Training

GDP
Good Distribution Practice

To ensure the quality of medicines in the distribution chain from manufacturer to patient, manufacturers, importers and wholesalers must comply with the Good Distribution Practice Guideline (2013/C 343/01) since 2013. Employees involved in the distribution process must have the right experience and knowledge in GDP for this purpose. This training provides the basic knowledge required.

Classroom | MBO/ HBO | 1 day | Hoevelaken

Approach

GDP - Good Distribution Practice is an interactive training at mbo-hbo level. During this training we pay a lot of attention to the risks for product quality in the distribution of medicines. We also discuss the legal framework, regulatory requirements and recent developments. We teach participants how to set up a quality management system and its main components. We also discuss the importance of documentation, points for attention in case of returns, recalls and the principles of the Rapid Alert System, risk management, validation and monitoring.

Target Audience

- Employees directly or indirectly involved in the storage and or transportation of medicinal products.
- If you work as a Responsible Person or intend to start doing so, we recommend you to participate in the training GDP - Responsible Person.

This training is also available in Dutch.

View the agenda and register via this QR code

Program

Introduction of GDP-regulations
- Laws and regulations governing medicinal products
- Licensing system
- EU guideline 2013/C 343/01
- Recent developments

GDP-Kwaliteitssysteem
- Key elements including Self-inspections, deviations, CAPA, Change control
- Complaints and recall, risk management

Temperature controle during storage and transport
- Cold Chain, storage temperature control
- Transport temperature control, validation and monitoring of temperature conditions

Warehouses, receipt and delivery of medicinal products
- Warehouse layout, receiving, storage, delivery, return goods

Qualification of customers and suppliers
- Qualification system, process and importance of customer qualification

Outsourcing activities
- Responsibilities, agreements, outsourcing of transportation

Falsified medicines
- EU-directive 2011/62/EU 'Falsified Medicines Directive' (FMD)