

Healthcare Failure Mode and Effects Analysis (HFMEA), 4th Edition for the Healthcare/Medical Device Industry

It costs far less to prevent a problem than it does to fix it after it has been designed into the process. The Process FMEA for Healthcare is a structured, disciplined approach to identifying and prioritizing potential problems before they are embedded into the Process Design. This powerful hands-on 2 to 3- day seminar shows you how to perform a Process FMEA that gets results and saves you money. *Note: Attendees will analyze and develop a HFMEA for a current organizational process of their choice.*

Hours: 8 a.m. – 4 p.m.
Length: 2-3 days

Course Objectives

Participants will learn:

- The importance of the HFMEA and how it can be used to error-proof a process
- The importance of maintaining the HFMEA after it is initially completed
- A systematic, consistent process for developing HFMEAs that will identify process weaknesses
- How to use the HFMEA to identify potential special characteristics
- How the HFMEA is used to build the Control Plan

Who Should Attend:

Healthcare administrators, department heads, supervisors, continuous improvement coordinators, and others as members of the FMEA Development team.

Related Seminars:

- ISO13485:2015 for the Healthcare/Medical Device Industry



Seminar Content

Risk and the FMEA

- The Nature of Risk
- The Failure Sequence
- The FMEA Process
- FMEA and APQP
- FMEA, 4th Edition changes

FMEA Basics

- The Function of the FMEA
- FMEA Structure
- Who is the Customer?
- Who is the Team?
- The FMEA as a Living Document

Mapping the Process

- The Importance of Understanding the Process
- Process Mapping
- Identifying the Micro-Flow
- Workshop: Mapping your Process Flow

Identifying Failure Modes

- Systematically Identifying Potential Failure Modes (Errors)
- Workshop: Identifying Failure Modes

Identifying Effects

- Systematically Identifying the Effects
- Ranking the Severity

- Workshop: Identifying and Ranking Effects

Identifying Causes

- Systematically Identifying the Causes
- Ranking Cause Occurrence
- Workshop: Identifying and Ranking Causes

Identifying Controls

- Prevention vs. Detection
- Workshop: Identifying Prevention and Detection Controls and Ranking Detection Controls

Calculating the Risk Priority Number (RPN) and Severity/Occurrence (SO)

- Calculating SO
- Calculating RPN
- Using the Rankings to Prioritize Risk Reduction

Risk Reduction Actions

- Reducing the Risk Through Prevention
- Reducing the Risk Through Detection
- Re-evaluating Risk after action Taken