Facility and Equipment Compliance

Quality & Compliance Essentials

"We need our production employees to understand the regulatory requirements on equipment maintenance and facility-related topics.

"We want to combine this training with our company-specific procedures and classroom events."

More than 200 QA and GMP training teams already rely on UL EduNeering's online courses to deliver "foundational" facility and equipment 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.

Through our new Quality & Compliance Essentials program, many Life Science organizations can gain affordable access to five of the most popular "facility and equipment maintenance" 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.

The Facility and Equipment Compliance set includes these five courses:

- Understanding GMPs for Facilities and Equipment
- Environmental Control and Monitoring
- Gowning for Sterile Manufacturing
- Maintenance and Cleaning of Drug Manufacturing Equipment
- Essentials of an Effective Calibration Program

See reverse side for course details

Understanding GMPs for Facilities and Equipment PHDV63

This course introduces the general layout and equipment used within a pharmaceutical or medical device manufacturing plant.

Topics in this course include: Facilities, Cleanliness, Process Flow, Equipment, Maintenance, Calibration, and Cleaning. After completing this course, learners will be able to identify the requirements that specifically apply to facilities and equipment.

Environmental Control and Monitoring PHDV87

This course examines FDA requirements for environmental control and monitoring elements employed for aseptic processing areas to prevent microbiological contamination of sterile products.

The course explains why aseptic processing poses unique challenges for producing sterile products, the importance of maintaining quality environmental conditions, components of a written program, and how to prevent contamination.

Gowning for Sterile Manufacturing PHA63

This course provides basic knowledge of sanitization and sterilization, the microbiological principles involved, and the importance of proper gowning and working in cleanrooms.

The course explains both US and EU regulations, and will help learners identify the sources and types of contamination in a manufacturing environment, recognize the importance of health issues and personal hygiene, and identify the staged entry and use of cleanrooms.

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.

Essentials of an Effective Calibration Program PHDV75

This course identifies the essentials of an effective calibration program. This course contains references to both U.S. and EU regulations.

Topics in this course include the four aspects of calibration, calibration standards, regulatory requirements, and calibration procedures.

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 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 Facility and Equipment Compliance set, or arrange a demo, please contact Pat Thunell at pat.thunell@ul.com.