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## Implementing the Failure Mode and Effects Analysis (FMEA) Reference Manual 4<sup>th</sup> Edition for Healthcare

Establish the foundation to void “Murphy’s Law” – the things that could go wrong don’t have to when you learn to use FMEAs successfully. This course will teach you the skills to understand and use FMEAs and the concept of risk reduction and defect prevention.

Turn your quality control around when you discover the impact of failure and how you can reduce the risk with FMEAs. Then, take your skill and knowledge beyond just the concepts by learning the specifics of successfully developing and maintaining design and process FMEAs for your company, which will include identifying and reducing risk factors.

Length: 1 days

CEUs: .7

Prerequisites: *None*

### WHAT YOU WILL LEARN

- Learn how to define FMEA customers
- Understand the relationship of FMEA to Advanced Quality Planning (AQP)
- The specifics of Design and Process FMEAs
- Develop an understanding of the concept of risk and how to reduce the risk of failure
- Hands-on development of FMEAs for your company or products, including how to complete an FMEA and understand the reasoning for specific parts of the FMEA

### PLEXUS LEARNING MODEL

Learning is maximized through participation. That is why Plexus training avoids lecture-based teaching and focuses on group activities, case studies and hands-on applications. *Learn by doing.*

### WHO SHOULD ATTEND

- Anyone involved in the implementation of ISO 9001 for Healthcare
- Individuals and cross functional teams interested in risk reduction and anyone who wants a better understanding of basic FMEA and risk management methodology
- Representatives from key functional groups involved in an organization’s quality management system

### INSTRUCTORS

*Plexus Master Trainers.* Plexus Master Trainers train and evaluate:

- ISO 9001:2008, ISO/TS 16949:2009, AS9100, ISO 14001:2004 Environmental Management Systems, ISO 22000:2005 Food Safety, ISO 9001:2008 for Healthcare and ISO 13485:2003 for Medical Devices.
- Plexus trains 3<sup>rd</sup> party auditors and wrote the materials used to certify all of them
- Supplier Auditors