



PROCESS FAILURE MODE AND EFFECTS ANALYSIS (PFMEA)

COURSE OVERVIEW

Process FMEA is a systematic, team-based method for identifying potential failures in manufacturing processes, assessing their severity, occurrence, and detection difficulty, and prioritizing corrective actions to prevent product defects and ensure quality. This course was developed by practitioners, for practitioners, to build robust manufacturing processes and support global regulatory compliance.

COURSE CURRICULUM

- FMEA Background & Standards
- FMEA Tool Introduction & Structure
- pFMEA & Process Validation (PV)
- Failure Modes Identification
- Failure Effects Analysis
- Failure Causes & 6M Framework
- Severity, Occurrence & Detection Ratings
- Control Types: Prevention & Detection
- Risk Priority Number (RPN) Calculation
- Severity-Weighted Prioritization
- pFMEA to Control Plan Translation
- IQ/OQ/PQ Validation Alignment
- pFMEA Examples & Case Studies
- pFMEA Best Practices & Living Document

COURSE AT A GLANCE Price: \$1,500 Lessons: 223 Video Content: 1.5 hours Quizzes: 14 Final Exam: 1 Time Limit: 60 days Certificate: Yes, upon passing Format: Self-paced	LIVE EXPERT SESSIONS Each student receives two live virtual sessions with a DQS expert: Before Class: 30-minute orientation session After Class: 60-minute Q&A and implementation support <i>90 minutes of personalized expert guidance included!</i>
--	--

DOWNLOADABLE FILES

- Complete course slides
- Sample pFMEA procedure and template
- Sample device and process exercises with DQS answers

LEARNING OBJECTIVES

- Explain foundational concepts of pFMEA and how it integrates with ISO 14971 and Process Validation requirements
- Apply systematic tools such as function analysis and process flow diagrams to identify failure modes
- Develop risk-appropriate prevention and detection controls using the 6M framework
- Evaluate failure mode risk using severity, occurrence, and detection to calculate RPN values
- Apply severity-weighted prioritization methods to focus on the highest-risk failure modes
- Translate pFMEA into comprehensive control plans aligned with IQ/OQ/PQ validation stages
- Develop and sustain pFMEA as a living document that improves with production data and learning
- Identify appropriate control types (prevention vs. detection) based on risk characteristics
- Apply pFMEA best practices to avoid common pitfalls and ensure audit readiness
- Connect pFMEA outputs to Process Validation protocols and manufacturing quality systems