Pharmaceutical GMP Compliance

Quality & Compliance Essentials

"As a GMP trainer, I have dozens of training programs to develop and conduct each year. It would be more efficient for our team to rely on an outside source to deliver training on core GMP regulatory topics."

More than 200 QA and GMP training teams already rely on UL EduNeering's online courses to deliver "foundational" GMP training to employees within operations, QA, management and more.

Written by industry-leading subject matter experts, as well as US FDA officials, our 90-course GMP library has been taken by more than 200,000 Life Science professionals in 2014 alone.

Our new Quality & Compliance Essentials program enables many more 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, 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 Pharmaceutical GMP Quality & Compliance Essentials program includes these five courses:

- Orientation to GMP Compliance
- Introduction to GMPs
- Principles of Good Documentation
- Maintenance and Cleaning of Drug Manufacturing Equipment
- Understanding the Practices and Principles of Process Controls

See reverse side for course details

Orientation to GMP Compliance PHDV73

This course removes the mystery out of GMP regulations by introducing learners to the GMP regulations and how they are applied and interpreted. Learners will better understand how the FDA and your own company's compliance professionals interpret and apply these important regulations.

This course walks through the Food, Drug and Cosmetic (FD&C) Act, and how that law is tied to the Code of Federal Regulations (21 CFR Part 210 and 211).

Introduction to GMPs PHA38

This course explains the reason behind GMP regulations, and how GMP requirements are applied to basic procedures within the manufacturing environment. The goal of the course is to help learners understand why GMP regulations are critical to the success of the company, so they can make more proactive decisions during the production process. For example, the course devotes a chapter on how employees can control contamination by keeping facilities and equipment clean throughout the manufacturing process.

Principles of Good Documentation PHA74

At the heart of Good Manufacturing Practices is a well-defined documentation process. This course explains which documents and records are required in the operations and production area, and the controls that should be in place. Both FDA and EU regulatory requirements are discussed. This course highlights the importance of data integrity issues, and the personal responsibility that all employees share to make sure documentation procedures are followed.

Maintenance and Cleaning of Drug Manufacturing Equipment PHA44

To consistently manufacture pure, high-quality products, equipment must be properly designed, constructed, cleaned, and maintained. In this course, learners will understand the steps involved in equipment selection, installation, qualification, and maintenance. Learners will understand proper cleaning and maintenance practices for equipment used in manufacturing.

Understanding the Practices and Principles of Process Controls PHA47

All employees need to understand the role that "process controls" play in ensuring that a pharmaceutical product will meet its specifications for quality, purity, strength, and safety. In this course, learners will understand the regulations focused on process controls, the ways that equipment affects process controls, but also batch production records, correct sampling and testing methods, proper reprocessing techniques, contamination control, and change control.

An Engaging Learning Experience

To ensure the learners retain the material, each course contains "interactive quizzes" that must be completed before learner 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 buttons that learners must click before continuing to the next page. This idea of "chunking" information 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 Pharmaceutical GMPs courses, or arrange a preview of the courses, please contact Pat Thunell at pat.thunell@ul.com.