ComplianceOnline Opens Registration for the Event ‘Navigating the Medical Device Post-Market Maze and Challenges’

"Navigating the Medical Device Post-Market Maze and Challenges during COVID-19 Pandemic" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, April 6, 2021 /EINPresswire.com/ -- ComplianceOnline, the largest GRC advisory network, announced that registration is now open for its 2-day seminar ‘Navigating the Medical Device Post-Market Maze and Challenges during COVID-19 Pandemic.’ The seminar will take place April 29-30 and former FDA CDRH Recall Branch Chief Rita Hoffman is the speaker.

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.

In this seminar, attendees will discover:

•How to overcome one of the biggest
•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.

- 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 attendees stop spinning their wheels with nonessential activities, and leave them 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.

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.

Learning Objectives:

- Understand how to comply with complicated Complaint 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 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

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: April 28-29, 2021 (10:00 AM - 3:00 PM EDT)

Speaker:
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.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

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