

Webinar on

Developing an Effective CAPA Management and Root Cause Analysis System

Learning Objectives

- Discuss what to do when problems occur*
- Outline the requirements of the CAPA process and procedure including building a CAPA file*
- Choose the most appropriate Root Cause Analysis methods for the situation*
- Establishing a CAPA plan: project summary, individual responsibilities, and expected completion dates*
- Management and Oversight of the CAPA system and its documentation*



Areas Covered

Definition of a CAPA

- o When a CAPA is needed*
- o Development of the essential pieces of a robust CAPA plan*

Root Cause Analysis Methods

- o Discussion of different Root Cause Analysis methods and benefits of each*

Establishment of the CAPA Plan

- o Project Summary development*
- o Responsibilities of individuals involved*
- o Establishing Completion Dates*
- o Creating meaningful effectiveness checks*





Management of the CAPA System

- o Maintaining proper documentation of the CAPA plans*
- o Ensuring CAPA plans are progressing*
- o Proper closeout of CAPA plans*

This webinar will include discussions proper CAPA system maintenance, root cause analysis, documentation of the Corrective and Preventative Actions and developing a robust CAPA plan. It will give tips on how to develop CAPAs pertaining to longer-term projects and ensure they stay on track.

PRESENTED BY:

Danielle DeLucy, MS, is the 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, 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 order to solve problems, every organization must know how to conduct an effective investigation, identify root causes, and implement workable corrective action in a timely manner. An effective CAPA process requires training internal investigators, who can also coach others in the organization, to employ critical thinking. The process must provide a common model and language within the organization, which allows investigators to master the process quickly and easily.



Who Should Attend ?

Quality Control Personnel & Management

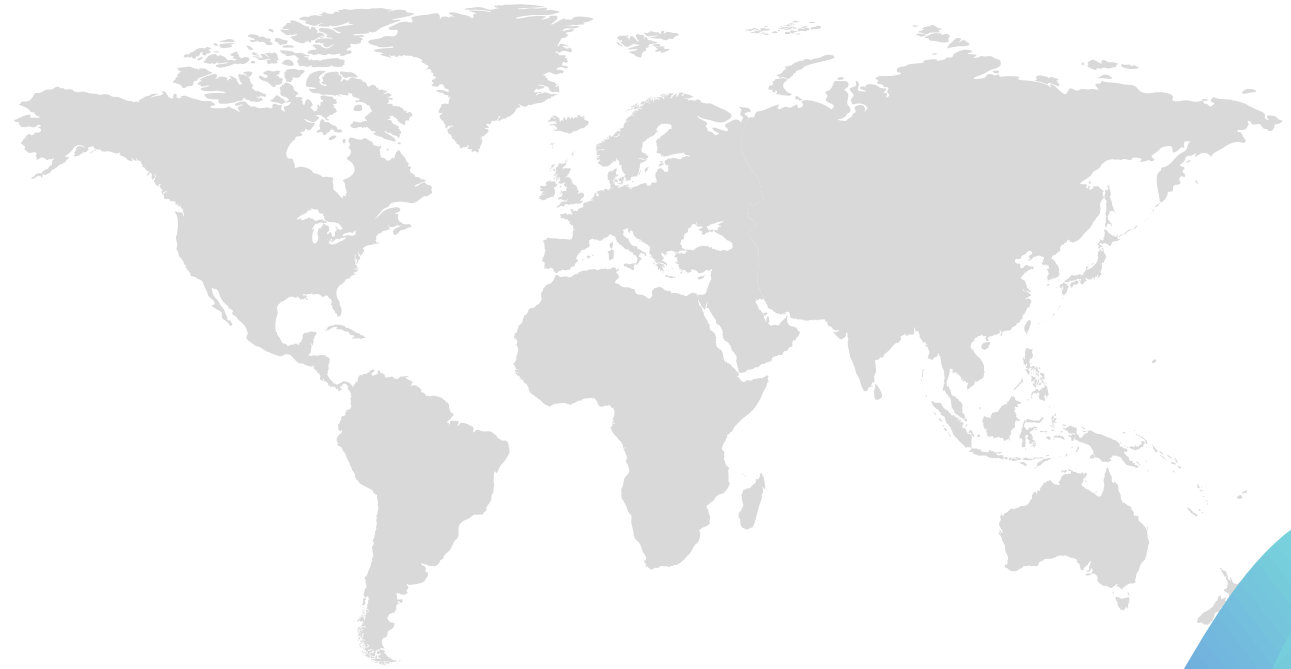
Manufacturing Personnel & Management

Senior Management

Regulatory Affairs Personnel & Management

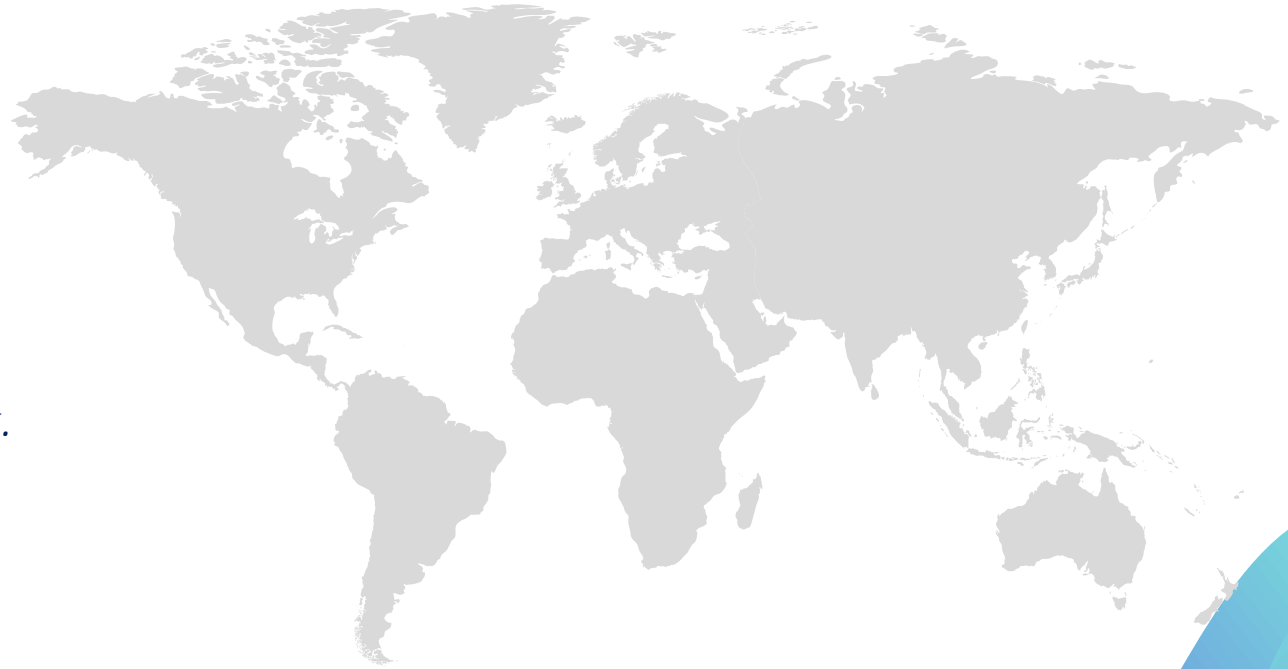
Quality Assurance Personnel & Management

Supplier Quality Personnel & Management



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