EU Qualified Person Regulations

Course Explains QP Requirement Noted in Annex 16

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UL EduNeering's Pharmaceutical GMP Library is continually expanded to include global GMP topics. Our latest course focuses on EU requirements for Qualified Persons.

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

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

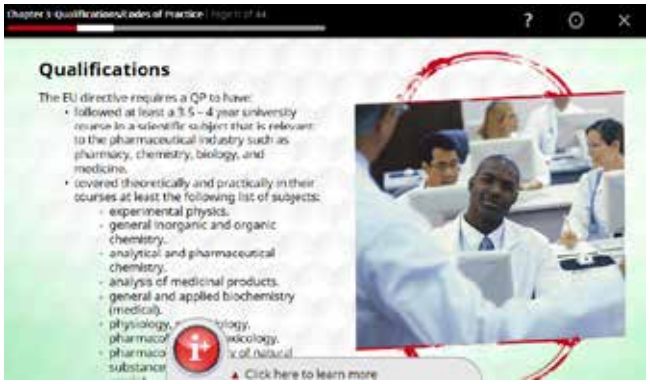
To provide increased confidence that all medicinal products sold within any European Union (EU) member state are safe and effective, the EU has a legal requirement that an individual, defined as a Qualified Person (QP), be responsible for certifying the quality of each batch of medicinal products before it is released for distribution to the market. The QP role was first established in 1975 and is important within EU legislation; it is unique to EU member states.

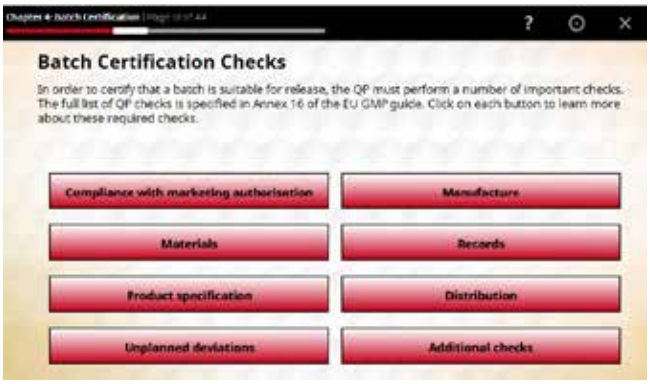
UL EduNeering's new course, **Role of the Qualified Person (PHA76)**, focuses on the EU regulations. The course, written by the experts at leading regulatory consulting firm EduQuest (www.eduquest.net) focuses on several EU regulations, most notably EU Guide to Good Manufacturing Practice, Annex 16, Certification by a Qualified Person and Batch Release, as well as Annex 13 (IMPs), Pharmacovigilance, and the EU Clinical Trials Directive.

The course explains that there is a QP defined within Annex 16 who is responsible for the system that monitors and responds to adverse reactions identified in medicinal products supplied to the market.

The EU law requires that the QP has obtained the necessary practical experience with at least two years experience with one or more authorised manufacturers of medicinal products.

Further, the QP needs to have gained experience in qualitative analysis of both medicinal products and active ingredients, and all the testing and checks required to ensure the quality of medicinal products.





EU Qualified Person Course Details:

PHA76 explains that the EU law requires that before a batch can be released, a QP named in the manufacturing authorisation must sign a register or equivalent document as a record that they have carried out a proper evaluation.

This record also ensures that if a product defect needs to be investigated or a batch needs to be recalled, the QP who certified the batch is readily identifiable.

Our EU-focused courses, including the new Qualified Person 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.
- EU Good Distribution Practices (PHDV75)
- 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.

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UL EduNeering is a business line within UL Ventures 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,