



AdvaMed

Advanced Medical Technology Association

MDRs, eMDRs, and Global Adverse Event Reporting

Washington, DC
November 9 – 10, 2009

Monday, November 9

8:30 – 9:00 **Breakfast**

9:00 – 9:10 **Welcome**

Tom Maeder, Executive Director, MTLI, AdvaMed

Jeff Secunda, Vice President, Technology & Regulatory Affairs, AdvaMed

9:10 – 10:00 **Medical Device Reporting – 21 CFR Part 803**

Sharon Kapsch, Director, Reporting Systems Monitoring Branch, Office of Surveillance & Biometrics, CDRH

Howard Press, Policy Analyst, Office of Surveillance & Biometrics, FDA/CDRH

- Purpose of MDR reporting
- Regulatory history of MDR reporting
- Current regulatory requirements
- What is a reportable event?
- Who does and does not need to report
- ASRs and exemptions
- When are supplemental reports required and how do you complete them?
- Unique Device Identifiers

10:00 – 10:45 **What Does FDA Do with the Data?**

David Buckles, Director, Division of Postmarket Surveillance, Office of Surveillance & Biometrics, CDRH

- How is the data analyzed, and what is done with the output?
- What triggers an AI (request for additional information) letter?
- Is there transparency in reporting?
- How can data be reviewed by the public?
- Examples of success stories
- What to do when a manufacturer receives information on a competitor's product.

10:45 – 11:00

Break

11:00 – 11:45 Implementing MDR requirements

Richard Roy, Technical Services Manager, AGA Medical Systems

- Complaint handling
- Complaints, MDRs, CAPA, management review – the big picture
- Design and implementation of a complaint handling system
- Risk assessment and the decision tree for deciding to report
- Consistent internal training on reportable events and reporting decisions
 - Interacting with FDA

11:45 – 12:30 Health Hazard Evaluation and Risk Assessment

Naunihal S. Viridi, Senior Manager, Product Safety, Medical Affairs, LifeScan (a Johnson & Johnson Company)

Monique Brooks, Recall Coordinator, FDA/CDRH

Kimber Richter, Deputy Director for Medical Affairs, Office of Compliance, CDRH

- Expectations and responsibilities for risk assessment and clinical evaluation of reportable events

12:30 – 1:30

Lunch

1:30 – 2:15 Global Adverse Event Reporting

Leighton Hansel, Director, Regulatory Affairs, Abbott Laboratories

- Current international landscape – similarities and differences
- GHTF Study Group 2 activities
- Practical challenges and responsibilities in global reporting
- Industry experience with uniform global reporting

2:15 – 3:15 MDRs and the Link to Inspections and Enforcement Actions

Robert Ruff, Medical Device Specialist, New Jersey District, FDA (invited)

- How do inspectors identify MDR deficiencies?
- Is there a means to appeal?

3:15 – 3:30

Break

3:30 – 4:30 Coding

Terrie Reed, Project Manager, Patient Safety Staff, Office of Surveillance & Biometrics, CDRH

Kathy Weil, Nurse Consultant, FDA/CDRH

- Problem codes (F10) (patient / device)
 - How are they established, and can they be changed?
 - How does one find the right code?
 - New problem codes and deadlines
- Evaluation codes (H6) (method / result / conclusion)
- Developing a hierarchy

4:30 – 5:00

Panel Discussion and Q&A on MDR Principles

Faculty

5:00 – 6:00 Reception

Tuesday, November 10

8:30 – 9:00 Breakfast

9:00 – 10:30 eMDR Implementation

Indira Konduri eMDR Program Manager, Office of Surveillance & Biometrics, CDRH

Presentation followed by FDA-industry panel discussion

- High volume and low volume reporters – choosing a pathway
- Resource allocation
- Frequently asked questions and challenges
- Collaboration between regulatory and IT
- Debugging the system

10:30 – 10:45 Break

10:45 – 11:45 The Shift to Electronic Communications

Stephen Sykes, Deputy Director, Office of Surveillance & Biometrics, CDRH

- MedWatch^{Plus} and Sentinel System Overview / Update
- The Gateway
- eMDRs
- HL7 coding

11:45 – 12:30 What Can Be Done Better?

Industry & FDA speakers/panelists

12:30 Adjournment