

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 this 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.

what else should I know

Course Fee: €750 per person for 1 day and €1250 for both days. The course fee includes all course material, lunch and refreshments. Please note that certain aspects of this course can be organised on an in-house basis. Please contact us for further information.

course content

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

session 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

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.

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 current EU GDP Guidelines and legislation.

Both sessions are suitable for applicant and existing RP's, though if an experienced RP was looking for a refresher, the second day may be sufficient.

how to apply

Applications can be made online at www.gxp.ie/training or by emailing training@gxp.ie

location and date

Day 1 will be based at the Carlton Hotel, Dublin Airport. Day 2 will be based in the Maldron Hotel Newlands Cross.