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Association of  
Medical Diagnostics  
Manufacturers

**2010 Educational  
Conference**

**Personalized  
Medicine**

**16th AMDM  
IVD Regulatory Focus  
Meeting**



*Educating industry  
for over 30 years.*

September 23 -24, 2010

Toll House Hotel  
140 S. Santa Cruz Ave.  
Los Gatos, CA 95030

### ***About the Conference***

AMDM's 16th IVD Regulatory Focus Meeting promises unique opportunities to concentrate on current and emerging issues and to learn about the latest regulatory changes. With a directed focus on personalized medicine, the presentations will highlight the regulatory changes that molecular and genetic tests have brought to the IVD industry. The topics will be appealing to both the new and established diagnostic/biotechnology manufacturer's needs. Subjects range from basic to advanced levels; from developing programs to special attention areas. Attendees are encouraged to network with others from industry, as well as the FDA staff.

### ***Speakers***

- **Elizabeth Mansfield, PhD**, FDA, CDRH, OIVD
- **Mary Ellen Demars**, Critical Path Institute
- **Michelle Schoonmaker**, Cepheid
- **Brook Bumpers**, Hogan Lovells
- **Alan Mertz**, ACLA
- **Paul Radensky**, McDermott Will & Emery LLP
- **Kathy Hudson**, The Genetics and Public Policy Center (invited)
- **Guido Brink**, Agendia BV
- **Peter Collins**, Qiagen
- **Perry Dimas**, Premier Source
- **Jean Amos Wilson**, PhD, FACMG, CGMB, Berkeley Heart Lab
- **Mitch Nelles**, XDX
- **John Sninsky**, PhD, Celera
- **Liz Lison**, Advoca
- **Sam Rua**, Ventana Medical Systems

**Thursday, September 23, 2010**  
**Larkspur Ballroom**

**7:30 - 8:15 AM Registration/Breakfast**

**8:15 - 8:30 AM Welcome and Introduction**

- Liz Lison, Advocea
- Sam Rua, Ventana Medical Systems

**8:30 - 9:15 AM Update on FDA Personalized Medicine Group**

- Elizabeth Mansfield, PhD, FDA/CDRH/OIVD

**9:15 - 10:00 AM What is CLIA?**

- Brook Bumpers, Hogan Lovells

**10:00 - 10:15 AM Break**

**10:15 - 11:00 AM NIH Genetic Testing Registry**

- The Genetics and Public Policy Center (invited)

**11:00 - 11:45 AM Critical Path Initiative**

- Mary Ellen Demars, Critical Path Institute (invited)

**11:45 AM - 1:00 PM Lunch**

**1:00 - 1:45 PM AdvaMed Tier Triage Proposal Testing**

- Michelle Schoonmaker, Cepheid (invited)

**1:45 - 2:30 PM ACLA Five Point Congressional Plan for Regulation of Laboratory Developed Tests**

- Alan Mertz, ACLA

**2:30 - 3:15 PM The APDx Model for Regulation of Personalized Medicine Tests**

- Paul Radensky, McDermott Will & Emery LLP

**3:15 - 3:30 PM Break**

**3:30 - 4:15 PM Discussion Panel on the Industry Proposals for Regulation of Personalized Medicine Tests**

- Michelle Schoonmaker, Cepheid
- Paul Radensky, McDermott Will & Emery LLP
- Alan Mertz, ACLA
- Elizabeth Mansfield, FDA/CDRH/OIVD

**4:15 - 4:30 PM Meeting Recap**

- Liz Lison, Advocea
- Sam Rua, Ventana Medical Systems

**Friday, September 24, 2010**  
**Larkspur Ballroom**

**8:00 - 8:30 AM Networking Breakfast**

- Meeting room is available to network with your colleagues, and discuss the topics over breakfast.

**8:30 - 9:15 AM The First FDA Recall of an IVD/IMA**

- Guido Brink, Agendia BV

**9:15 - 10:00 AM Legislation Affecting Genetic Testing**

- Paul Radensky, McDermitt Will & Emery LLP

**10:00 - 10:15 AM Break**

**10:15 - 11:00 AM Companion Diagnostics: FDA's Perspective**

- Elizabeth Mansfield, PhD, FDA/CDRH/OIVD

**11:00 - 11:45 AM Companion Diagnostics: The Manufacturer's Perspective**

- Peter Collins, Qiagen

**11:45 - 12:30 PM Achieving Reimbursement for Your Personalized Medicine Test**

- Perry Dimas, Premier Source

**12:30 - 1:45 PM Lunch**

**1:45 - 2:30 PM LDTs in the Clinical Laboratory**

- Jean Amos Wilson, PhD, Berkeley HeartLab

**2:30 - 3:15 PM Panel Discussion: New Business Models for Personalized Medicine Tests**

- Mitch Nelles, XDx
- Pathwork Diagnostics
- John Sninsky, PhD, Celera
- Jean Amos Wilson, PhD, Berkeley HeartLab

**3:15 - 3:30 PM Recap and Meeting Close**

- Liz Lison, Advocea
- Sam Rua, Ventana Medical Systems

## Hotel Information

The conference will be held at:

Toll House Hotel  
140 S. Santa Cruz Avenue  
Los Gatos, CA 95030

Individual guest reservations can be made by calling the hotel directly at **1-800-238-6111** or on-line at <http://www.tollhousehotel.com>.

A block of rooms has been reserved under "Association of Medical Diagnostics Manufacturers" or Group Code "GCCR11." Guests need to make reservations before **8/23/2010** in order to receive the special room rate of \$129.00 (single or double) plus applicable taxes. All reservations must be guaranteed for late arrival by a valid credit card.

## Cancellation Policy

Prepaid registrations will be refunded if cancellations are received in writing by August 20, 2010 to [amdmd\\_secretary@sbcglobal.net](mailto:amdmd_secretary@sbcglobal.net). A \$50 handling fee will be deducted from any refunded amounts. Substitutions from the same company will be allowed. 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. AMDM also reserves the right to substitute speakers and topics at its discretion.

**Register On-Line at [www.AMDM.org](http://www.AMDM.org)**

**Or send completed forms to:**

**Association of Medical Diagnostics Manufacturers**

Lisa Brown, Executive Secretary

7210 N. Nebo Road

Muncie, IN 47304

Home Office: 765-288-1776

E-mail: [amdmd\\_secretary@sbcglobal.net](mailto:amdmd_secretary@sbcglobal.net)

Website: [www.amdm.org](http://www.amdm.org)

## Registration Form

Please complete one form for each attendee.

	<u>Rate</u>	<u>Charges</u>
<b>Regulatory Focus Meeting:</b>		
<input type="checkbox"/> Member Rate	<b>\$695.00</b>	
<input type="checkbox"/> Non-Member Rate	<b>\$995.00</b>	
<input type="checkbox"/> Government Employee	<b>\$495.00</b>	
<input type="checkbox"/> Press (Circle day Thurs / Fri)	<b>\$30/day</b>	
	<b>Total</b>	<input type="text"/>

Attendee's Name

Company / Organization Name

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City  State  Zip

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- Corporate Check — Mailed separately
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