Apex
Quality Assurance

2-Day

ISO 14971 APPLICATION OF RISK MANAGEMENT FOR MEDICAL DEVICES–PFMEA

Medical Device Quality Management Systems

Register by phone

919-635-5581

Register online

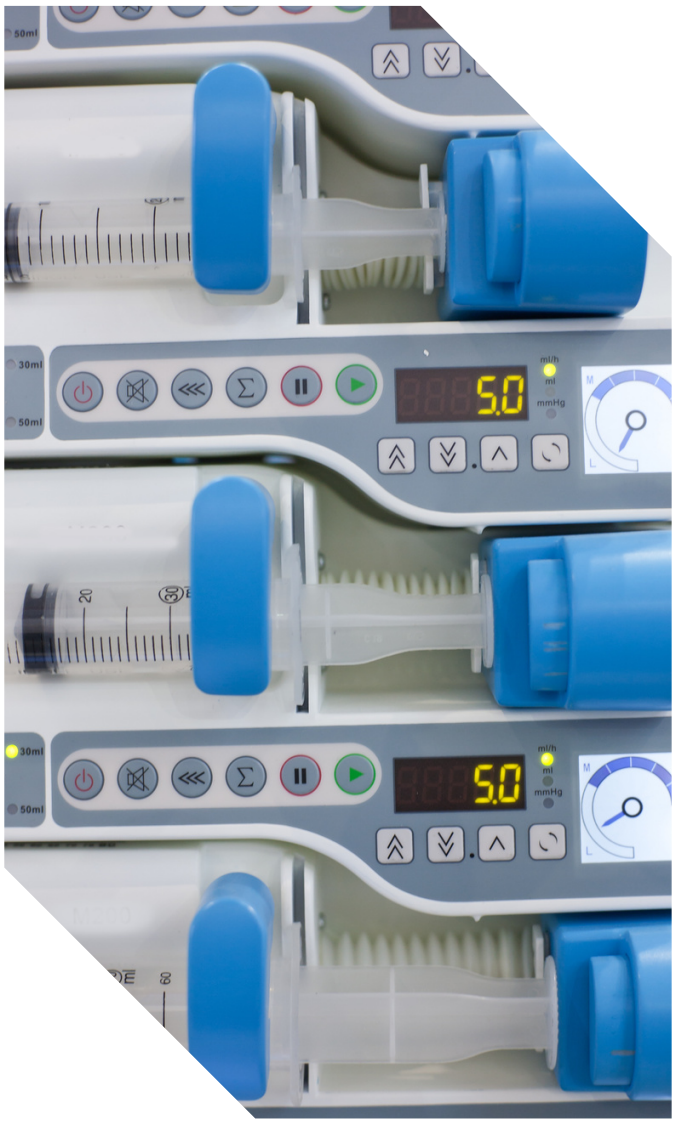
www.apexqualityassurance.com

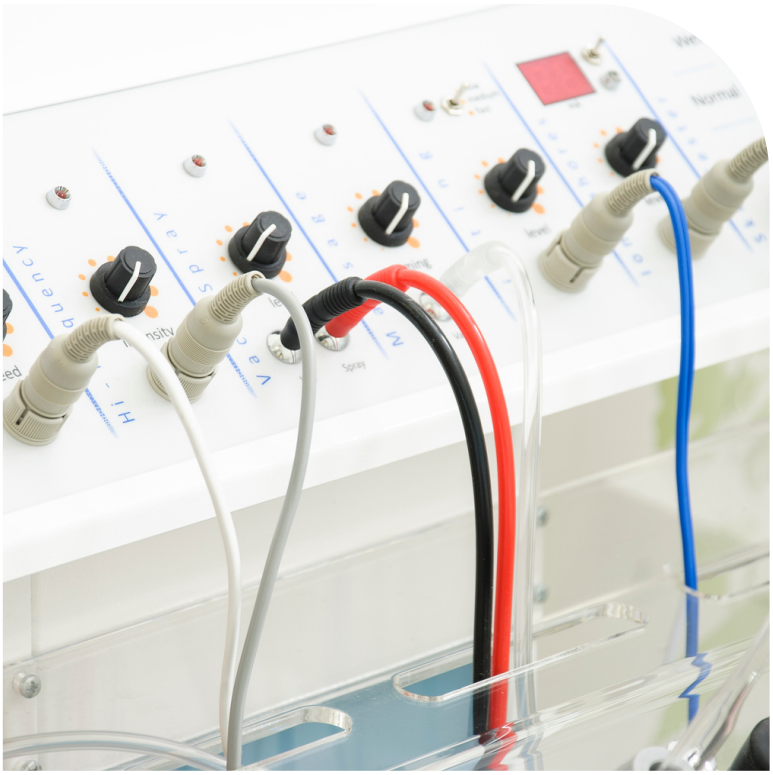
Who Should Attend

ISO 14971 APPLICATION OF RISK MANAGEMENT FOR MEDICAL DEVICES–PFMEA

This seminar is designed for those responsible for introducing new medical devices or new manufacturing processes and systems including quality managers, quality engineers, design developers, and others who are responsible for the medical device development and improvement.

Quality Assurance and Regulatory Affairs professionals within medical device organizations currently active in participating jurisdictions and organizations expanding their market reach to jurisdictions participating in ISO 13485:2016 will also benefit from this course.





Seminar Goals

ISO 14971 APPLICATION OF RISK MANAGEMENT FOR MEDICAL DEVICES–PFMEA

- Application of FMEA approach to ISO 14971
- Use of PFMEAs as a process in the organization
- Overview of the steps of the FMEA Frameworks for Managing Risk
- Manufacturing Processes and Risk Control (PFMEA)
- Process Requirements
- Process Flow Diagram
- Process Failure Modes
- Potential Causes
- Process Controls
- Risk Evaluation
- Risk Treatment
- Monitoring and Review

Attendees successfully completing the examinations provided in conjunction with this course receive a Certificate of Completion from Apex Quality Assurance.

The Certificate of Completion provides evidence of knowledge competency as a Quality Management Systems Auditor.

Even though ISO 13485:2016 is used as the model for teaching systems and audit, this course enables students to develop and apply auditing skills using any applicable management system standard.