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Webinar on

Complaint Handling And Adverse Event Reporting, CAPA, Recalls, And Product Life Cycle Management

Areas Covered

- *Complaint Definition*
- *Medical Device and Drug Complaint Handling Requirements (US)*
- *The interrelationship of Complaint Handling, CAPA, Change Control, Adverse Event Reporting, and Recalls*
- *Reportable Events*
- *When Does a Complaint Become a Reportable Adverse Event*

- *How Does User Error Relate to Adverse Event Reporting*
- *Voluntary and Mandatory Reports, and Reporting Timelines*
- *Complaint Handling Life-Cycle Process*
- *Recall Classifications*
- *Challenges*

This webinar we will touch upon reportable events and why it is important to be able to identify them both in terms of definition and when they manifest as reportable.

PRESENTED BY:

Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Currently, Danielle assists companies who are faced with warning letters, consent decrees and those wishing to improve compliance establish more robust quality systems so that the company can succeed.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Complaint handling is essentially the beginning of the process if not one crucial aspect of the process of collecting data concerning the product that is in the marketplace. It is your first “tip-off” that something might not be going as intended. Complaints are ignored at your peril and ignoring them results in a significant risk to the organization and to the patients that use your products.

Complaint handling is only the start of a critical process to collect critical product information from the marketplace for either medical devices or drugs that ultimately ensure the safety of our patients, and assures the efficacy, purity, and safety of our drugs, and the effectiveness, reliability, and safety of our medical devices.

Who Should Attend ?

