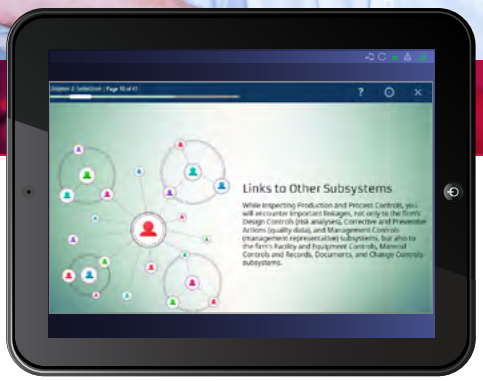
FDA QSIT Essentials for Medical Device Organizations

Quality & Compliance Essentials



"We would like to conduct training to help QA, auditors and product development teams prepare for an investigation from FDA."

"In addition, we would like the training materials to be available as reference items if our firm is inspected."

FDA's Quality System Inspection Technique (QSIT) program was developed to ensure thorough coverage of the Quality System Regulation (21 CFR Part 820), while also ensuring consistency of inspections.

QSIT audits are conducted by FDA CDRH and in some cases, third-party auditors acting on behalf of FDA. Within QSIT, four of the seven QSR subsystems are considered "major" subsystems

- Management Controls
- Design Controls
- Corrective and Preventive Actions (CAPA)
- Production and Process Controls (P&PC)

The UL EduNeering QSIT Essentials program enables medical device organizations to gain affordable access to five QSIT eLearning courses for a single price.

QA teams can deliver these courses to senior management, auditors, operations and other key areas of the organization, sharing insight into the QSIT approach, and providing a valuable electronic resource should the organization face a QSIT investigation.

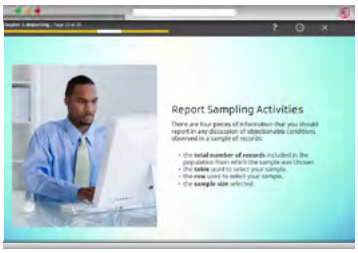
The QSIT Essentials program includes these five courses:

- QSIT 1 - Beginning the Inspection
- QSIT 2 - Subsystem
- QSIT 3 - The Design Controls Subsystem
- QSIT 4 - The Corrective and Preventive Actions Subsystem
- QSIT 5 - The Production and Process Controls Subsystem

QSIT 1 -- Beginning the Inspection FDA50

This course provides an overview of the QSIT inspectional approach, and also explains the key elements that make up a firm's quality system. Specifically, the course focuses on the subsystems of the Quality System Regulation (21 CFR Part 820).

This course is ideal for those new to the medical device regulatory environment.



QSIT 2 - Subsystem FDA51

One of the main purposes of a QSIT inspection is for the FDA investigator to determine whether management with executive responsibility is ensuring that an adequate and effective quality system has been defined, documented, implemented, and maintained at the firm.

This course will cover the Inspectional Objectives related to the Management Controls subsystem.

QSIT 3 -- The Design Controls Subsystem FDA52

This course provides the investigator with guidance on the Design Controls subsystem, which ensures that devices meet user needs, intended uses, and specified requirements.

This course explains what the investigator should focus on within the design process. For example, the course suggests that the investigator spend a full day inspecting the firm's Design Controls subsystem.

QSIT 4 -- The Corrective and Preventive Actions Subsystem FDA53

Through the CAPA system, a firm collects and analyzes information to investigate existing and potential causes of product and quality problems.

This course explains the steps that FDA investigators should take to review and familiarize themselves with a firm's CAPA procedures, to determine whether the procedures adequately address the seven elements required in 21 CFR 820.100(a).

QSIT 5 -- The Production and Process Controls Subsystem FDA54

The purpose of the Production and Process Controls (P&PC) subsystem is to manufacture products that meet specifications.

This course explains the steps taken to inspect a firm's Production and Process Controls. For example, a firm must understand when deviations from device specifications could occur as a result of the production process or environment.

An Engaging Learning Experience

To ensure the learners retain the material, each course contains "interactive quizzes" that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

In addition, courses contain a number of interactive activities that engage learners. These interactions also "chunk" critical information, which has been proven to improve retention in adult learners.

Affordable Pricing

Pricing for the set is based on an organization's employee size. For a firm with 500 employees, for example, the subscription cost works out to approximately $40 per learner. Courses can be delivered in one of three methods:

- SCORM: Course files are provided in SCORM, so they can be delivered via your organization's SCORM-compliant learning management system. Optional maintenance fees are available, in the event that the courses are updated to reflect new regulations.
- AICC: Course files are delivered as AICC, so they can be delivered via your organization's AICC-compliant learning management system.
- ComplianceWire®: Courses can be delivered through UL EduNeering's ComplianceWire learning management system for an additional fee.

Get Started

To learn more about the QSIT courses, or view a demo, please contact Pat Thunell at pat.thunell@ul.com.