FDA Recalls – Before You Start, and After You Finish

2 Day Virtual Seminar

OVERVIEW

This course will teach 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."

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

WHO WILL BENEFIT

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

KNOW YOUR FACULTY

Kelly Thomas, Vice President at America's Quality Operations, has 20 years of hands-on experience in the industry. She has worked with reputed facilities like FDA, EMEA, IMB, JP, and Health Canada. Her core expertise includes computer system validation, equipment process validation, and facilities validation.

FDA Recalls – Before You Start, and After You Finish

2 Day Virtual Seminar

TRAINING AGENDA DAY 01

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

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

Health Hazard Evaluation for Recall Classification

- FDA's internal evaluation
- Vulnerable subpopulations
- Scoring
- Participants

TRAINING AGENDA DAY 02

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
- Preparing for FDA oversight
- Recall notification to FDA's District Office
- Recall notification to the public
- Root cause identification
- Correction and Prevent Action (CAPA)

FDA inspectional follow up

Enforcement: FDA administrative and legal remedies

End

REGISTRATION FORM

Name _____ **Email** _____

Organization _____ **Department** _____ **Position** _____

Phone _____ **Mobile** _____

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.