COURSE

MEDICAL DEVICES CAPA

This course is intended to provide students with the elements of a corrective and preventive action (CAPA) system, taken to eliminate causes of non-conformities or other undesirable situations.

This course is broken down into three modules. The first module identifies the primary elements and sequence of activities for conducting a CAPA. The second module explains how to define a problem statement and conduct the root cause investigations, tools that can help you in effectively investigating problems.

The third module explains how to implement and effectively close out a CAPA.

Duration
12 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

COURSE

MEDICAL DEVICES CAPA

COURSE CONTENT

1. **Initiate – Investigation Plan – Correction/Containment .**
   - Introduction to CAPA
   - Initiation
   - Investigation
   - Plan
   - Containment / Correction
2. **Investigation, Root Cause Analysis – Solution V&V.**
   - Root Cause Analysis
   - Solution V&&
3. **Implementation-VoE-Closure.**
   - Implementation
   - VoE
   - Closure

Duration
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At the end of the course you will be able to

- Understand FDA's and other regulatory officials' expectations for "what CAPA is" and the steps required to get you there.
- Know how to improve your CAPA process, from CAPA sources and preventive actions through root cause analysis, action plans and effectiveness check.
- Understand the main elements and sequence of activities for conducting a CAPA.
- Understand how to define a problem statement, the conducting of root cause investigations, tools that can aid you in effectively investigating problems.
- Recognize how to close the CAPA loop and the requirements to close CAPAs in a timely and complete manner.
- Understand how to establish a compliant Corrective Action and Preventive Action (CAPA).