



# Quality-One International

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## CAPA Course Outline

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- Introduction to Corrective Action Preventive Action (CAPA)
- Team Problem Solving Principles
- Process Description (9-step Process)
- Team Structure (Cross Functional Team)
  - Roles / Functions of Team members
  - Team Agenda
  - Rules and Documentation
- Origin of Failure
- Inductive vs. Deductive Problem Solving
- Change Induced vs. Never Achieved Problems
- Review of Analytical Tools used in CAPA
  - Brainstorming Rules
  - Ishakawa / Fishbone
  - Affinity Diagram
  - Control Charts
  - FMEA Relationship
  - 5 Why (3-legged 5 Why Approach)
  - Is / Is Not
  - Interfaces and Noise Factors
  - Error Proofing Introduction
- How to Define the Problem / Issue
- What is Interim Containment
- Root Cause Analysis
  - Comparative Analysis Techniques
  - Difference and Change Analysis
  - Theory Development
  - Most Likely Causes
  - Root Cause Verification



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- Permanent Corrective Action
  - Wants and Must Haves
  - Choice Development and Selection
  - Rational Choice Selection - Pugh Matrix
  - Risk Assessment / FMEA
  - Selection of Balanced Choice
  - Implement Permanent Corrective Action
    - Plan, Do, Study/Check, Act
    - Validation
- Preventive Action
  - Review Similar Problems
  - Process and Procedure Review
  - Update Current Tools (FMEA/Control Plans)
  - Prepare and Share Lessons Learned
- Project Closure
  - Closure of Documentations
  - Team Member Recognition
  - Close CAPA Process and Archive the Problem