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Webinar on

Laboratory Investigation Of Out-Of-Specification (OOS) Results

Learning Objectives

The objective of this webinar is to develop an understanding of how a compliant laboratory handles the investigation of out-of-specification (OOS) test results and how the laboratory interfaces with other units through the laboratory investigation process. The discussion will be based on the FDA guidance on handling OOS laboratory results.

This live webinar training will provide a clear process for compliant laboratory OOS investigations.

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PRESENTED BY:

John G. (Jerry) Lanese is an independent consultant with a focus on Quality Systems and the components of an effective Quality System. He has managed Analytical Research, Quality Control and Quality Assurance functions in several pharmaceutical firms.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Inadequate investigation of out-of-specification (OOS) results in the laboratory is a common observation cited in FDA 483s and Warning Letters. It is clear that regulatory investigators throughout the world are looking at laboratory operations very closely. Specifically, there is a concern as to whether the laboratory and the company apply good science to the investigation of laboratory test results that are out-of-specification or outside of statistically expected ranges.

The FDA is inspecting laboratory operations very closely, with an emphasis on how the laboratory investigates Out-of-specification and out-of-tolerance observation investigations. All Laboratory and Quality Assurance management, analysts and reviewers should be aware of the FDA expectations for procedures that define a complete, scientifically sound investigation of each out-of-specification and out-of-trend laboratory observation and evidence that laboratory personnel are following the procedures. This training will build the foundation for the implementation of adequate procedures and provide a review of existing procedures and practices.

Who Should Attend ?

Laboratory managers

Laboratory supervisors

Laboratory analysts

Quality Assurance managers

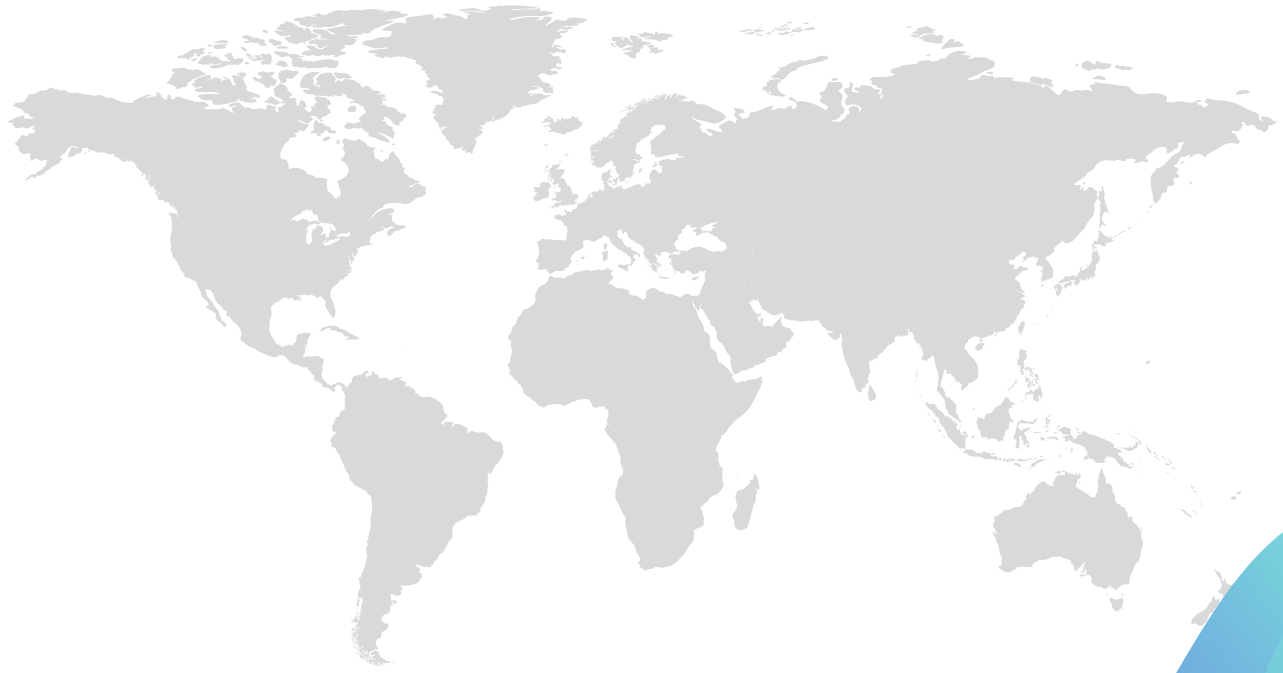
Quality Assurance record reviewers

Branded pharmaceutical companies

Generic pharmaceutical companies

OTC pharmaceutical companies

Contract laboratories



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