

GDP – Responsible Person

1-day training

This training aims to provide a useful insight in the current regulations regarding the storage, transportation and distribution of pharmaceutical products. The training covers the most important elements of the EU GDP Guideline and the most recent changes. The training provides a practical explanation of the guideline and several suggestions for its practical implementation. During the course of the training, a variety of practical examples will be discussed and there will be much room for questions and answers. The trainers all speak from experience.

Target audience

This training is designed for Responsible Persons and other managers, supervisors and staff members who are involved (directly or indirectly) in the storage, transportation and distribution activities of pharmaceutical products. Participants are expected to have some prior GDP knowledge and experience.

Subjects/Approach

During this training we will explain and discuss the EU GDP guideline in theory, however the main focus will be on the practical implementation of the guideline and the responsibilities of the Responsible Person. The training will be completed with an exam.

PROGRAMMA

GDP Regulations

Laws and regulations
Licenses
EU Guideline 2013/C 343/01
What's new in the revised GDP Guideline?

Personnel & Responsible Person

Responsibilities

Quality Management System

GDP Quality system
Outsourced activities
Management review
Complaints, recalls
Deviation control, CAPA
Change control
Self-inspections

Risk Management, qualification & Validation

Risk Management within the EU GDP Guideline
Risk analysis
Qualification of suppliers and customers
Validation within the EU GDP Guideline

Receipt & Storage

Receipt
Traceability
Status control, returns

Delivery & Transport

Delivery and transport requirements
Cold-chain

Falsification of medicinal products

Risks and responsibilities

Number of participants: at least 5 and up to 12 **Training times:** 09.00 AM till 05.00 PM (lunch included)

Location: Hoevelaken (Pharmatech trainingfacility) **Sign up:** www.pharmatech.nl