

Webinar on

Proper Root Cause Analysis

Learning Objectives

- Know what to do when problems occur*
- Define, validate and decide if the problem should be solved*
- Use a team approach and understand team dynamics*
- Take appropriate interim actions*
- Choose the most appropriate RCA methods for the situation*
- Determine and implement the best sustainable solution*



This Webinar involves data collection; cause charting, root cause identification and recommendation generation and implementation.

PRESENTED BY:

Danielle DeLucy, MS, is currently an independent consultant to the biologics and pharmaceutical industries specializing in the areas of quality assurance and quality systems. Prior to this role, Ms. DeLucy has been in the industry for 15 years serving in numerous quality management roles, such as the director of product quality, the oversight of sterility assurance practices and provided QA oversight of numerous filling and packaging operations.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

In many companies, deviation/non-conformance investigations are often criticized for the lack of a robust root cause analysis. The proper root cause can help a company in many ways. Root cause analysis helps identify what, how and why something happened, thus preventing recurrence. Root causes are underlying, are reasonably identifiable, can be controlled by management and allow for the generation of recommendations. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.



Who Should Attend ?

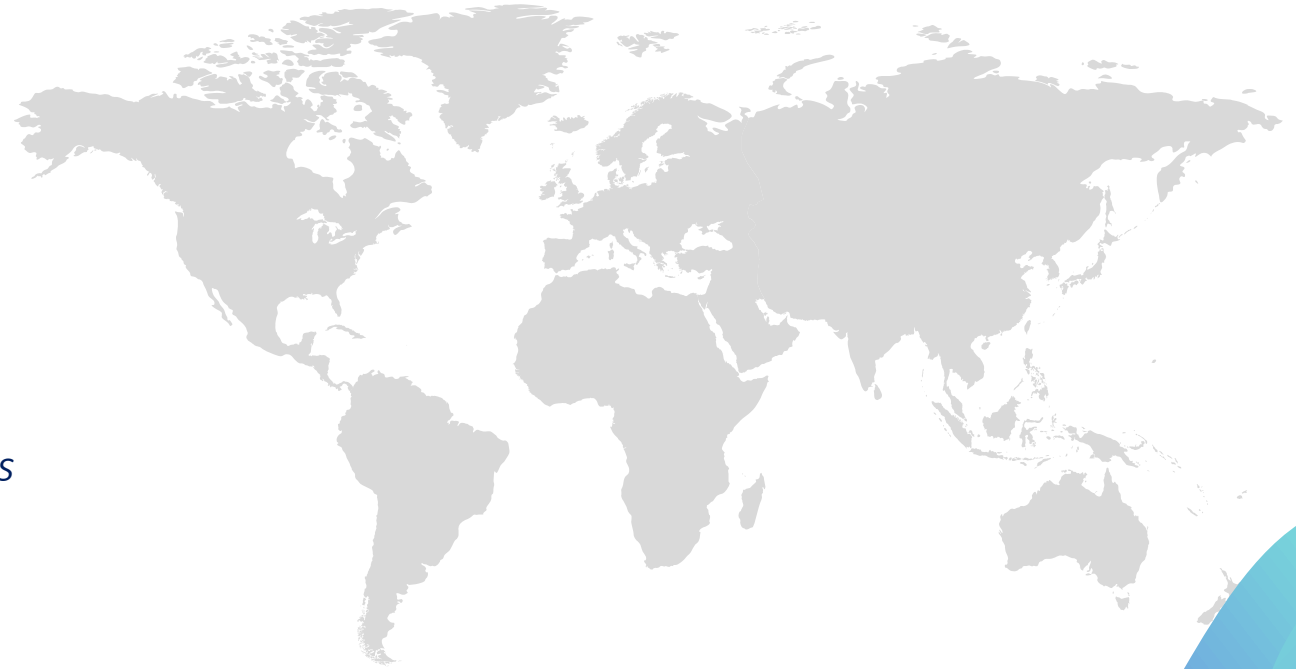
Site Quality Operations Managers

Quality Assurance personnel

Plant Managers and Supervisors

Manufacturing Superintendents and Managers

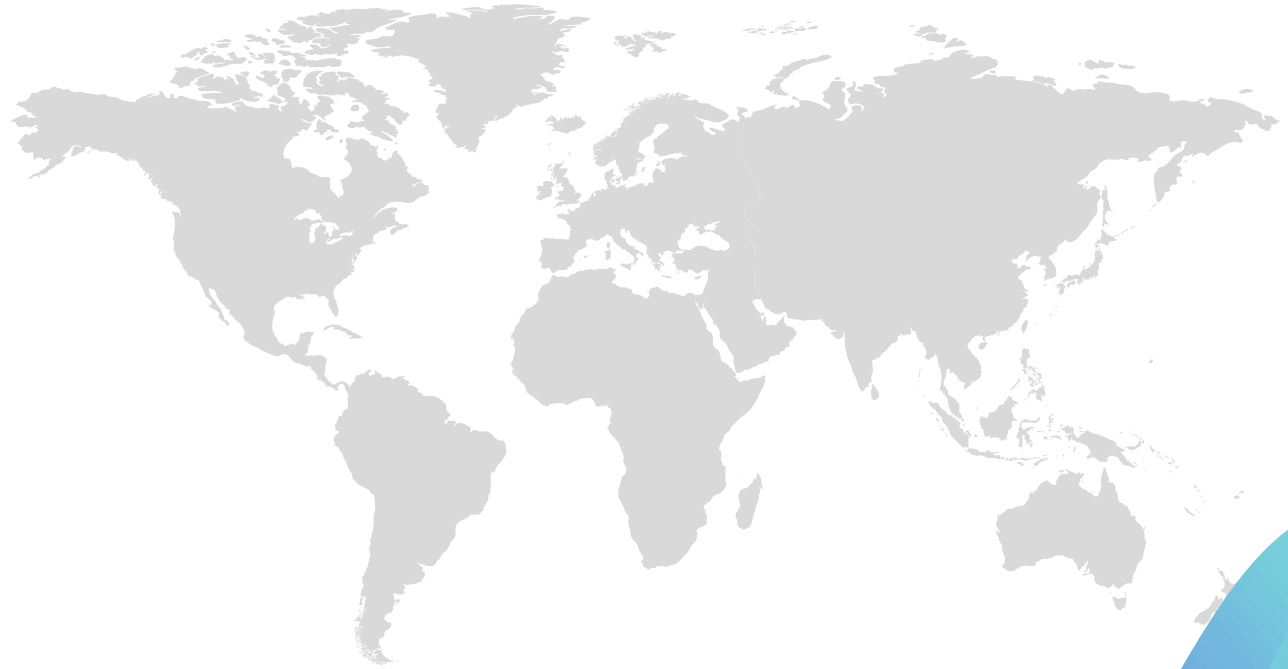
Regulatory Affairs Managers



Why Should Attend ?

If you have reoccurring problems showing up in your quality systems, your Quality system is not effective and you have not performed an in-depth root cause analysis to be able to detect through proper problem-solving tools and quality data sources, the true root cause of your problem. Unless you can get to the true root cause of a failure, nonconformity, defect or other undesirable situation, your Quality System will not be successful.

Historically, 483s in the pharmaceutical industry related to CAPAs, are due to lack of inadequate root cause investigations, among other factors.



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