

Webinar on

Deviation Management – Investigations to Root Cause Analysis

• Areas Covered

○ Investigation Steps

- Interviewing
- Record Review
- Product/Material inspection
- Equipment / Facility Inspection
- Operation Observation
- Simulations

○ Root Cause Analysis Tools

- Brainstorm
- Cause and Effect Diagrams
- 5 Whys
- Comparison

○ Corrective Action Tools

- Nominal Voting
- Matrix Analysis
- Affinity Diagram

○ Implementation

This presentation describes the tools and techniques for performing good investigations, identifying true root causes, and implementing corrective actions.

PRESENTED BY:

David W. Husman - Over 30 years of diverse international industry experience in Quality Assurance, Quality Control, and Regulatory Affairs. Last 19 years as a consultant to biopharma, pharma, and device industries. Ph.D. in Biochemistry, Certified as a GMP expert and in Regulatory Affairs. Expert level in Compliance and Quality System development

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

The fundamental failure identified by regulators evolves from companies not knowing how to conduct investigations, how to identify the root cause, and how to select actions to correct the problems such that they never recur. The key to performing effective investigations is the timely gathering of all the facts necessary to understand what happened, and more importantly, what is wrong before we can begin to understand how we are going to fix it such that it never happens again. Having a good toolbox, however, doesn't help if you don't know how to use the tools or when one tool is more appropriate than another. There are reasons for gathering facts in a particular order, documenting what is and is not working along the pathway, and ensuring you have enough information before you start trying to determine causes. Once you have the data, it is important to evaluate it, consider multiple opinions, confirm the opinions are supported by the facts you have collected, and then decide what are the facts telling you. If more than one cause is identified, which one or ones are you going to attempt to eliminate. But just identifying the cause is not the end of the process. Our job is to eliminate the



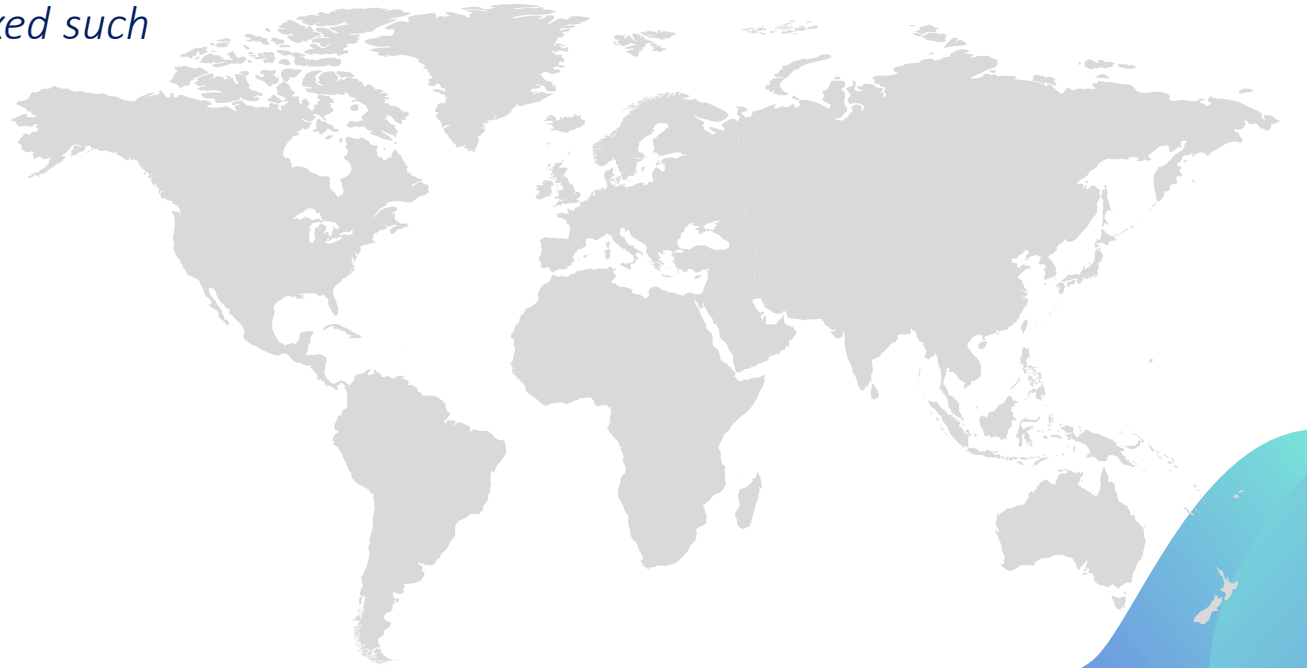
problem and make sure it never happens again. We must consider both short-term and long-term solutions when deciding how to correct a problem. Once everything is done, we also need to ensure our documentation reflects a thorough, complete, and comprehensive discussion of what was done, how we did it, and how we assured ourselves the problem will not recur. This presentation provides suggested tools and process steps for performing effective investigations, root cause analysis, and identifying and implementing corrective actions.

