



[www.capatrak.com](http://www.capatrak.com)

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# Corrective and Preventive Action (CAPA) Workshop Detailed Description

CAPAttrak's outstanding and intense full day CAPA Workshop is offered several times throughout the year in beautiful Westlake Village, California, just north of Los Angeles. This full-day training program provides comprehensive and detailed coverage of the elements of an effective Corrective and Preventive Action (CAPA) system.

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## **COURSE FEE:**

- \$295.00 USD per participant (group discounts are available)

## **REGISTRATION OPTIONS:**

- Register Online at [www.CAPAttrak.com](http://www.CAPAttrak.com) or Call Customer Service at (805) 522-5005 or email [register@capatrak.com](mailto:register@capatrak.com)
- Group Discounts - For details, call Diane Kulisek at (805) 320-7879 or email [dkulisek@capatrak.com](mailto:dkulisek@capatrak.com)
- Have this Training presented at your Company - Call 805-522-5005 or email [training@capatrak.com](mailto:training@capatrak.com) to arrange a date.

## **TRAINING OBJECTIVES:**

Upon successful completion of this course, participants will:

- Be able to demonstrate their understanding of the essentials for an effective CAPA system.
- Understand what is required for compliance with general regulatory and contractual requirements.
- Know how to use elements of the course to support implementation of a continual improvement program.
- Understand important factors for Corrective and Preventive Action Request Initiation.
- Be able to effectively select from and apply problem verification and root cause analysis methods for effective identification of actual or potential problem sources.
- Be able to prepare a suitable Corrective and Preventive Action Plan/Response.
- Be able to assess the effectiveness of actions taken to eliminate recurrence of actual problems or prevent occurrence of potential problems.
- Be able to determine the effectiveness of the Corrective and Preventive Action System.

## **WHO SHOULD ATTEND?**

Instruction is targeted to:

- Top Managers accountable for assigning resources in association with participation on Corrective Action Review Boards
- Engineers and other Technical Personnel accountable for preparing Corrective and Preventive Action Plans



## Corrective and Preventive Action (CAPA) Workshop Detailed Description (continued)

- Operations Managers, Supervisors and Lead Personnel accountable for implementing Corrective and Preventive Action Plans
- Quality Assurance Personnel, Regulatory Affairs Professionals and Auditors accountable for assessing the effectiveness of and performing trend analysis for Corrective and Preventive Action Systems, Programs and Responses.

### **COURSE FORMAT AND MATERIALS:**

This fast-paced program utilizes an interactive learning approach.

- Case studies and analysis of specific situations taken from industry are included.
- "Best Practices" will be presented for use as benchmarks for system implementation and maintenance.
- A hardcopy Training Workbook and a CD of related templates are provided to each participant for reference and use upon return to the workplace.
- Each participant will be completing a variety of hand-on exercises with fellow attendees to experience how certain CAPA tools function.
- Training will begin and end with a competency assessment of each participant that will be suitable for use in demonstrating compliance with personnel competency assurance programs.
- Participants who successfully complete the closing competency assessment will receive a certificate of completion.
- Participants unable to demonstrate competency after training will be invited to attend a subsequent offering of the program at a significantly reduced rate or may opt for private tutoring to achieve a more expedient successful outcome.

### **COURSE INSTRUCTOR:**

Diane Kulisek, MSEM, CMQ/OE, CQE

- Diane has over 20 years of experience with successful development, implementation and maintenance of Corrective and Preventive Action Systems for both regulated and unregulated operations. For a detailed description of Diane's background and track record of success, please see her profile on the CAPAtrak People page.

### **PROGRAM OUTLINE:**

#### **I. Introduction**

- Terms & Definitions (CAPA, 8-D, etc.)
- Accountability
- Corrective Action Review Boards
- Problem-solving Teams
- Product and Process Improvement Teams
- Scope
- Applicable Documents, Guidance, Standards and Regulations/Directives

#### **II. Types of CAPA**

- CAPA for Customer Complaints
- Supplier Performance CAPA
- Quality Management System (QMS) CAPA and Internal Audits
- CAPA for Improvement of Products and Processes
- Regulatory CAPA and Common FDA Warning Letter Citations

#### **III. Requesting Corrective or Preventive Action**

- Problem Description, Timing, Concurrent Events and Circumstances, Scope, Business Impact, Suspected Cause, Cost



## **PROGRAM OUTLINE (continued)**

### **IV. Problem Verification, Classification and Prioritization**

- The Problem of Blame
- Isolated Incidents
- Generic or Chronic Problems
- Risk and Liability
- Methods for Verifying the Problem

### **V. Root Cause Analysis**

- |                                |                           |
|--------------------------------|---------------------------|
| • 5 Why Analysis               | • Run Charts              |
| • Brainstorming                | • Scatter Plots           |
| • Fishbone Diagrams            | • Control Charts          |
| • Fault Tree Analysis          | • Paynter Charts          |
| • Process Maps and Flow Charts | • Is/IsNot Analysis       |
| • Check Sheets                 | • Change Analysis         |
| • Pareto charts                | • Root Cause Confirmation |

### **VI. Remedial (Corrective) Action Plans**

- Containment
- Repair or Replacement
- Warranty Credit
- Customer Service and Satisfaction

### **VII. Recurrence Control Plans and Preventive Action Plans**

- Plan-Do-Check/Study-Act (PDCA/PDSA)
- Define-Measure-Analyze-Improve-Control (DMAIC)
- Root Cause Removal or Mitigation

### **VIII. Process Validation, Effectiveness Checks and Timeliness**

- Product and/or Process Validation or Revalidation
- Effectiveness Indicator(s)
- Assessment of Effectiveness (Follow-Up)

### **IX. Traceability, Documentation and Tracking Systems**

- CAPA Policies and Procedures
- CAPA Request Forms
- CAPA Response Forms
- Purchase Order Provisions for CAPA
- CAPA Codes
- Automated CAPA Tracking Systems

### **X. Management Oversight and Review**

- CAPA Performance Metrics
- Management Review Meetings