



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

The Regal Sun Resort
Orlando, FL
January 20 – 21 2009

Tuesday, January 20th

8:30 – 900

REGISTRATION AND CONTINENTAL BREAKFAST

9:00

Welcome

Thomas Maeder, Executive Director, MTLI, AdvaMed

9:05– 9:45

Complaints - Definitional Questions

Michael Heyl, Associate, 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

Florida District Compliance and Inspection Speakers TBA

- 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

Charles Goldberg, Director, Quality Assurance, Cordis Corporation (a J&J Company)

- 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

Michael Heyl, Associate, 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?
- 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

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

5:00

ADJOURNMENT

Wednesday, January 21st

8:30 – 9:00

REGISTRATION AND CONTINENTAL BREAKFAST

9:00 – 10:15

Part 806 Reports of Removals and Corrections

Richard Roy, Technical Services Manager, AGA Medical

Michael Heyl, Associate, 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?

10:15 – 10:30

BREAK

10:30 – 11:15

An Introduction to Health Hazard Evaluation (HHE)

Gaurang Patel, MD, Medical Director, Complaint Handling and Safety Surveillance, Cordis Corp. (a J&J Company)

- 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

11:15 – 12:00

Recalls and Other Field Actions

Michael Heyl, Associate, Hogan & Hartson

Gaurang Patel, MD, Medical Director, Complaint Handling and Safety Surveillance, Cordis Corp. (a J&J Company)

- 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

12:00 – 1:00

LUNCH

1:00 – 2:00

Postmarket Information and CAPA

Sue Jacobs, Principal Consultant, QMS Consulting, Inc.

- What are the relationships to CAPA
- When should you consider a postmarket event to be a CAPA
- How do you use a risk-based approach

- 2:00 – 3:00** **Exercise - Managing Product Problems**
Faculty
- Discuss and answer a multiple choice quiz
- 3:45 – 5:00** **Faculty Panel Discussion – pre-submitted questions**
Faculty
- 5:00** **ADJOURNMENT**

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