

QP Law and Administration



Course Overview

The Qualified Person (QP) must have a thorough knowledge and understanding of European and UK Laws related to the manufacture and distribution of medicinal products for human and veterinary use.

This course provides a comprehensive overview of the requirements of the UK Study Guide and, by using interactive questions and scenarios, shows how the Qualified Person or anyone with a responsible position within the pharmaceutical industry can keep up to date and assure compliance.

Suitability

An essential course for candidates who expect to apply for their QP Viva within one year. The course also provides a valuable contribution to Continuing Professional Development for existing QPs and all other managers or supervisors with responsibilities for manufacturing medicinal products.

For those not directly related to manufacturing, it provides a valuable overview of the regulatory framework by which medicines are controlled.

Learning Outcomes

By the end of the course you will know and understand:

- The UK laws and European Directives for the manufacture and distribution of medicinal products for human and veterinary use
- Clinical Trial Legislation
- Product and Site licensing in the UK and EU
- The role and structure of the EMA, MHRA & VMD
- Pharmacovigilance requirements
- The role of the pharmacopoeias and EDQM
- International harmonisation, ICH, PIC/S and Mutual Recognition Agreements



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