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EVENTS LIST

Understanding FDA Post Market Regulations (com) A

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Organizer : NYMT

Venue :

Location : San FranciscoSan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 0001

Bad Things Happen, But It Can Get Worse - Understanding FDA Post Market Regulations

***** LIMITED TIME OFFER: FREE $100 AMAZON GIFT CARD! *****
REGISTER TODAY!

You can participate in an interactive course led by Ms. Rita Hoffman, former FDA CDRH Recall Branch Chief and Casper Uldriks, former Associate Director of CDRH. They will explain how participants can mitigate the risk of regulatory enforcement actions; avoid future recalls by using the Total Product Life Cycle TPLC paradigm that CDRH uses.

Discover how to overcome one of the biggest obstacles device manufacturers face, developing and implementing the proper handling of complaints, complaint filings under the Medical Device Reports (MDR) regulation and effective action with other state and federal public health and regulatory The seminar will cover how to conduct a correction and removal actions so you can void a recall crisis due to key factors that you face in real life experiences of FDA.

Course materials include creating Standard Operating Systems for Post-Market Quality Systems, how risk guidance document intertwines with Recalls and ORA Inspection Realignment Structure.

This Seminar will have you stop spinning your wheels with nonessential activities, and leave you with a comprehensive learning package that has only been offered by Casper Uldriks and Rita Hoffman, who bring over 68 years of combined experience.

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Seminar Fee Includes:

Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar

Learning Objectives:

- Learn about the FDA's agency-wide legal and procedural steps and investigational operations for post market issues
- Understand how to comply with complicated Compliant Handling, MDR and Recall requirements
- Firms MDR reporting and FDA's handling of MDR 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

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

Topic Background:

Post Market compliance for a Medical Device firm are expensive, time consuming and can lead to serious financial consequences. Customer satisfaction plays a significant role in measuring a product's postmarket performance. It is an indicator of how effective the product performance is managed. Both the quality system regulation (QSR) and the International Organization for Standardization (ISO) require procedures and processes to monitor and control your post market problems. The complaint-handling mechanism not only collects feedback from unsatisfied customers, but also provides means for failure investigations and subsequent corrective and preventive actions (CAPA).

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) 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.

Recalls involve regulatory obligations, such as Post-Market regulations, complaint handling, Medical Device Reports, and a required report to the FDA under the Corrections and Removals regulation. Those are the easy issues to understand, in reality, it is much more complicated. Over 80% of FDA Inspections target observations for lack of compliance in these areas.

AGENDA

DAY 01(8:30 AM - 4:00 PM)

- 08.30 AM - 09.00 AM: Registration
- 09.00 AM: Session Start
- Introduction to class (20 min)
- New ORA Alignment and Inspection Changes(30 min)
- What to expect during Inspection (60 min)
- Complaint Handling and FDA Expectations (90 min)
- Medical Device Reporting Procedures (MDR) Procedures and Regulations (60 min)
- MDR reporting by firm, agents and exemptions(30 min)
- MDR FDA Perspective and MedSun (30 min)
- User Error/Malfunction (30 min)
- FDA’s Legal Basis for Recalls and Enforcement(30 min)
- FDA’s Agency Wide Recall Investigation Procedure (60 min)
- End of Day Close-out Discussion (15 min)

DAY 02(8:30 AM - 4:00 PM)

- FDA's Agency-wide Standard Regulatory Procedures (60 min)
- Recalls: Definitions and Legal Authority for CDRH (45 min)
- Risk Based Guidance Documents Effecting Recalls (30 min)
- Preparing Standard Operating Procedures (20 min)
- Correction Action or Preventative Action Plan and Determining Root Cause Analysis (CAPA)(45 min)
- Alternatives to Reports of Corrections and Removals (15 min)
- Being Recall Ready - Proactive Steps to Avoid Management Crisis (45 min)
- Evaluating Risk and Health Hazard Evaluation (HHE) (60 min)
- Developing effective Strategies and Communicating with FDA Field Experts (90 min)
- Silent Recalls vs. Product Enhancements (20 min)
- Negotiating and Meeting with FDA(30 min)
- End of Day Close-out Discussion (15 min)

DAY 03(8:30 AM - 4:00 PM)

- Recap from Days 1 & 2 (30 min)
- Device Software Cybersecurity (60 min)
- Software enterprise systems and assignment of recall responsibility (15 min)
- Notification Letters and Press Releases (45 min)
- Product Retrieval Issues, Effectiveness Checks and Status Reports (50 min)
- Termination of a Recall (15 min)
- Recall Follow Up & Voluntary destruction (30 min)
- Retrospective Assessment (15 min)
- FDA Follow Up Planning (60 min)
- FDA's Use of Recall Data (30 min)
- Mock Recall and Wrap-up (35 min)

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.

Casper (Cap) Uldriks,
Former Associate Center Director of FDA's CDRH

Casper (Cap) Uldriks, through his firm “Encore Insight LLC,” brings over 32 years of experience from the FDA. He specialized in the FDA’s medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health. He developed enforcement actions and participated in the implementation of new statutory requirements. His comments are candid, straightforward and of practical value. He understands how FDA thinks, how it operates and where it is headed. Based on his exceptionally broad experience and knowledge, he can synthesize FDA’s domestic and international operational programs, institutional policy and thicket of legal variables into a coherent picture.

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