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Webinar on

FDA Adverse Event Reporting

Date : 17 May 2019

Areas Covered

- *GMP requirements for complaint documentation and management*
- *GMP standards for an effective recall system*
- *To identify the key issues in product complaint and recall handling*
- *To understand the specific requirements for organization, procedures, and resources*

- *How the FDA responds to adverse event reports and the regulatory consequences for not reporting*
- *Best practices related to documentation, management, and regulatory reporting*
- *To understand and develop actions to resolve current issues applicable to you*

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In this webinar, you gain a clear understanding of what FDA inspectors look for when evaluating complaint handling and medical device reporting programs.

PRESENTED BY:

Upon earning a degree in Zoology at North Carolina State University, Joy made her debut in the pharmaceutical industry in 1992 at Pharmacia & Up John performing Environmental Monitoring and Sterility Testing. Her hard work allowed her to move into a supervisory role at Abbott Laboratories where she oversaw their Quality Control Lab. In 1998 Joy moved to Wyeth Lederle and worked in Quality Assurance, performing GMP Compliance audits, batch record reviews, and holding annual GMP training for new employees.

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Date : 17 May 2019

Time : 01 : 00 PM EST

Duration : 90 Minutes

Price: $229

Webinar Description

This training program will provide the regulatory requirements for complaint handling in the pharmaceutical & medical device industries. The course will touch on complaint sources and details will be furnished on the interrelationships regarding complaint handling and product recalls. The course will also include timeline requirements associated with adverse event reporting.

Who Should Attend ?

