



# Quality-One International

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## Healthcare FMEA Course Outline

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- Introduction to Healthcare Failure Mode and Effects Analysis (HFMEA)
- History and Purpose of FMEA
- Quality-One Healthcare FMEA Three-Path Model
- Team Structure and Rules for Efficiency
- How to Determine Risk and When to Take Action
- JCAHO Defined Standard for HFMEA Principles
  - Leadership
  - Reduction in Sentinel Events
  - Reduction of Medical / Healthcare Errors
  - Identify High Risk Processes
  - Identify Failure Modes and Effects of Failure
  - Conduct a Root Cause Analysis on items with highest Severity
  - Re-design Process to Mitigate Risks
  - Protect Patient from Effects of the Failure
  - Test to Verify Effectiveness of Process Changes
  - Maintain Effectiveness
- Practical Application of the HFMEA Technique
  - Pre-work
    - Failure Mode Avoidance (FMA)
    - Sentinel Events
    - Past Experiences with Failure
  - Path 1
    - Define the Topic
    - Assemble a Cross-Functional Team of Healthcare Professionals
    - Create a Process Flow Chart or Diagram
    - Select Focal Point from Process Flow (if complex process)
  - Path 2
    - Perform Hazard Analysis



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- Failure Modes and Effects
  - Causes of Failure
  - Rankings for Severity and Probability
  - Hazard Score
  - Decision Matrix / Decision Tree for Single Point Failure, Existing Controls and Detectability
- Path 3
    - Assign Action Type
    - Determine Actions to Improve Tests and Verification Techniques
    - Action Clarification Follow-up & Responsibility / Management Concurrence
    - Closure of the Issue
    - Revisit Rankings
    - Establish Standard Work Practices