Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Root Cause Analysis: Foundation of Investigations and CAPA

Philadelphia

May 16th & 17th, 2018

9:00 AM to 5:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

Register for 10 attendees

Price: **$7,122.00** You Save: $5,828.0 (45%)*

~~$12,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

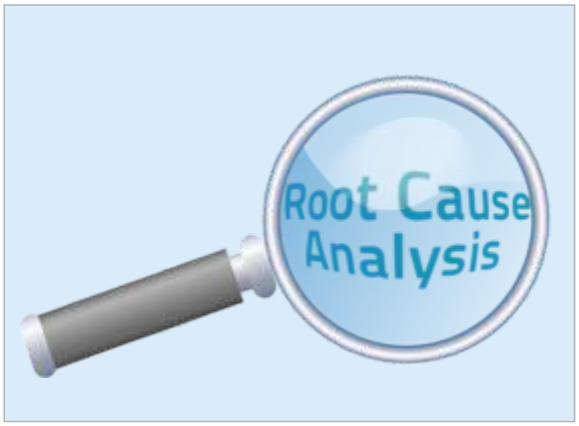
David R. Dills

Global Regulatory Affairs & Compliance Consultant and President, NovaQual

David R. Dills, Global Regulatory Affairs & Compliance Consultant, Interim President, currently provides global regulatory affairs, compliance and quality consultative services for early-stage and established Class I/II/III medical device, including combination products, In Vitro Diagnostics, nutraceuticals/supplements, cosmetics and biopharmaceutical manufacturers in multiple medical specialties and therapeutic areas on the global landscape, and has an accomplished record with more than 26 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by medical device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities and services involving consent decrees, CIA's, warning letters,483 observations, and customer generated compliance events, and prepares for and conducts QS and regulatoryaudits. He is currently acting and interim President at NovaQual LLC.

He has been directly involved with constructing, reviewing, and/ or remediating regulatory submissions, including 510(k), PMA, IDE applications, IND, BLA and NDA submissions, preparing responses to AI's/deficiency letters, Supplements, Amendments, acting U.S. Agent, works closely with the key stakeholders and Agency/Center Reviewers regarding submission meetings and negotiations; clinical affairs and study submissions; and provides regulatory submissions and post-market project leadership and guidance covering different therapeutic and medical specialties based on classification.

Mr. Dills has astrong background in the interpretation and applicabilityofFDA regulations,including 21 CFR 210/211, 820 QSR/cGMP, Quality System implementation and compliance requirements, GxP training, leads and directs activitiesfor the registration and approval process andworking with Agencies in Asia Pacific, EU and The Americas, including but not limited to FDA



Agenda:

Day One

Lecture 1: Regulatory Expectations for Investigations

- Background and History
- FDA Regulations and Regulatory and Compliance Aspects
- Regulatory Expectations for Investigations
- FDA (21 CFR and Guidance Documents)
- EU references
- ICH
- FDA 483s and Warning Letters
- CAPA and RCA: root cause investigations follow steps such as identify the problem; evaluate its magnitude, which includes assessing risk; investigate and assign responsibility; and analyze and document the root cause of the problem.

Lecture 2: What is RCA and Typical Problems

- Why most problem-solving models don't get to the root cause, and a solution
- How analytical and creative thinking must be both separated and integrated
- Difference between content and process thinking

Lecture 3: Investigation Process Overview

- Purpose, basics and sources (types and categories) of investigations\
- Elements of a thorough investigation process (Discovery through
- Closeout)
- Classification levels
- Investigation planning, action items and documentation
- Company culture

Lecture 4: Skills and Tools of an Effective Investigator

- Characteristics and techniques
- Reading and documentation practices
- Technical writing

Day One

Lecture 5: (Re) Introduction to Root Cause Analysis (RCA)

- Principles of root cause analysis
- Why root cause analysis is difficult
- Methodology of root cause analysis

STEP 1 - Problem Definition

- How to ensure that the right problem is being worked on
- Tools and filters for priority setting
- Developing a clear and sufficient problem statement (includes practice)

STEP 2 - Understanding the Process

- How every problem is a process failure
- How diagrams can set boundaries and define interrelationships
- Using flowcharts to drill down into the right part of the process (includes practice)

STEP 3 - Identifying Possible Causes

- Multiple ways to identify possible causes
- Options for selecting or eliminating causes
- Logic trees as a cause and effect diagram and other tools for investigations

Lecture 6: Defining the Deviation

- The problem statement
- Active listening and interviewing
- Process mapping
- Brainstorming tools
- "Is/Is Not" technique

FDA Enforcement Actions and Industry Trends

Agenda:

Day Two

Lecture 1: Identifying Root Cause

- 5 Whys
- Relations Diagram
- Ishikawa diagrams (Fishbone)
- Fault Tree Analysis vs. Failure Modes and Effects Analyses (FMEA)
- Challenges

STEP 4 - Data Collection

- Population versus sampling; options for sampling
- Check sheets, graphs, and tables for discrete data collection
- Surveys, interviews, and field observation for opinions or less precise data

STEP 5 - Data Analysis

- Tools for discrete data analysis (run charts, histograms, pareto diagram, modified scatter diagram, pivot tables)
- Tools for softer type data (affinity diagram, relationship digraph)
- Integrative data analysis tools

Lecture 2: Corrective and Preventive Actions (CAPA)

- What is the CAPA System
- Definition and regulatory interpretation
- Identifying and writing of corrective actions
- Abuses of the CAPA system
- Discuss robustness and effectiveness review

Lecture 3: Management of the Investigation

- Members of the Investigation Team
- CAPA management/team

Lecture 4: Members of the Investigation Team

- Culture
- Compliant document extensions and interim reports (justification)

Day Two

Lecture 4: Members of the Investigation Team

- Management communication and notification
- Metrics and trending
- Interim controls, timetables and other reports
- Policy and Standard Operating Procedures
- Escalation action assessment
- Common barriers and solutions
- Investigator training

Lecture 5: Consulting Case Study Practice - Incident/Events

- Participants role play consulting with instructor on a problem
- Review of key learning points

Lecture 6: Case Study Practice

- Practice on a project relevant to participants' organization

FDA Enforcement Actions and Trends

Lecture 7: Interactive Exercises and Discussions

- Case studies
- Identification of noncompliance and questions to ask to determine the root cause
- Identification of necessary corrective actions and preventive actions

Questions and Summary

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

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1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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