good distribution practice fundamentals and inspections

Good Distribution Practice (GDP) is the standard set down in European Directives to which wholesalers of medicinal products must comply. GDP forms the basis of the Quality Management System operated by wholesalers. Since the revised EU GDP Guidelines were implemented in 2013, new challenges have arisen for the Pharmaceutical Wholesaling environment.

about the course

The course will be delivered over a period of two days with a visit to a wholesaling operation on each day to see the practical implementation of GDP.

Day 1 will include the basic requirements for GDP, focusing on the new legislation, how to apply for and maintain a wholesaler's authorisation and the minimum requirements required. Day 2 will focus on advanced aspects of GDP, including focus on the areas of responsibility for applicant and existing Responsible Persons.

who should attend

The course is suitable for those persons involved in wholesaling of medicinal products and for those wishing to strengthen their knowledge of the revised EU GDP Guidelines and legislation.

course content

day one

Basic GDP Requirements
Training
Establishing Bona Fides
Falsified Medicines
Contractual Agreements
How to apply for and maintain a Wholesaler's Authorisation
Wholesaler visit - DHL Supply Chain

day two

Advanced GDP (cold chain, parallel importing, exempt medicinal products, controlled drugs)
The Responsible Person
Current Hot Inspection Topics
Typical GDP Deficiencies
How to Prepare for and Survive a Regulatory Inspection
Wholesaler visit - United Drug

about the presenters

Paula Dillon is an ex-Inspector with the Irish Medicines Board, IMB (now the Health Products Regulatory Agency) and over 9 years of experience in the regulation of controlled drugs and GDP. Paula has represented Ireland at European and International level, including as a member of the GDP Drafting Group which was responsible for establishing the new GDP Guidelines.

Stan O'Neill is a qualified pharmacist and ex-Senior Inspector with the IMB, Stan has over 10 years of experience in the field of regulatory inspection. He has represented Ireland at European level for the negotiation of standards of inspection for medicinal products. He has also trained inspectors at Irish, European and International Level.

what else should I know

Course Fee: €650 per person for one day and €1000 for both days. The course fee includes all course material, lunch and refreshments. Please note that certain aspects of this course may also be organised on an in-house basis. Please contact us for further information.

how to apply

Applications can be made online at www.compliancegroup.eu or by emailing courses@compliancegroup.com

location and date

Day 1 will be based in the Carlton Dublin Airport Hotel.

Day 2 will be based in the Maldron, Newlands Cross, Dublin.