



Training Workshop Agenda

Workshop Title	Good Distribution Practices for Medicinal Products and Medicinal Product Ingredients
Duration	1 day
Venue	Worldwide, in company or public
Presenter	Aidan Madden BSc MSc Qualified Person, Certified Auditor, European Union Pharmaceutical Best Practices Expert
Training Company	www.fivepharma.com
Target Audience	<ul style="list-style-type: none"> • Pharmaceutical Industry staff including technicians, supervisors and managers and • Pharmaceutical Wholesalers • Responsible Persons • Qualified Persons • Logistics and Transport companies involved in the storage and movement of medicinal products
Learning Objectives	<p>Upon completion of this workshop, delegates will have a clear understanding of the relationship between Good Distribution Practice directives/guidelines and the design, qualification and management of the supply chain distribution processes. In addition this workshop provides insight in how to continually comply with competent authority inspection requirements and how to design, qualify and maintain temperature controlled transport processes. Furthermore, the attendees will get a basic insight into Brand Protection and anti-counterfeiting developments.</p>

Workshop
Contents

General Content

- The History of Pharmaceuticals
- The Major Regulators (FDA, EU, Japan)
- GDP Regulatory Legislation and Guidance
- Global Quality Systems Development
- ICH Quality Systems
- ICH Risk management
- EU GMP Quality Systems
- The Components of a GDP System
 - Introduction
 - Principle
 - Personnel
 - Training*
 - The Responsible Person*
 - Documentation
 - Procedures*
 - Records*
 - Managing Contracted Services
 - Transport Companies*
 - Driver Training*
 - Contractor Assessment*
 - Other Contracted Service providers*
 - Sourcing and Selling products
 - Bona Fides of Suppliers*
 - Bona Fides of Customers*
 - Responsibility for the wholesaler and the pharmacy*
 - Premises and equipment
 - Receipt*
 - Temperature Mapping*
 - Temperature Monitoring*
 - Storage*
 - Deliveries to customers
 - Temperature mapping (Shipping Lane Validation)*
 - Temperature Control*
 - Product labelling*
 - Shipping Containers*

Vehicles and Equipment

Returns

Dealing with Returns

Product recalls

Self inspections

Managing the Self-inspection programme

Internal Auditor Training

Performing Self-inspections

Corrective Actions plans

Special Topics

- Product Complaints
- Product Recalls
- Counterfeiting

Workshop Team Exercises:

- A series of scenarios are presented to the delegates. Each scenario describes a problem(s) identified in an EU based wholesaling operation by either a self inspection or a regulatory audit.

Quiz Content:

- A series of quizzes are presented based on delivered content, delegates work in groups to answer the questions
- Questions are then discussed and corrected

Assessment of Learning Outputs from this Workshop

- The Quizzes described above will be signed by delegates and corrected and countersigned by the tutor as evidence of this requirement.