IT Validation

Quality & Compliance Essentials

"Our QA and IT teams need to be trained on software validation and 21 CFR Part 11 topics.

"We would prefer eLearning rather than workshops, so they can gain more comprehensive reference materials to refer back to, and because we have a tight training budget."

More than 200 QA, IT and GMP training teams currently rely on UL EduNeering's IT Validation courses to deliver "foundational" system validation training to employees within IT, QA, Operations, Management and more.

Written by industry-leading subject matter experts, as well as US FDA officials, this set is part of our 90-course GMP Library, which has been taken by more than 200,000 Life Science professionals since 2011. In most cases, training teams embed our IT Validation courses into their existing computerized system validation (CSV) and GAMP 5 policy training process.

The IT Validation set enables Life Science organizations to gain affordable access to five of the most popular systems validation courses in our GMP Library – for a single price.

QA teams can deliver these courses to as many learners as possible, to stretch their training budget and eliminate the need to develop this regulatory training content on their own, without sacrificing the quality of the training content.

The IT Validation program includes these five courses:

- Requirements for Computerized Systems Validation and Compliance
- Approach to Computerized Systems Validation and Compliance
- Writing Validation Protocols
- Computerized Systems Inspections in the Pharma / Medical Device Industry
- Documenting Validation Activities

Requirements for Computerized Systems Validation and Compliance — ISPE02

This course describes regulatory requirements and expectations regarding the validation and compliance of computerized systems used in the manufacture of Life Science products.

The course draws from 10 regulations and guidance documents, including the ISPE GAMP 5 document, A Risk-Based Approach to Compliant GxP Computerized Systems), and explains FDA expectations around qualification testing (IQ, PQ, and OQ).

Approach to Computerized Systems Validation and Compliance — ISPE01

This course describes an approach to the validation and compliance of computerized systems used in the manufacture of Life Science products that are required to meet FDA's regulations. It identifies ways to organize policies and procedures, and plans FDA expects a manufacturing company to establish. This course draws on current industry good practice.

Writing Validation Protocols — PHA51

This course explains key components of the validation protocol, such as information related to materials, equipment, and acceptance criteria. The course also introduces the content of the documentation that comprises validation.

Learners will gain a deeper understanding of the key elements in validation protocols and the three types of qualifications.

Computerized Systems Inspections in the Pharmaceutical (or Medical Device) Industry — ISPE03 or ISPE04

This course explains how computerized systems are used in either the pharmaceutical or medical device manufacturing process and provides an approach to inspecting these systems.

The course focuses on the systems that automate part of the drug or device production process or part of the quality system. This course views the inspection process from the US FDA perspective, giving learners unique insight into the key audit priorities of the FDA investigator.

Documenting Validation Activities — PHA55

The key to successful validation is the understanding that validation must be documented. This course illustrates the process of documenting validation activities for US FDA acceptance. Course topics include: Validation, Documents, Equipment, Materials, Process, and People.

After completing this course, learners will be able to recognize FDA's definition of validation and identify the required components of the validation process.

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 1,000 employees, for example, the subscription cost works out to approximately $20 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 IT Validation courses, or view a preview of the courses, please contact Pat Thunell at pat.thunell@ul.com.