



QA ✓ RA Compliance Connection, Inc.
presents

Design Controls

An In-depth Perspective

P.O. Box 448 * Odessa, Florida 33556 * (813) 784-8457

Design Controls

An In-depth Perspective

A Two-Day Comprehensive Training Program

Why is design control so important?

Both the FDA QSR and ISO 9001 require that design controls be implemented to ensure products are safe and effective for their intended use. The ability of an organization to implement an effective design control system is critical for both compliance with regulatory requirements and to meet customers expectations. This course is designed to provide participants with the knowledge and skills necessary to implement an effective design control program which meets ISO 9001 and FDA QSR requirements. Interactive exercises help participants understand first hand how to apply design control concepts/requirements.

This course is for you if:

- You manufacture Class III, Class II and select Class I medical devices.
- You are responsible for leading or participating on a project team subject to FDA or ISO design control requirements.
- You manage the development process or participate in quality system audits.

You'll be provided with:

- An in-depth review of design control requirements
- "Real life" interactive implementation examples
- FDA's Inspection Technique
- Typical auditor questions related to design control requirements

COURSE OUTLINE

Introduction to Design Controls

General Requirements and Applicability

Benefits of Design Control

FDA Inspection Technique

Typical Areas of Non-Compliance

Design & Development Planning

Design Input

Design Output

Design Review

Design Verification

Design Validation

Risk Analysis

Design Transfer

Design Changes

Design History File

COST: \$700 per person