GMP Inspection Readiness for Pharmaceutical Companies

"We need to help our QA, Auditing and Operations teams understand what's expected during a FDA and EU GMP inspection."

"After the training, we would like to make this content available at their fingertips, at a moment's notice."

Quality & Compliance Essentials

More than 200 QA and GMP training teams trust UL EduNeering's GMP Inspection Readiness courses to deliver "foundational" inspection awareness training to employees within QA, Operations, management, and more.

Written by industry-leading subject matter experts, as well as US FDA officials, these courses have been taken by more than 200,000 life science professionals since 2011. In most cases, training teams have embedded eLearning into their "Inspection Readiness" programs, which may include workshops, internal training and other sources. Our eLearning courses serve as "digital repositories" that employees can reference as needed.

The GMP Inspection Readiness set is part of UL EduNeering's Quality & Compliance Essentials program, which are subsets of our larger libraries, and enable Life Science organizations to gain affordable access to five of the most popular courses in our GMP Library - for a single price.

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

The GMP Inspection Readiness program includes these five courses:

- Awareness of FDA Inspections for Pharmaceutical Manufacturers
- Principles of Auditing
- Handling an FDA Inspection
- Pre- and Post-Approval FDA Drug Inspections
- EU Directives and Inspection Readiness

Awareness of FDA Inspections for Pharmaceutical Manufacturers — PHA65

This course provides a general awareness of FDA inspections of pharmaceutical testing and manufacturing facilities, including purpose, types, and areas/operations typically inspected.

Learners will also understand how to handle FDA inspections and interact effectively with FDA Investigators.

Principles of Auditing — PHDV69

This course focuses on the purpose and conduct of internal and external quality audits. The course begins with actual preparation, conduct, and follow-up associated with an internal audit.

The importance of establishing corrective action and follow-up is also explained in this course.

Handling an FDA Inspection — PHDV74

This course explains how to clarify roles and responsibilities of personnel during an FDA inspection.

The course reviews the basics of handling an FDA Good Manufacturing Practice (GMP) inspection and features an interactive, fictional inspection that will help reinforce the lessons learned.

Pre- and Post-Approval FDA Drug Inspections — PHA75

This course explores pre-approval and post-approval drug FDA inspections. Specifically, the purpose and focus of each type of inspection will be discussed, along with the key inspectional targets of each.

Key discussion points will include: evaluation of bio-clinical batches, raw materials, manufacturing process, finished product, and general GMP compliance. For post-approval inspections, the course focuses on general GMP compliance issues, and the potential outcomes of inspections.

EU Directives and Inspection Readiness — PHDV96

The EU has strict requirements for the manufacture and supply of medicinal products, which are defined in EU directives and GMP guides.

This course identifies the regulatory background regarding EU inspections, the expectations inspectors may have, and how to prepare for EU inspections.

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 $20 per learner. These 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 GMP Inspection Readiness courses, or view a preview of the courses, please contact Pat Thunell at pat.thunell@ul.com.