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One and a Half-day In-Person Seminar by Ex-FDA Official:

Post-Market Compliance for Medical Devices and Evolving Reporting Requirements: Complaint Handling, MDR/eMDR and Recalls including UDI update

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

Location 1: June 11-12, 2015 | Chicago, IL
Location 2: August 6-7, 2015 | Minneapolis, MN
Location 3: October 15-16, 2015 | St. Louis, MO

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
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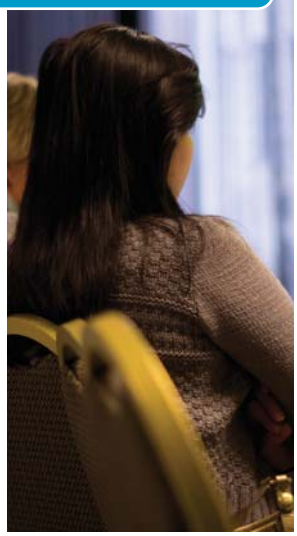
Course "Effective Complaint Handling, Medical Device Reporting and Recalls -- Avoiding Costly Errors" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.





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.

COURSE DESCRIPTION

This interactive one and a half day course led by Ms. Rita Hoffman, Former FDA CDRH Recall Branch Chief, who has more than 36 years' experience with the FDA will provide the participants tools to minimize risk of regulatory enforcement actions.

During the seminar, Ms. Hoffman will explain 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. She will also discuss 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.

Medical Device Reporting (MDR) and recall compliance are critical to the continue survival of all device manufacturers. The FDA is continuing their efforts to issue numerous FDA Warning Letters and serious enforcement actions, including criminal & civil penalties levied on companies that failed to properly report events and take proper corrective and removal actions. The number of device companies having their recall classified as a Class 1 (most severe) recall has surged in the past three years. Additionally, product liability and financial risks are staggering when companies fail to properly report and take action when required. This course will provide an understanding of MDR & recall compliance and the interrelationship of Complaint Handling, CAPA, and Risk Management processes. It will be beneficial to all device manufacturers and is recommended for any individuals or teams that are involved in medical device reporting (MDR) and correction & removal processes, including recalls.

AGENDA

DAY ONE (8.30AM – 5.00PM)

Registration Process: 8:30 AM - 9:00 AM

Session Start: 9:00 AM

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

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

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

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
10+ Attendees	-	Get 30% off

Call Toll Free +1-888-717-2436 if you have any queries.

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.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
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Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $150 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($150) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Effective Complaint Handling, Medical Device Reporting and Recalls -- Avoiding Costly Errors

Date & Location: .....

Attendee Details:

Register for 3 and 4th person gets a free pass.

	Name	Title	Email
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Attendee 2			
Attendee 3			
Attendee 4			

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The Largest GRC Advisory Network
www.complianceonline.com
2600 E. Bayshore Road Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-963-2556