Training

GDP
Responsible Person
Follow-up

Have you followed Pharmatech's GDP-RP training in the past, and do you need to refresh your knowledge and deepen your understanding of a number of topics? This training complements our successful GDP-RP training. How has the GDP Directive developed? What is the importance of risk management within a GDP quality system? How can we apply validation in practice? What are the consequences of serialisation for a wholesaler/distributor? What developments are there to prevent the falsification of

Classroom   HBO+   1 day   Hoevelaken

Approach

Eudra-GMDP database, international GDP Certificates, counterfeit medicines, risk mangement, ICH Q9, validation storage and tranport, serialisation, GDP for API's, transport temperature control, mapping, ambient transport, softwarevalidation, GAMP5, QMR.

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 and if possible followed the GDP-RP training.

This training is also available in Dutch.

Program

❯ **GDP and RP: developments and responsibilities**
- Recent development - points for attention
- International GDP Certificates
- Risk management of the logistics process
- Temperature control during transport
- Introduce serialisation in EU as of Feb. 2019
- Definitive use of Eudra GMDP-database for supplier and customer monitoring
- GDP fo active commodities
- The (changing) role of RP

❯ **Case study regarding responsibilities**

❯ **Validation and Qualification**
- Validation principles
- Validation in practice
- Qualification of refrigerated storage
- Mapping of a Warehouse
- Software validation (GAMP 5)

❯ **Quality Risk Management (QRM)**
- ICH Q9, Quality Risk Management tools
- Application QRM within GDP

❯ **Workshop**
- Risk analysis

View the agenda and register via this QR code