
Failure Mode Effects Analysis

Purpose

Students learn to perform an FMEA that helps drive decisions and prioritize critical compliance project.

Objectives At the completion of the class, students will be able to:

1. Conduct a process review.
2. Brainstorm potential failure modes.
3. List potential effects of each failure mode.
4. Assign a severity rating for each effect.
5. Assign an occurrence rating for each failure mode.
6. Assign a detection rating for each failure mode and/or effect.
7. Calculate the risk priority number for each effect.
8. Prioritize the failure modes for action.
9. Take action to eliminate or reduce the high-risk failure modes.
10. Calculate the resulting Risk Priority Number as the failure modes are reduced or eliminated.

Prerequisites

None.

Who should attend this class?

This class is for anyone who is responsible for performing an FMEA analysis or reviews and approves the analysis of others.

About the Class

1. This class uses company specific corrective and preventive actions to practice the techniques taught.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 25 people.
5. Duration: 4 hours.

Topics Covered

CGMPs and FMEA

1. The CGMPs
2. FDA Guidance on FMEA

Tools

1. Brainstorming
2. Reaching consensus

Conduct a Process Review

1. Process mapping
2. Client maps
3. As-is maps
4. Should-be maps

List Potential Effects

1. Brainstorming
2. Grouping
3. Combinations
4. Separations

Assign a severity rating for each effect

1. Rating scale
2. Description of the scale
3. Definition
4. Activity: Develop a severity scale

Assign an occurrence rating for each failure mode

1. Rating scale
2. Description of the scale
3. Definition
4. Activity: Develop an occurrence scale

Assign a detection rating for each failure mode and/or effect

1. Rating scale
2. Description of the scale
3. Definition
4. Activity: Develop a detection scale

Calculate the risk priority number for each effect.

1. Severity
2. Occurrence
3. Detection

Prioritize the failure modes for action.

1. Pareto Charts
2. Cumulative percent

Take action to eliminate or reduce the high-risk failure modes.

1. Eliminate
2. Reduce
3. Specific actions to take to reduce high-risk ratings

Calculate the resulting Risk Priority Number as the failure modes are reduced or eliminated.

1. Rating
2. Description
3. Definition

Company Specific Project