

To Facilitate a Closed-Loop Problem Resolution System

Date : Jan 17, 2018 - 10:00 AM

Event URL : <http://www.BostonEventsList.com/events/to-facilitate-a-closed-loop-problem-resolution-system-jan-2018>

Organizer : Netzealous LLC DBA - Compliance4All

Venue : online

Location : 161 Mission Falls Lane, Suite 216,,
Fremont, California, United States, ZIP: 94539
Phone: 8004479407

Ticket Price: One Dial-in One Attendee Price: \$150.00

Overview:

Defined Failure Investigation and Root Cause Analysis is a major tool in product complaint, non-conformance, and OOS failure investigations.

Why should you Attend:

Expectations for meaningful CAPA, supported by results-driven Failure Investigation and Root Cause Analysis, that addresses and resolves underlying product problems, are growing among regulatory agencies world-wide.

Areas Covered in the Session:

Regulatory "Hot Buttons"

The 4 Basic Steps to Problem Solving

A Suggested Investigation Template

ID / Document the Problem - CAPA, et al

Who Will Benefit:

Senior management in Drugs, Devices, Biologics, Dietary Supplements

QA

RA

R&D

Engineering

Production
Operations

Speaker Profile:

John E. Lincoln is a medical device and regulatory affairs consultant. He has helped companies to implement or modify their GMP systems and procedures, product risk management, U.S. FDA responses. In addition, he has successfully designed, written and run all types of process, equipment and software qualifications/validations, which have passed FDA audit or submission scrutiny, and described in peer-reviewed technical articles, and workshops, world wide.

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Event Categories :