Navigating the Maze for Post-Market Compliance -- Complaint Handling, MDRs, Recalls and Proposed Guidance on FDA Risk Benefits: One and a Half-day In-Person Seminar by Ex-FDA Official

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.

New to Course will be creating Standard Operating Systems for Post-Market Quality Systems.

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 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

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