

Good Distribution Practice

 **Delivery:** Online, Inhouse

 **Duration:** 1 day

 **Cost:** £780 (+VAT)

Course overview

This intensive course provides an extensive and detailed introduction to Good Distribution Practices in the Pharmaceutical industry. Covering best practices with practical examples and an overview of the regulatory framework.

As you would expect, there is extensive reference to Directive 2001/83/EC, Directive 2004/27/EC, EU Guidelines on Good Distribution of Medicinal Products for Human Use 2003/C343/01 and the requirements included in the MHRA Orange/Green Guides. By attending you will gain a practical understanding of GDP and be in a position to implement against the current directives and guidelines.

Who should attend?

This course is suitable for those who are new to Good Distribution Practice for medicinal products as well as those who are looking for an update to their existing knowledge, in particular relating to the latest current regulations, whether you are Responsible Persons (RP), deputy RP, quality manager, auditor or regulatory/compliance personnel.

The course is aimed at any company that has, or is, considering obtaining an MHRA/EU Wholesale Distribution Authorisation (WDA) license, Also, wholesalers/distributors, manufacturers, pharmaceutical suppliers, brokers, service/transport providers and partners who carry out any GDP activities on behalf of license holders.

Course programme

The course covers the following topics:

- Overview of GDP regulations and framework
- GDP guideline overview, structure and content
- How to interpret and translate GDP into your everyday work
- The Pharmaceutical Management System (Quality Management System)
- Special attention aspects – storage and transport, cold chain or frozen products (biologicals), difficult situations
- Controlled Drugs
- Common issues and how to avoid them

Learning outcomes

The course is a highly interactive 'hands on' learning experience, by the end of which you will:

- Gain an understanding of GDP directives, guidelines & regulations
- Know how to interpret and translate GDP into your everyday work
- Be familiar with the requirements of your Pharmaceutical Management System (Quality Management System)
- Understand specific hot topics such as storage and transport, cold chain or frozen products (biologicals)
- Be familiar with able to handle Controlled Drugs
- Understand common inspection deficiencies and how to avoid them

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