



Complaints, MDRs, Reports of Removals & Corrections, and Recalls

Chicago, IL
October 22 – 23 2009

Thursday, October 22nd

8:30 – 900

REGISTRATION AND CONTINENTAL BREAKFAST

9:00

Welcome

Thomas Maeder, Executive Director, MTLI, AdvaMed

9:05– 9:45

Complaints - Definitional Questions

Edward Wilson, Partner, Hogan & Hartson

- What is a complaint
- How do you distinguish among a product complaint, a satisfaction complaint and a customer inquiry
- What is a service call
- What is the difference between a service call and a complaint
- When are service calls complaints
- Does the FDA differentiate an instrument repair from a complaint
- Should companies document all service calls as complaints

9:45 – 10:30

Setting Up a Complaint System

Sue Jacobs, Principal Consultant, QMS Consulting, Inc.

- What are the elements of an effective complaint management system?
- How does risk management influence complaint handling decisions?
- What department within a company should have primary responsibility for the complaint management system?
- How do service and sales calls fit into your complaint handling procedures?
- How do you motivate your Service and Sales personnel to report complaints?
- How do you train your Customer Call Center employees to identify complaints while talking to the customer on every-day issues?
- What are the responsibilities of other departments?

- What is the best way to train customer contact employees?
- Where should the files be maintained, who should maintain them, and for how long?
- What is the relationship to your CAPA system?

10:30 – 10:45

BREAK

10:45 – 11:30

Handling Complaints & Trending

Richard Roy, Technical Services Manager, AGA Medical Corporation

- Why is it important to establish a process for handling complaints?
- What are examples of SOPs for sorting out potential MDRs and product complaints?
- What steps would the FDA expect to see the departments taking that sorts out potential MDRs, product complaints and other reportable events?
- How do you perform trending?
- What are examples of how companies trend and analyze service calls and product complaints?
- Are companies required to trend resolution to complaints as well as complaints?
- What is FDA's expectation about trending complaints from non-US markets?

11:30 – 12:15

Current FDA Inspection & Enforcement Trends

Lorelei Jarrell, Pre-Approval Manager, Compliance Officer, FDA/Chicago District

- FDA perspective on postmarket issues and field actions
- Current enforcement trends
- FDA inspectional activities

12:15 – 1:30

LUNCH

1:30 – 2:30

Measuring the Effectiveness of Your Complaint System

Paul Carlson, Program Manager, CAPA Certification, Abbott Laboratories

- What is an appropriate complaint handling system in a risk-based p market environment?
- How do you audit a complaint handling system?
- From your audits, how do you judge that your complaint handling system is effective?
- How do you ensure that your electronic records database handling complaints complies with 21 CFR Part 11?
- How do you perform a failure investigation and what documentation would you maintain?
- How do you investigate complaints when samples are not available or product is not returned?
- What guidelines should you provide to your employees about how and when to respond to customer complaints?

2:30 – 2:45

BREAK

2:45 – 4:15

Understanding MDRs

*Richard Roy, Technical Services Manager, AGA Medical Corporation
Edward Wilson, Partner, Hogan & Hartson*

- What are the key terms, definitions and forms?
- How should you investigate complaints to determine if they are MDRs?
- What constitutes a reportable malfunction or MDR?
- What does an MDR flow chart look like?
- Coding
- How do you conduct risk assessment?
- When should you not report an incident?
- If you make an MDR report do you also have to report under 21 CFR Part 806?
- Are there any steps in between?
- How do you manage international reporting requirements under your complaint handling system?
- Is 'Summary Reporting' appropriate?
- What about other alternative reporting mechanisms?

4:15 – 5:00

Exercise - Managing Product Problems

Faculty

- Discuss and answer a multiple choice quiz

5:00

ADJOURNMENT

Friday, October 23rd

8:00 – 8:30

REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 9:15

eMDRs

Deb Kacera, Senior Product Manager, Regulatory Products, Pilgrim Software

- The electronic MDR program
- Implementation and practical challenges of eMDRs

Lessons learned from early adopters

9:15 – 10:30

Part 806 Reports of Removals and Corrections

Ted Wilson, Partner, Hogan & Hartson

- Relationships between MDRs, Corrections, Removals, and Recalls
- What are the key elements of 21 CFR Part 806?
- What are examples of items that need to be reported?
- Should you file an 806 if you have a recall or advisory notice?
- What information needs to be reported?
- What types of records do companies need to keep?
- Prior to notifying FDA, what steps should you have taken?

- What are the dos and don'ts when informing FDA of a product problem?
- Should you have a different strategy for removals and corrections than for recalls?

10:30 – 10:45

BREAK

10:45 – 11:30

An Introduction to Health Hazard Evaluation (HHE)

Thomas Morrissey, Vice President, Product Safety, Edwards Lifesciences

- What is a Health Hazard Evaluation
- When should an HHE be initiated
- What are the elements of a well-documented HHE
- What are the common mistakes
- How are they documented
- Who should approve
- How are records maintained
- What is FDA's involvement in health hazard evaluation and classification

11:30 – 12:15

Recalls and Other Field Actions

Thomas Morrissey, Vice President, Product Safety, Edwards Lifesciences

Ted Wilson, Partner, Hogan & Hartson

- What is the clinical context for recalls and other field actions?
- Who should be involved in the decision process?
- Who should be responsible for communicating with FDA?
- What are the consequences of a recall?
- What factors should you consider when determining whether or not to get your product back?
- How do you prepare for a post recall inspection?
- What customer and other outside communications are necessary?
- What documentation should be prepared?
- How should the product liability implications of recall communications be handled?
- What is an effectiveness check?
- How should you write your recall correspondence?
- How do you determine that your recall is completed?
- What do you do to close your recall internally and with FDA?
- Case studies

12:15 – 1:00

What's New?

Sue Jacobs, Principal Consultant, QMS Consulting, Inc.

Deb Kacera, Senior Product Manager, Regulatory Products, Pilgrim Software

FDA Chicago District Speaker(s) TBA

- Update on recent changes in policies and procedures

1:00

ADJOURNMENT

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.