Regulatory compliance professionals

Quality assurance professionals

Quality control professionals

Regulatory affairs professionals

Complaint handling professionals

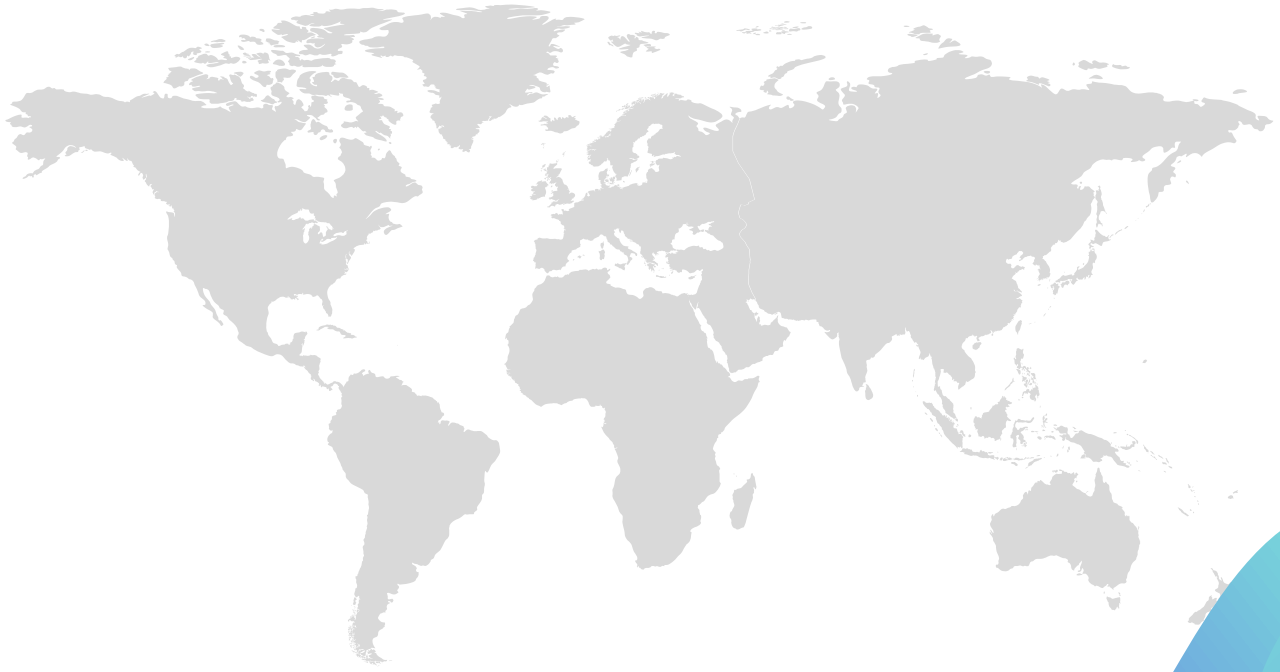
Quality engineers, Production personnel

Service technicians and engineers

Manufacturing and design engineers

Process development personnel

Senior management, Quality assurance/control



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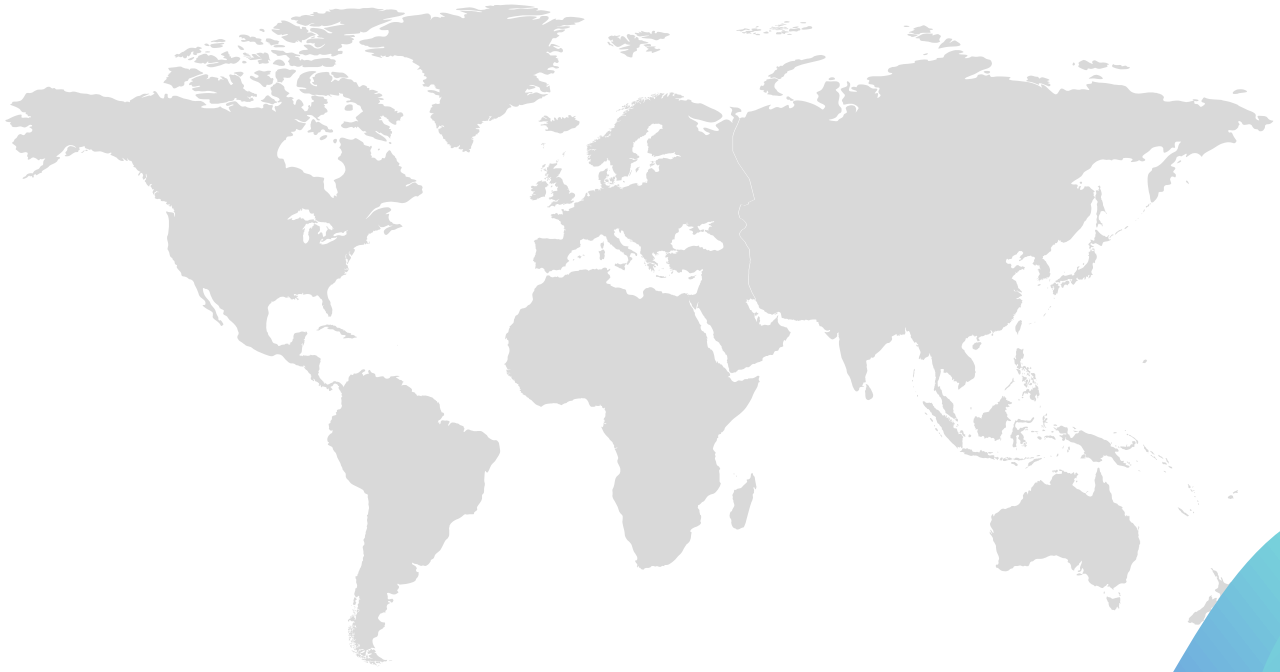
Why Should Attend ?

This webinar will describe the key elements and requirements for a compliant system and a system for conducting recalls. Anyone in the pharma or FDA regulated industries must attend. You will learn how to electronically submit and manage your adverse event reports which should be integrated with a complaints management system. This will assist you to centrally manage and control your adverse event reporting. In this webinar, you gain a clear understanding of what FDA inspectors look for when evaluating complaint handling and medical device reporting programs.



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