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In-Person Seminar by Ex-FDA Official (New course materials has been added)

Navigating the Maze for Post-Market Compliance -- Complaint Handling, MDRs, Recalls and Proposed Guidance on FDA Risk Benefits

By: **Rita Hoffman,** RAC, Managing Partner Regs & Recall Strategies, LLC and Former FDA CDRH Recall Branch Chief

Location: November 16-17, 2017 | Boston, MA



SPEAKER

Rita Hoffman, RAC, Managing Partner Regs & Recall Strategies, LLC and Former FDA CDRH Recall Branch Chief

Rita Hoffman, RAC. Managing Partner Regs & Recall Strategies, LLC .Ms. Hoffman has more than 36 years of FDA experience across the device, drug and veterinary industries. She has an intimate understanding of FDA regulatory and compliance issues from the perspective of both FDA and regulated industry. As an FDA compliance consultant, she provides clients with regulatory insight, advises on critical compliance deficiencies, performs compliance and new product audits, provides insight and guidance on recall strategies to the medical device industry, and advises on jurisdiction determinations for combination products.

Ms. Hoffman retired from the FDA in January 2011 as the Recall Branch Chief for the Center for Devices and Radiological Health (CDRH), where she was responsible for oversight and review for all medical device recalls. Ms. Hoffman held several positions including the Center for Drug Evaluation and Research (CDER) Jurisdiction Review Officer (providing guidance on drug/device product designation, combination products and co-packaging), Acting Associate Ombudsman, Small Business Liaison, and was a Policy Analyst for eight years in the Office of the Commissioner. She served as co-chair of RAPS' Baltimore/Washington Metropolitan Area Chapter for 2-terms, and in 2008 was presented with the Special Recognition Award by RAPS.

Seminar instructor Ms. Rita Hoffman is the former FDA CDRH Recall Branch Chief and has more than 36 years of FDA experience across the device, drug and veterinary industries.

LEARNING OBJECTIVES

- Understand how to comply with complicated Compliant Handling, MDR and Recall requirements.
- Firms MDR reporting and FDA's handling of reports.
- Company preparation in the event of a Recall, recall strategy, notification letter and communicating with the FDA.
- Minimize your risk of regulatory enforcement actions.
- Assist with the creation and maintenance of effective procedures for handling complaints, reportable events and recalls.
- Understand the relationship and interaction with other quality system elements as they relate to complaints and reportable events.
- Walk-through of case examples.
- Step-By-Step guide to designing Standard Operating Systems for communicating process for firm's success.
- Discussion of FDA's New Guidance's on Risk and how it interacts with Recalls.

COURSE DESCRIPTION

Post-Market activities, Complaint Handling, MDRs, and Recalls are expensive, time consuming, and often lead to more serious financial consequences. Over 80% of FDA Inspection target observations for lack of compliance in these areas.

By attending this seminar, you will discover:

- how to overcome one of the biggest obstacles device manufacturers face
- how the FDA expects you to develop and implement proper handling of complaints reportable or non-reportable, product complaint handling and documentation
- how and when to file Medical Device Reports (MDR), effective and appropriate communication with the appropriate regulatory agencies in the event of a recall.
- how to conduct a correction and removal actions to avoid a recall crisis, including required recordkeeping, expectation from FDA and other regulatory agencies in the event of a recall and key factors in implementing and maintaining compliance with the regulations and real life experiences of FDA.

****New course materials have been added, updated content will include:**

- **Creating Standard Operating Systems (SOPs) for Post-Market Quality Systems and**
- **What to expect from the changes in ORA with Inspection Structure Realignment**

This Seminar will have you stop spinning your wheels with nonessential activities, and leave you with a comprehensive learning package that only Rita Hoffman, a former FDA CDRH Recall Branch Chief with experience across the device, drug and veterinary industries can provide.

Spend one and a half days in an interactive course led by Ms. Rita Hoffman, Former FDA CDRH Recall Branch Chief with over 36 years with FDA and leading Industry Expert, who will provide the participants with tools to minimize risk of regulatory enforcement actions.

AGENDA

DAY ONE (8.30AM – 5.00PM)

08.30 AM - 09.00 AM: Registration

09.00 AM: Session Start

Introduction to class (20 min)

Complaint Handling and FDA Expectations (70 min)
- What is a complaint?
- Firms Responsibilities and Definitions
- Complaint Forms
- FDA Expectations for written procedures on complaint files

Medical Device Reporting Procedures (MDR) (60 min)
- Understand the MDR regulation 21CFR 803
- Definitions 21 CFR 803.3
- MDR Procedures 21 CFR 803.17
- Types of MDR reports
- MDR reporting by firm, agents and exemptions

MDR FDA Perspective (30 min)
- CDRH Mandatory vs. Voluntary Reporting
- What happens to an MDR report submitted to FDA
- Manufacturer and User Facility Device Experience (MAUDE)
- Medical Products Safety Network (MedSun)

User Error Malfunction
- Identifying a Malfunction
- Malfunction --To report or not to report
- Serious injury triggers
- Person Qualified Makes Medical Judgment

Preparing Standard Operation Programs (30 min)

Recalls: Definitions and Legal Authority (45 min)
- What is a recall?
- Legal Authority (Chapter 7, 21CFR 806)
- Voluntary vs. Mandatory recalls
- Definitions – Corrections, Removals
- Reporting requirements for non-recall field actions
- Classification system – Classifying a Recall?
  - What is different about Class 1 recall

Being Recall Ready –Proactive Steps to Avoid Crisis (45 min)
- Internal Decision Making
- Early warning signs
- Assembling "The Team" – Assigning decision making authority
- Examples of Close-calls
- Guidelines and best practices for having contingency plan in place

Evaluating Risk and Health Hazard Evaluation (HHE) (60 min)
- Analyzing adverse event and product quality reports
- Identifying trends, Data and factors to consider
- Assessing need to conduct HHE
- HHE Procedures
- Human Factors Issues
- Opening a CAPA to Determine Root Cause

DAY TWO: (8.30AM – 12.00PM)

Developing effective Strategies and Communicating with FDA (80 min)
- Elements of a good Recall Strategy
- What does the FDA expect strategy to contain?
- Effective Notification Letter to minimize consequences
- Knowing when to contact FDA District
- Discussing Recall Strategy with FDA – Seeking input and support of your strategy to avoid common pitfalls
- Issuance of Press Release and communication with customers

Silent Recalls vs. Product Enhancements (20 min)
- Device changing environment
- Product improvement (Repair or Modification)
- Decision 803 or 806

Product Retrieval Issues, Effectiveness Checks and Status Reports (50 min)
- Receiving and accounting for returned products
- Supply chain challenges – distribution, wholesale, repackaging
- Global recall market
- Designing an efficient Effectiveness Checks
- Coordination and Discussion with FDA
- Evaluating recall effectiveness Data
- Developing and formatting status reports

New ORA Alignment and Inspection Changes (30 min)

Termination of a Recall (15 min)
- Who, how and when does termination happen
- Exporting a Recalled Product
- Communication between firm and District Office
- Requesting formal closeout by FDA

Mock Recall and Wrap-up (35 min)

WHO WILL BENEFIT

This course will benefit anyone in the medical device industry that handles functions involving product complaints, recalls, medical device reporting.

- Regulatory Affairs
- QA/QC
- Project Managers
- Regulatory Professional
- Risk Managers
- Complaint Handling Teams
- CAPA Teams

Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
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Seminar Topic: Navigating the Maze for Post-Market Compliance -- Complaint Handling, MDRs, Recalls and Proposed Guidance on FDA Risk Benefits

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