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Webinar on

CAPA, Failure Investigation and Root Cause Analysis to Meet FDA Expectations

Learning Objectives

- *Identify why human error is often designated as the root cause of deviations and discrepancies*
- *Identify why your CAPA's are less effective than you hoped*
- *Understand why human error is not the real cause of the deficiencies and deviations*
- *How to probe further to identify the causes or contributing factors that really cause the problems you are seeing*
- *How to develop a true CAPA for these problems*

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This live interactive presentation will also discuss the regulations associated with the detection, correction, and prevention of human errors in GMP manufacturing and laboratory processes.

PRESENTED BY:

Angela Bazigos is the CEO of Touchstone Technologies Inc. She has 40 years of experience in the Life Sciences & Healthcare Industries. Experience combines Quality Assurance, Regulatory Compliance, Information Technology, Project Management, Clinical Lab Science, Microbiology, Food Safety and Turnarounds. Past employers / clients include Roche, Novartis, Genentech & PriceWaterhouseCoopers, Public Health Service

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

Analysis of investigation reports reveals that human error is one of the top root causes for deviations, discrepancies and quality incidents in pharmaceutical manufacturing. And when you examine the CAPA's that are developed from these, retraining and rewrite of SOP is top the list. Yet on further re-examination, you find that these problems keep resurfacing again and again. Put in another way, the CAPA's are ineffective. Does it mean that the CAPA's were wrong or is it pointing to another problem? Namely, that the investigation did not pinpoint the root cause of our most probable contributing factors to the problem. Most often "human error" is not really the problem but a symptom of a system or facility or operation that is not designed to be run by humans. Humans do contribute to problems but more often than not, because what we are asking them to do is not designed with humans in mind. So a true CAPA should be developed to solve the problems with the system, facility, and operation rather than focus on remediation of people. This requires investigations to focus on getting to the real root cause and contributing factors.

Who Should Attend ?

