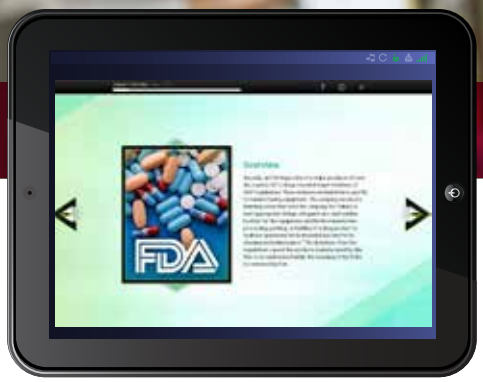
EU GMP Regulations

Quality & Compliance Essentials



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

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

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

Written by industry-leading subject matter experts, 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 pharmaceutical organizations can gain affordable access to five of the most popular "EU GMP Regulations" 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 EU GMP Regulations set includes these five courses:

- A Tour of Health Europe
- EU GMP Requirements for Computerised Systems
- EU Directives and Inspection Readiness
- Role of the Qualified Person
- Good Distribution Practices

See reverse side for course details

A Tour of Health Europe — PHDV90

This course explains the organizations that oversee the health industry in Europe, including the European Union and the Council of Europe.

Learners will also understand how health products can be approved for sale to the public and the system for reporting and tracking defective products.

EU GMP Requirements for Computerised Systems — PHDV95

This course introduces the European Union's GMP requirements for computerised systems that are associated with the manufacture of medicinal products.

Reference is also made to FDA expectations. This course covers requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

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.

Role of the Qualified Person — PHA76

This course explains the EU law (within Annex 16) that requires that before a batch can be released, a Qualified Person named in the manufacturing authorisation must sign a register or equivalent document as a record that they have carried out a proper evaluation.

Good Distribution Practices — PHA77

This course explains the EU requirements for maintaining product quality and integrity at each stage in the distribution process as defined in Directive 2001/83/EC and revised guidelines 2013/C 68/01.

The course also cites the recent U.S. draft guidance related to the Drug Supply Chain Security Act.

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 EU GMP Regulations set, or arrange a demo, please contact Pat Thunell at pat.thunell@ul.com.