Post-marketing Adverse Event Reporting for Non-prescription Human Drug Products Marketed Without an Approved Application

Description: This webinar is designed to review the guidance documents related to adverse event reporting for OTC drugs. A review of the applicable requirements for adverse events reporting will assist an organization to adhere to the law as well as meet reporting timeframes. Pharmaceutical OTC manufacturers must make a good faith effort to follow-up with consumers on all events reported in order to meet the intent of the law. Knowing regulatory expectations will prevent regulatory action to include Warning Letters and Consent Decrees.

Objectives of the Presentation:

- Overview of Dietary Supplement and Nonprescription Drug Consumer Act of 2006
- Learn the minimum data elements for a Serious Adverse Event Report
- Label submission guidelines are reviewed.
- How to adhere to the reporting timeframes
- Various mechanisms for receiving a report of an adverse event
- FDA expectations for reporting submissions

Why Should you Attend:

Documenting of adverse events has always been part of the record-keeping requirements of the current Good Manufacturing Practice (cGMP) regulations related to complaint files. However, the reporting of adverse events was not required for over-the-counter (OTC) products unless marketed under a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). This requirement changed with the passage of the Dietary Supplement and Nonprescription Drug Consumer Protection Act in 2006. The law mandates that manufacturers, packers and distributors submit reports of serious adverse events received on their OTC product to the FDA. In June 2015, all serious adverse event reports received on OTC drugs must be submitted to the FDA through the FDA's Adverse Events Reporting System (FAERS) in electronic format.

Who can Benefit:

- Quality Assurance Professionals
- Senior Management
- Regulatory Affairs Professionals
- Quality Project Managers
- Auditors
- Pharmacovigilance Professionals

Topic Background:

With the widespread use of OTC drugs, the reporting of these serious adverse events is a crucial step in monitoring their safety. Manufacturers, packers and distributors should develop procedures and programs to ensure that this regulatory obligation is managed competently and efficiently to assist the FDA in its mission to protect public health.

Contents:

Areas Covered:

- Introduction
- Background
- Minimum Data Elements for an Individual Case Safety Report (ICSR)
- Submitting the Label
- Reporting Formats for Paper or Electronic Submissions
- Paperwork Reduction Act of 1995
- Conclusion/Summary
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