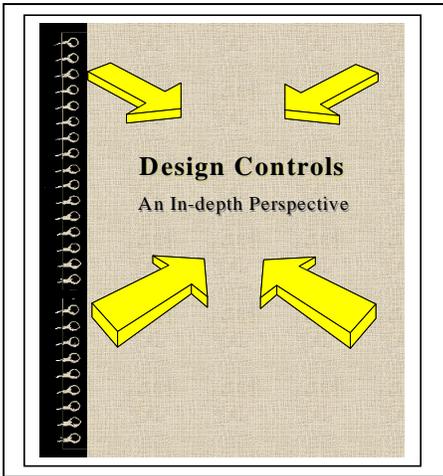


DESIGN CONTROLS – AN IN-DEPTH PERSPECTIVE

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Course Objectives

- ✓ Provide an in-depth review of design control requirements to meet ISO 9001 and FDA QSR requirements
- ✓ Introduce FDA Quality System Inspection Technique (QSIT) for design control
- ✓ Review typical areas of non-compliance
- ✓ Identify benefits of design control
- ✓ Present techniques used to implement design control requirements
- ✓ Identify typical auditor questions

Course Outline

- Introduction to design controls
- General requirements/applicability
- Benefits of design control
- FDA Inspection Technique
- Typical areas of non-compliance
- Design and development planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Risk Analysis
- Design Transfer
- Design Changes
- Design History File

Both the FDA QSR and the ISO 9001 standard require 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 program is critical for compliance with mandated regulatory requirements and to the achievement of organizational goals related to customer satisfaction. An effective design control system can help you “do it right the first time” and save invaluable time and money.

QARA Compliance Connection’s Design Control module is essential to those companies looking to comply with ISO 9001 and FDA QSR design control requirements. Considered a prerequisite for designing and developing products, it is also applicable to companies that need to conduct effective internal and external quality system audits.

The Design Control module provides participants with an in-depth knowledge and understanding of design control requirements. The requirements are presented in simple, easy to understand language and clarification and/or techniques for implementing the requirements is offered.

The module includes an introduction to design controls and identifies reasons for compliance and benefits associated with implementing and maintaining an effective design control system.

Additionally, the FDA Quality System Inspection Technique (QSIT) with regard to design controls is provided and typical areas of non-compliance as cited by prior FDA inspections are illustrated.

For more information, contact us today!

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General Requirements *Applicability*

- May be applied to any product development process
- May be initiated for a variety of reasons
- All FDA Class III, majority of Class II, and select Class I medical devices
- Not applicable to the development of concepts and feasibility studies
- Applicable to the life of the product

Design controls must be carried out under controlled conditions

General Requirements *Benefits*

- Identifies discrepancies early
- Early problem detection allows for correction and resource allocation adjustment
- Better understanding of conformance requirements
- Enhances communication and coordination of interfaces
- Provides an interrelated set of practices and procedures

General Requirements *Benefits – Notes Pages*

Implementing design controls at the outset of the design and development process helps to reduce the overall project and product costs by permitting the identification and correction of problems earlier in the design cycle.

Identification of discrepancies in design input requirements earlier in the process reduces the amount of costly redesign and rework, and improves the quality of the product.

Early detection of problems allows the team to make any essential corrections and adjust resources as needed.

Project team members acquire a more complete understanding of conformance requirements and their responsibilities.

The communication and coordination amongst individual functions and departments is enhanced.

Design controls provide an interrelated set of practices and procedures – e.g. system of checks and balances.