.**” Guests need to make reservations before 3/19/10 in order to receive the special room rate of \$199.00 (single or double) plus applicable taxes. All reservations must be guaranteed for late arrival by a valid credit card.

AMDM Now Offers 2 Evening Sessions

As AMDM is recognized as the educational resource to the IVD industry for regulatory information, our conference offerings now include two evening sessions that allow meeting attendees the opportunity to learn even more about the regulatory processes unique to the IVD industry. There is an additional charge to attend these evening sessions and space is limited. Please include these options in your on-line registration.

April 19, 2010 (Monday)

Regulatory Affairs 101

5:00 PM Registration
 5:30 – 9:00 PM Meeting
 Dinner Included

AMDM representatives help those new to Regulatory Affairs in understanding:

- FDA Organizational Structure
 - Submission Pathways
 - Terminology & Acronyms
 - Helpful Resources
- (Space is limited. Additional charges apply.)

April 21, 2010 (Wednesday)

Pre-IDE/Pre-Submission Workshop

6:00 Registration
 6:30 – 9:00 PM Meeting
 Dinner Included

OIVD staff outline the Pre-IDE process and Pre-Submission activities including:

- Design & development process alignment with statistical considerations
 - Documentation content and format
 - Possible outcomes
 - Future guidance documents
- (Space is limited. Additional charges apply.)

Registration Information

<u>Meeting</u>	<u>Rate</u>
<input type="checkbox"/> Regulatory Affairs 101	\$175.00
<input type="checkbox"/> Pre-IDE/Pre-Submission Workshop	\$175.00
<input type="checkbox"/> OIVD Submission Workshop	\$395.00
<input type="checkbox"/> Annual Meeting:	
<input type="checkbox"/> Member Rate	\$695.00
<input type="checkbox"/> Non-Member Rate	\$995.00
<input type="checkbox"/> Government Employee	\$495.00
<input type="checkbox"/> Press	\$30

Register On-Line at www.AMDM.org

Cancellation Policy:

Prepaid registrations will be refunded if cancellations are received in writing by March 20, 2010 to amdm_secretary@sbcglobal.net. A \$50 handling fee will be deducted from any refunded amounts. Substitutions from the same company will be accepted. No telephone cancellations can be accepted. Payment is expected for each registration, regardless of attendance.

AMDM reserves the right to cancel this program at its sole discretion, whereupon registration fees will be refunded in full. AMDM also reserves the right to substitute speakers and topics at its discretion.

Association of Medical Diagnostics Manufacturers

Up-to-date agendas and other meeting information will be provided at www.amdm.org.

Other questions or concerns, please contact:

Lisa Brown, Executive Secretary

Home Office Phone: 765-288-1776

Fax: 765-288-1278

E-mail: amdm_secretary@sbcglobal.net