Compliance

Engineering

Marketing

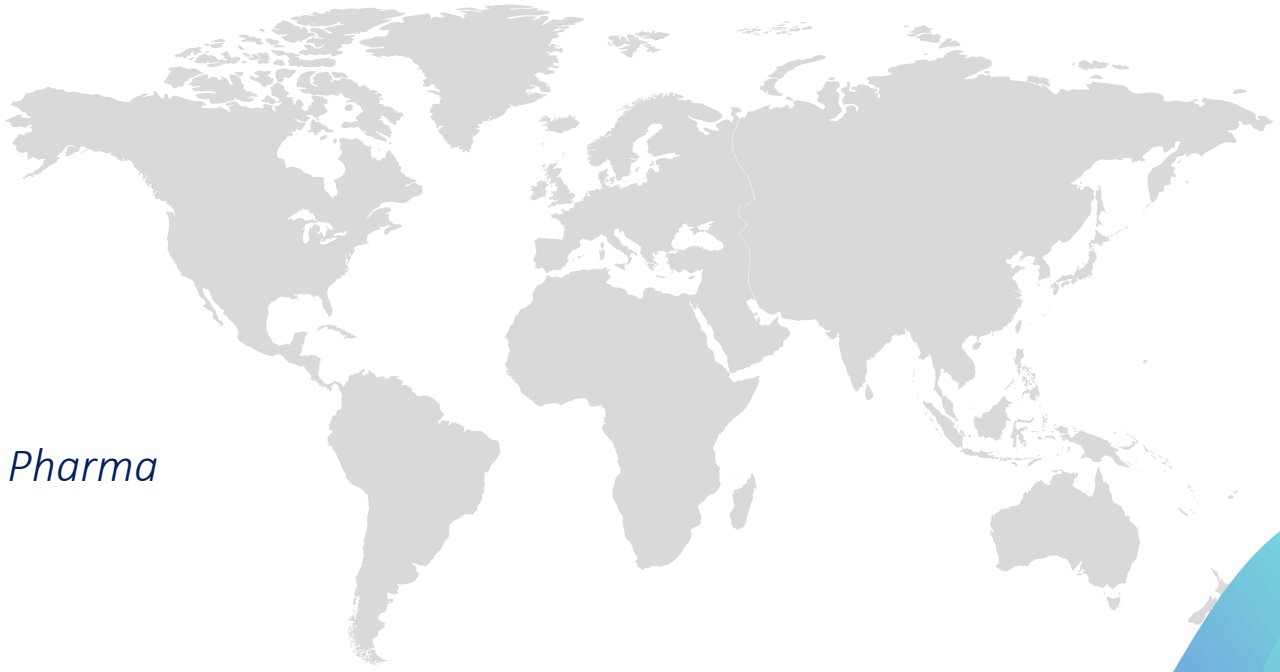
Regulatory documentation

Research & development professionals in the Pharma

Biologics, and Medical Devices

Directors

Managers and associates



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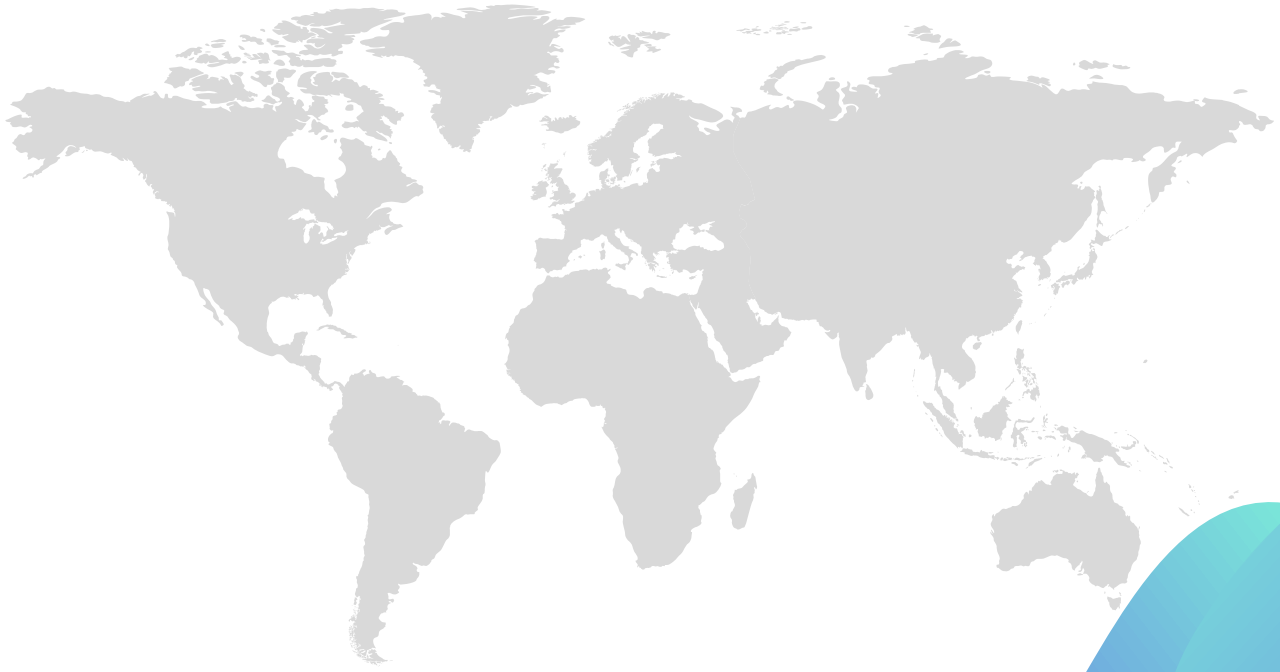
Why Should Attend ?

Clearly, complaint handling is one link on the postmarket surveillance chain. There is a clear interrelationship between complaint handling, CAPA, change control, adverse event reporting and recalls. Because this interrelationship covers the entire subject we will touch upon those throughout the webinar. We will touch upon reportable events and why it is important to be able to identify them both in terms of definition and when they manifest as reportable. We will look at the complaint handling life-cycle and we will complete the webinar by reviewing the recall process and its classifications and discussing the specific challenges that face manufacturers today relative to this subject.



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