Basic understanding of regulations related to Deviation Management



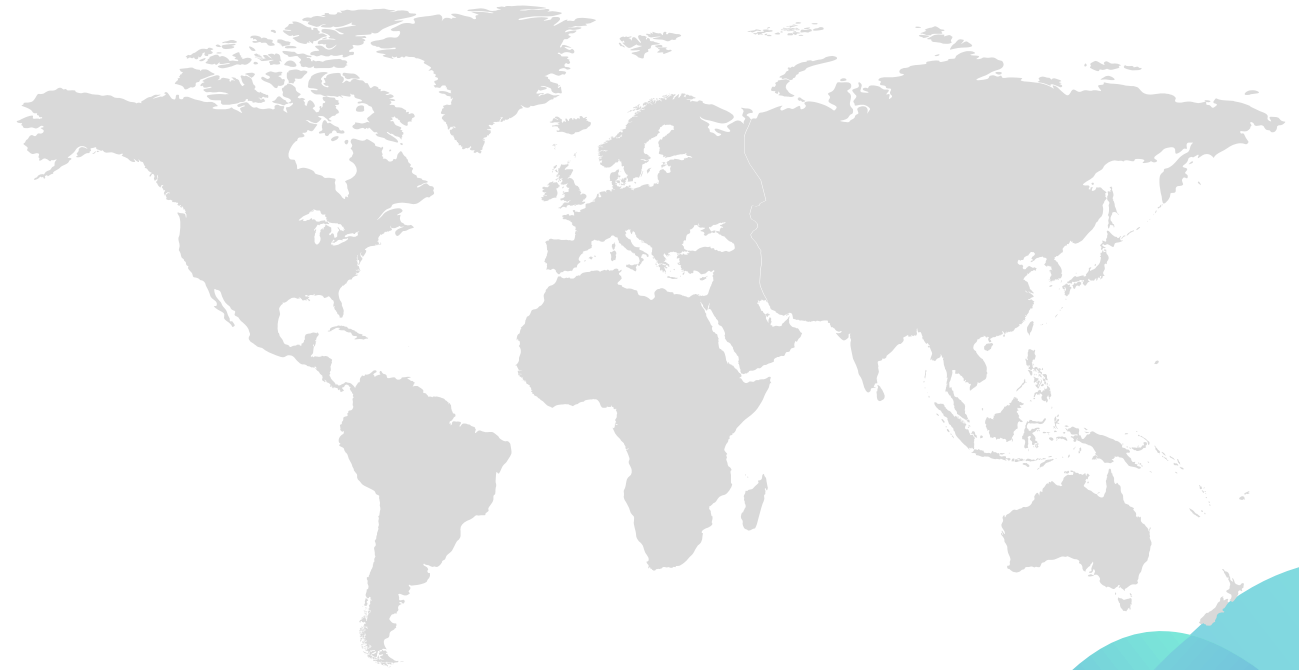
Who Should Attend

All members of the regulated industry involved in managing deviations and ensuring problems are fixed such that they do not recur.



Why Should You Attend ?

Failures in investigations and root cause analysis have been in the top five of compliance observations for over thirty years. Fundamental in these observations is that companies have failed to uncover the true root cause of problems encountered, too often settling on symptoms, such as human error. The net result is that problems continue to recur, products are released to the field with one or more issues, and patients are put at risk. Additionally, businesses are adversely impacted due to responding to warning letters, managing complaints and product recalls. Although there are numerous seminars available, most focus on root cause investigations – investigating to get to the root cause. More often than not, this approach does nothing more than reinforcing preexisting opinions on what we think is going on, rather than gathering facts of what specifically happened in this instance. This presentation describes the tools and techniques for performing good investigations, identifying true root causes, and implementing corrective actions.



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