AdvaMed
Advanced Medical Technology Association
Events & Education

Medical Device Complaints, MDRs, and Reports

April 4 - 5, 2018
801 Pennsylvania Ave NW | Conference Center
Washington, DC

April 4, 2018

8:30 – 9:00 am **Registration Check-In and Continental Breakfast**

9:00 – 9:05 am **Welcome and Introductions**

9:05 – 10:00 am **Complaints – Definitional Questions**

- 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

10:00 – 10:45 am **Setting Up a Complaint System**

- 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?

10:45 – 11:15 am **Break**

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11:15 – 12:00 pm **Handling Complaints & Trending**

- 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?

12:15 – 1:00 pm **Lunch**

1:00 – 2:00 pm **Communication Strategies for Recalls and Other Field Actions**

- Who should be responsible for communicating with the FDA?
- What should you keep in mind when developing a internal communications plan?
- What customer and other outside communications are necessary?
- What should you keep in mind when developing a field team communications plan?
- What documentation needs to be included on the notification letter?
- What is an effectiveness check?
- How should you write your recall correspondence?
- How do you determine that your recall is completed?

2:00 – 3:00 pm **Understanding MDRs**

- 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?

3:00 – 3:15 pm **Break**

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3:15 – 4:15 pm **Q&A with the FDA**

- FDA's point of view on how they see the regulations
- Clarification points on any relevant regulations of interest from the audience

4:15 – 5:00 pm **An Introduction to Health Hazard Evaluation (HHE)**

- 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

5:00 – 6:00 pm **Networking Reception**

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8:00 – 8:30 am **Continental Breakfast**

8:30 – 9:00 am **Reporting and Products Liability**

- Implications and impact from incorrect reporting on products liability

9:00 – 10:00 am **Part 806 Reports of Removals and Corrections**

- 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?

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10:00 – 10:15 am **Break**

10:15 – 11:15 am **Current FDA Inspection & Enforcement Trends**

- FDA perspective on post-market issues and field actions
- Current enforcement trends
- FDA inspectional activities
- FDA expectations for the industry

11:15 – 12:15 pm **Measuring the Effectiveness of Your Complaint System**

- What is an appropriate complaint handling system in a risk-based post-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?
- How to get the data and what to do with it

12:15 pm **Adjournment**