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Webinar on

Step By Step Process For Successful Sterility Failure Investigations

Learning Objectives

- *FDA Regulations and Guidance on Sterility Failure Investigations*
- *Stages of Investigation: Lab Investigation vs. Manufacturing Investigation*
- *Tools to use to help determine Root Cause*
- *How to categorize sterility results*
- *How to address the impact to lots affected*
- *Areas, parameters and variables to investigate as part of the investigation*
- *Proper documentation of the Investigation*
- *CAPA plans that address root cause*

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This webinar will review when it is appropriate to investigate a result that may seem "out of the ordinary."

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. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management Roles.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

There are many different types of microbial contamination that can occur in pharmaceutical manufacturing. Some of the sources include water, raw materials, excipients, in-process materials and samples, the manufacturing process, the product itself, the environment and the like. As such, there is no one size fits all investigation.

Microbiological testing covers a wide range of products, processes, and environments, therefore representative samples from each of these categories form the basis of what gets investigated. The role of QC Microbiology in the identification and investigation of various results from manufacturing areas and finished product testing is extremely important.

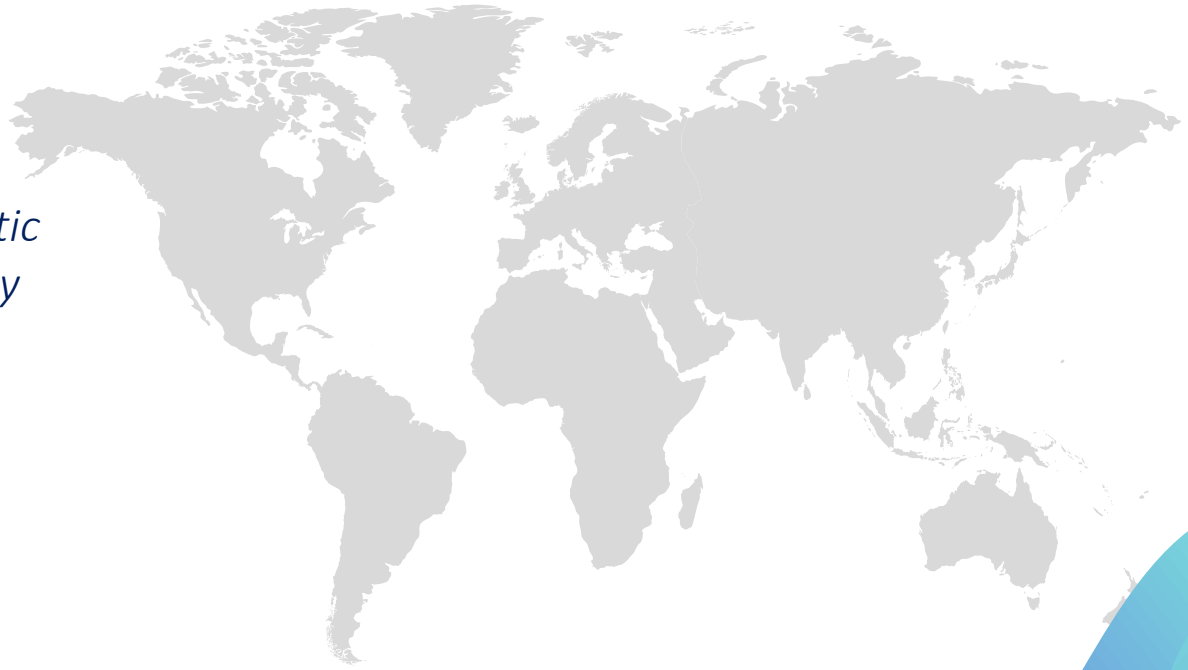
When the need for an investigation arises, it is common for a cross-functional team to convene involving all levels of management from various departments:

Quality Control Chemistry & Microbiology
Manufacturing
Quality Assurance
Facilities & Engineering

One of the important elements of the investigation is to decide which failing result comes from the appropriate category: product, process or environment. Once you determine where the failure has occurred, the investigation begins into finding out why it failed and how to correct it.

This course will describe the actions that should be taken when a sterility test failure occurs. What happens when a suspect microbial result is reported? What does it look like, and how should you react? This webinar will review when it is appropriate to investigate a result that may seem “out of the ordinary.”

Who Should Attend ?



This course will be of benefit to anyone working in a GMP regulated environment on the global or domestic scale that is responsible for – or affected by – Sterility control and deviations. This includes the following personnel:

QA and Manufacturing staff and management
QC Lab personnel
Microbiologists

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