



Quality System Regulation

This course provides an overview of the Quality System Regulation and ISO13485, providing a common frame of reference for individuals at all levels within an organization. The format is approximately 40% lecture and 60% group work. Group work involves determining where current internal procedures align or are out of alignment with standards, and also issues outlined in warning letters. Multiple reference sources will be utilized for these activities, including the preamble, guidance documents, Small Entity QSR FDA guidance document and others.

Additional topics covered include “do’s and don’ts” during an external audit and FDA inspection techniques.

LEARNING OBJECTIVES

- Ability to appropriately interpret the requirements for your company and department.
- Development of action plans to address common audit and warning letter findings.
- Ability to identify QS Regulation requirements and ISO 13485 requirements which relate to your job responsibilities.
- Ability to relate examples of audit findings and warning letter cites to your department, job responsibilities and the QS regulation and ISO requirements.
- Understanding the “do’s and don’ts” during external audits.

AUDIENCE

This course is appropriate for individuals who are involved or may be involved in a third party quality system audit.

Examples include:

- Directors, managers and supervisors
- Those making decisions within the quality system
- Those making changes to QS procedures and records
- Those responsible for QS compliance in their area

DELIVERY

Quality System Regulation Training is taught using a blended approach of classroom and real-life work application. This approach to learning significantly increases training and skill-set retention, as well as allowing participants to apply what they have learned in a training setting. PathWise facilitators have an extensive background in teaching Quality System Regulation Training in an FDA regulated environment.