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2-Day In-Person Seminar by Ex-FDA Official

FDA Recalls - Before You Start, and After You Finish

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

Location: San Francisco, CA | March 26-27, 2020

SPEAKERS

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.

TOPIC BACKGROUND

The products regulated by the FDA can cause serious adverse health consequences or death. The FDA's recall program is designed to make sure firms' recalls can mitigate such problems, even when the adverse consequence seems remote. The FDA's recall program has remained relatively the same over several years. How the FDA and industry manage recalls and learn from their mistakes continues to evolve. In some ways recalls have become more efficient through the benefit of technology. In other ways the reason for recalls remains substantially the same. The FDA's recall procedures and regulatory management of any risk to health are still sufficient to determine whether a recall is effective and whether manufacturers learn from their mistakes.

LEARNING OBJECTIVES

- Understand FDA's recall authority and policy
- Learn how to manage recalls under FDA oversight
- Learn how to interact with FDA
- See how to develop health risk determinations
- Learn critical recall strategy components
- Manage possible FDA enforcement actions

COURSE DESCRIPTION

FDA's recall authority and program launches you into a project of crisis management. You will learn how to establish a roadmap for conducting recalls. The knowledge you gain will sharpen your recall management decisions and strategy. You will learn how to use the FDA's health risk criteria so you can develop effective recall procedures. One critical aspect of recalls involves the identification of the root cause of the recall and how you could or should prevent that problem from happening again. Your corrective and preventive action program (CAPA) and quality assurance functions require a rigorous approach to prevent a chronic history of recalls. Reiterative recalls lead the FDA to the conclusion that, "You don't get it."

Your compliance competency becomes a regulatory issue for the FDA if your recall is deemed ineffective. The seminar will cover critical performance targets for conducting an effective recall. You will learn how missteps in the recall process become an expensive problem in terms of money and a sloppy corporate image.

You will take away practical knowledge on how to work with FDA staff during a recall, and how you can prepare for inspectional follow up or a regulatory action, and in some cases a legal action. You will learn that your approach to recalls plays a major role in mitigating direct and indirect damage to your firm's business. A firm with a history of chronic recalls needs to learn how to get out of that downward spiral. Likewise, for established and new firms you will learn how you can reduce the negative impact of a recall with the use of proper planning.

AGENDA

Day One (8:30 AM - 4:30 PM)

08.30 AM - 09.00 AM: Registration

09.00 AM: Session Start

Day 1 - Morning

FDA's Regulatory Authority

- Recall Regulations
  - Voluntary recall: 21 Code of Federal Regulations (C.F.R.) Part 7
  - Mandatory recall actions
    - 21 C.F.R. Part 810
    - 21 C.F.R. Part 806
- Recall Classification
  - Violation of the law

Break (10:30 AM – 10:45 AM)

- Risk to Health
- Precedents
- Exemptions
  - Stock Recovery
  - Product Withdrawal
  - Product Improvement

Lunch (12:00 PM to 1:00 PM)

Day 1 / Afternoon

Recalls and risk to health

- Risk to health categories
  - Death
  - Serious injury / serious illness
  - Non-reversible / reversible
  - May cause, if it were to recur
  - Remote possibility

Break (2:30 PM – 2:45 PM)

- Health Hazard Evaluation for Recall Classification
  - FDA's internal evaluation
  - Vulnerable subpopulations
  - Scoring
  - Participants
  - Industry HHE equivalent
  - FDA's recall database

Day Two (8:30 AM - 4:30 PM)

Day 2 - Morning

FDA's Recall Procedures

- Understanding FDA's program and implementation
- FDA's agency-wide recall procedures
- The FDA's investigator's job
- Preparing a recall strategy

Break (10:30 AM – 10:45 AM)

- Preparing for FDA oversight
- Recall notification to FDA's District Office
- Recall notification to the public

Lunch (12:00 PM to 1:00 PM)

Day 2 / Afternoon

- Root cause identification
- Correction and Prevent Action (CAPA)

Break (2:30 PM – 2:45 PM)

- FDA inspectional follow up
- Enforcement: FDA administrative and legal remedies
- End

WHO WILL BENEFIT

- Recall managers
- Quality assurance managers
- Regulatory affairs directors
- Risk and product liability managers
- Manufacturers' sales and marketing managers
- Own label distributors

Companies and departments:

- Manufacturers
- Own Label Distributors
- Importers
- Healthcare institutions
- Nursing homes
- Medical practice groups

Registration Form

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Seminar Topic: FDA Recalls - Before You Start, and After You Finish

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