Roles and Duties of a Qualified Person

Course Overview

A Qualified Person (QP) must certify that each batch of medicinal product (for human or veterinary use) complies with its Marketing Authorisation or Clinical Trial Application, GMP and certain other requirements. Their conduct overall must comply with the Code of Practice for QPs.

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 can comply with the legal and operational requirements of the role.

Suitability

The module is essential for all candidates who expect to take the QP Viva. It forms a valuable contribution to Continuing Professional Development for those QPs who qualified some years ago.

Other Managers and Supervisors from within pharmaceutical manufacturing will benefit from attending this course as they will gain a thorough understanding of the relationship of the QP with their own role.

Learning Outcomes

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

- The legal responsibilities of a QP within the EU
- The Code of Practice for the QP
- The regulatory framework pharmaceuticals in the EU/EEA
- The certification process for a medicinal product according to Annex 16 and other applicable guidelines
- The QP and the Pharmaceutical Quality System
- How to deal with typical product problem situations
- The interpersonal skills associated with the role of the Qualified Person within the pharmaceutical industry

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