# Medical Devices CAPA

## Course description

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.

### At the end of the course you will 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).

## Main topics

1. Initiate – Investigation Plan – Correction/Containment.
2. Investigation, Root Cause Analysis – Solution V&V.
3. Implementation – VoE – Closure.

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## Course features

- Instructor Led
- Duration: 12 hours
- Tools and templates
- Simulated learning
- Course certification