Quality Assurance Personnel

Quality Control Personnel

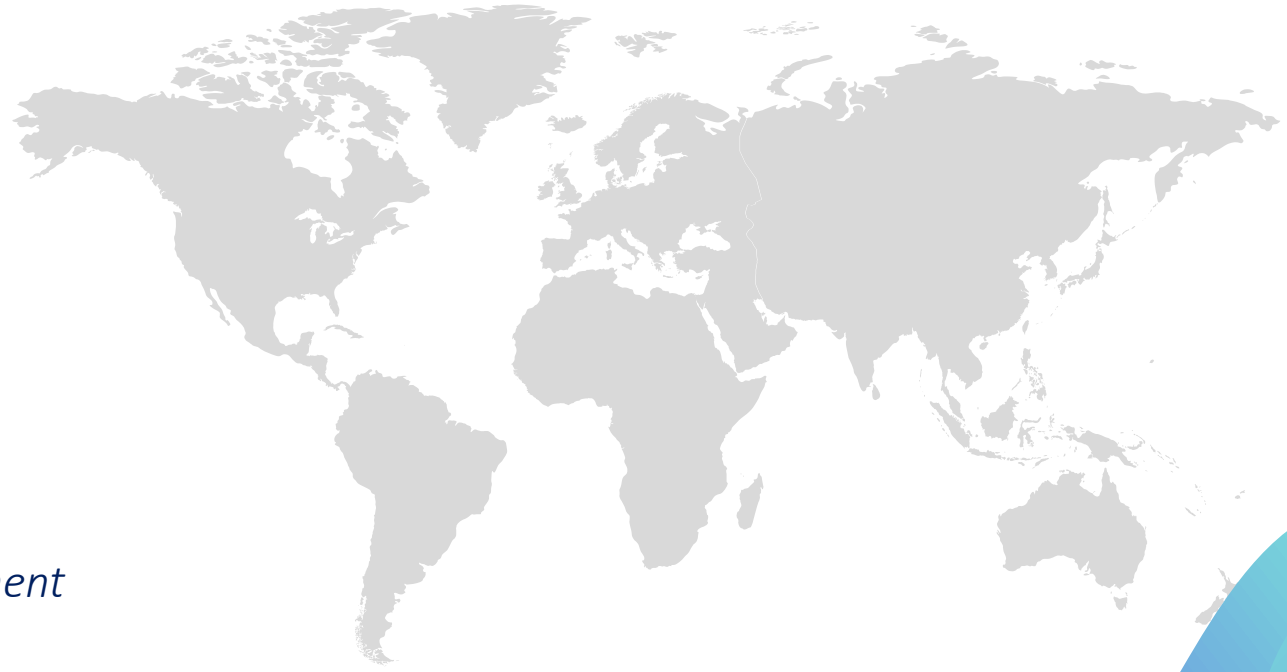
Supply Chain and Logistics Managers

Regulatory Affairs Professionals

Process Development Scientists and Management

Manufacturing Management and Scientists

Project Managers working in the CMC arena



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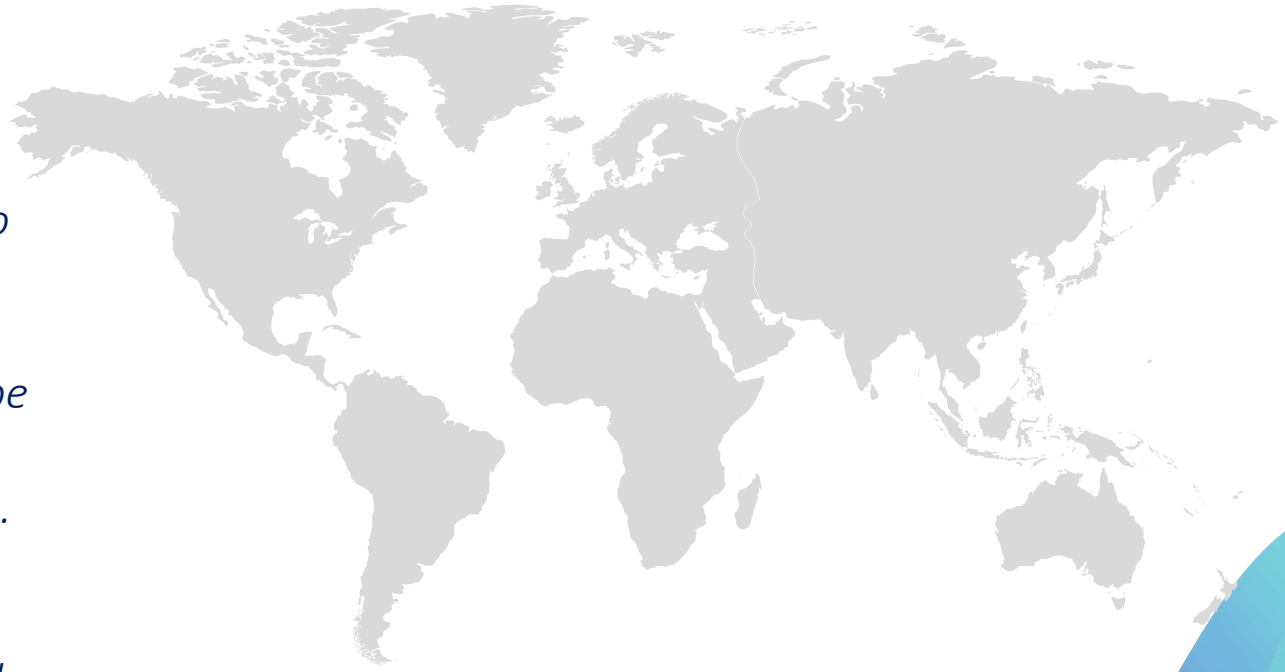
Why Should Attend ?

We are often quick to ascribe fault to people rather than our systems, facilities, and operations. However, in this class, we will learn how to tell if you are too quick to ascribe guilt to people rather than probe deeper. We will focus on improved techniques to get to the real cause of the problem. With this information, you will be able to develop meaningful CAPAs that have a chance to remedy these problems, the first time. We will focus on how to assess the success of these CAPA's. This will lead to a significant reduction of repeat observations which will lead to improved efficiency and right-first-time operations. This live interactive presentation will also discuss the regulations associated with the detection, correction, and prevention of human errors in GMP manufacturing and laboratory processes.



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