

Failure Mode and Effects Analysis "FMEA" ES 211

Instructor: Ray Lotfi

RU: 0.9

Prerequisite: None

FMEA is a required body of knowledge in order to comply with ISO 13485:2003 of medical and pharmaceutical industries. It is also part of the ISO 9001 and other international quality standards.

An outstanding FMEA action once completed will result with improve quality, reduce cost, increase safety, increase confidence, and will lead to recognition as the FMEA champion. Taking the ES-211 will help the individual to achieve the benefits mentioned.

ES-211 FMEA course consist of 3 main section as follows:

- 1.0- Course definition and information
 - 1.1- History, development, and correlation with ISO
 - 1.2- Definition, specification and method of generating FMEA
 - 1.3- Relation of FMEA and risk management
 - 1.4- Roll of statistic and probability to excel FMEA
 - 1.5- Team building and FMEA champion or leader

- 2.0- Examples Development
 - 2.1- Discussion and best course of action
 - 2.2- Design FMEA
 - 2.3- Process FMEA
 - 2.4- Applications of FMEA

- 3.0- Summary and areas of connection to other Quality/Engineering discipline
 - 3.1- Utilization of other products/process made
 - 3.2- FMEA as a dynamic tool
 - 3.3- FMEA and CAPA - a great place for auditors
 - 3.4- Key success of FMEA (team playing)

Who Should Attend

Professionals in Quality, Engineering, Manufacturing, Regulatory, Marketing and Sales.

Schedule

Total of 9 hours equally divided into 3 sessions