Good Distribution Practices

eLearning Addresses EU Regulations – And Beyond

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UL EduNeering's Pharmaceutical GMP Library is continually expanded to include global GMP topics. Our latest course focuses on Good Distribution Practices.

The new GDP course is graphically-rich and can be taken from desktop, laptop, and mobile devices (e.g., iPad, iPhone).

In addition, the course is available in four languages: English, German, French and Spanish. Clients can request additional languages as needed.

For many years, the EU required medicine manufacturers to maintain product quality and traceability throughout the distribution chain.

As supply chains grew more complex, thus increasing the risk to product quality and patient safety, the EU sought more concrete GMP and distribution regulations. In 2013, the EU GDP Directive, 2013/C 68/01, came into EU law, and it has served to modernize EU regulations on the issues of quality and integrity of medicines through each stage in the distribution chain.

The scope of the EU regulations spans wholesale distribution activities that include procuring, holding, supplying or exporting medicinal products, and also the manufacturers who are involved with any of these activities.

UL EduNeering's new course, **European Union Good Distribution Practices (PHA77)**, focuses on these new GDP regulations. The course, written by the experts at leading regulatory consulting firm EduQuest (www.eduquest.net) explains the responsibilities of all organizations involved with wholesale activities — including storage, transport, purchase, and supply. The course addresses controls required to prevent falsified or fake products entering the supply chain, and cites the 2013/C 68/01 regulation.

In addition, the course cites several US regulations and guidance documents including 21 CFR 211, Sections 150, 196 & 142, and 21 CFR 205.50; United States Pharmacopeia, Good Storage and Distribution Practices for Drug Products; and FDA Draft Guidance for Industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, June 2014.

As with any of the courses in the UL EduNeering Pharmaceutical GMP Library, when the regulations change, the course will be updated to reflect these changes.

GDP Course Details:

PHA77 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.

Learners will be able to identify the documentation required and the responsibilities for achieving and maintaining ongoing compliance with the EU GDP requirements. The course also cites the recent U.S. draft guidance related to the Drug Supply Chain Security Act.

Our EU-focused courses, including the new GDP course, can be combined with UL training and consulting services, conducted at a client's site.

If you have any questions, please contact the UL EduNeering Client Services team at prn.technologysupport@ul.com.

Here are just a few of the other UL EduNeering Courses that cite EU Regulations:

- A Tour of Health Europe: (PHDV90)
- Principles of Good Documentation (PHA74): This course references EU Guidelines to Good Manufacturing Practice of Medicinal Products for Human and Veterinary Use, Volume 4, Chapter 4, Documentation.
- EU Directives and Inspection Readiness (PHDV96): This course explains the regulatory background regarding EU inspections, the expectations inspectors may have, and how to prepare for inspections.
- Qualified Person (Annex 15): This course is expected to launch in Q3 2015.
- Understanding the GMP Requirements for Facilities and Equipment (EU): (PHDV63-EU)
- EU GMP Requirements for Computerised Systems (PHDV95): This course explains the requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.