Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Effective Complaint Handling, Medical Device Reporting and Recalls

Baltimore MD

March 19th & 20th 2020

9:00 AM to 6:00 PM

Price

Price: **$999.**

(Seminar for One Delegate)

Register for 5 attendees:

Price: **$3,999.**

Register for 10 attendees

Price: $7,999.

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar*

David R Dills

Regulatory Affairs & Compliance Consultant,

David R. Dills, Global Regulatory Affairs & Compliance Consultant, has an accomplished record with more than 26 years of experience within regulatory affairs, compliance and quality consultative services for early-stage/established Class I/II/III medical devices, IVDs, and bio/pharmaceutical manufacturers on the global landscape.

Overview :

An effective complaint handling system is an extremely important part of any quality system. Manufacturers should understand that any complaint received on a product shall be evaluated and, if necessary, thoroughly investigated and analyzed, and corrective action shall be taken.

The results of this evaluation should lead to a conclusion regarding whether the complaint was valid, what the root cause of the complaint was, and what action is necessary to prevent further occurrences. Complaints cannot be ignored. They are an excellent indicator of problems with the use, design, and/or manufacture of a product. A single complaint that is thoroughly investigated may lead a company to take remedial or corrective action. It may also take an ongoing analysis of numerous complaints before a trend is spotted that causes a company to initiate changes in their product, labeling, packaging or distribution.

Agenda:

Day One

Lecture 1: Complaint Handling

- •What are the elements of an effective complaint management
- •system?
- •How does risk management influence complaint handling
- •decisions?
- •What are the responsibilities of other departments?
- •What is the best way to train customer contact employees?
- •What steps would the FDA expect to see the departments taking that sorts out potential MDRs, product complaints and other reportable events?
- •What and how do you perform trending?
- •What are examples of how companies trend and analyze service calls and product complaints?
- •Understand how and why CAPA is tied in to product complaint investigation
- •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?
- •Assignment of responsibility
- •Manufacturer should develop a method for maintaining records of complaints and investigations that: is functional and economical, meets company needs, and meets FDA requirements and expectations
- •Identify designated complaint handling unit
- •Instructions for documenting complaint information
- •Process for evaluating complaints
- •Process for investigating complaints
- •Identify and process MDR's
- •How to process customer returns
- •Records and trend analysis

Day Two

Lecture 1: Medical Device Reporting

- •eMDR Electronic Medical Device Reporting
- •How to Report a Problem
- •Event Problem Codes and Manufacturer Evaluation Codes
- •MedWatch: Safety Information and AER Program
- •Completing Form FDA 3500A
- •What form should I use to submit reports of individual adverse events and where do I obtain these forms?
- •Where and how do I submit reports and additional information?
- •Does the information in my report constitute an admission that the device caused or contributed to the reportable event?
- •What are the requirements for developing, maintaining, and implementing written MDR procedures and maintain records/files that apply to me?
- •Requirements for Individual Adverse Event Reports
- •User Facility Reporting, Importer Reporting and Manufacturer Reporting Requirements

Lecture 2: Recalls

- •What happens in a medical device recall: Firm-initiated recall vs. mandatory recall
- •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?
- •Who should be involved in the decision process?
- •Who should be responsible for communicating with FDA?

Agenda:

Day One

- •Complaint closure
- •Examples of tools currently being used to conduct investigations
- •How far and in-depth do you go with your investigations
- •What are current FDA "hot" buttons and trends, benchmarks and best practices for investigations
- •How to become a "good" investigator and the emphasis on closed-loop investigations
- •Written Procedures: Designated Complaint Handling Unit, Training and Records
- •Recent Enforcement Actions

Lecture 2: Medical Device Reporting

- •Introduction to Medical Device Reporting
- •What are the key terms, definitions and forms?
- •MDR procedures and processes
- •What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?
- •How do you manage international reporting requirements under your complaint handling system?
- •Consider the relationship between MDRs and Risk Assessments

Lecture 3: Exercise and Recap of Day 1

- •Exercise on Product Complaints/Complaint Handling
- •Quiz

Day Two

- •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?
- •Health Hazard Evaluations are conducted by FDA
- •How should you write your recall correspondence?
- •How do you determine that your recall is completed and what do you do to close your recall internally and with FDA?
- •Create and use a recall operational
- •Understand what is required for the recall strategy as expected by FDA
- •Depth of recall and using a viable, sustainable and effective strategy
- •Understand why the documentation and paper trail are so critical and termination of a recall
- •Discuss most recent recalls not only for devices but pharmaceuticals and why the numbers are alarming

Lecture 3: Exercise and Recap of Day 2

- •Exercise - MDR and Recall
- •Quiz

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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