

Webinar

GDP Responsible Person

To ensure the quality of medicines in the distribution chain from manufacturer to patient, manufacturers and wholesalers must comply with the Good Distribution Practices guideline (2013/C 343/01) since 2013. The RP (Responsible Person) is responsible within the company for implementing and complying with this guideline(s). An RP must have specialist knowledge in the field of GDP in order to fulfil his or her task properly.



Approach

This webinar 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 prior GDP knowledge and experience.

Target Audience

GDP – Responsible Person is a training given at HBO+ level. The key elements of the GDP regulations and the design of a quality management system for GDP. The responsibilities and tasks of the Responsible Person, the importance of documentation, application of risk management, outsourcing activities, validation, continuous improvement and dealing with counterfeit medicines.

The training concludes with a test. The participant will receive a certificate when the test is finished with a passing grade.

[*This training is also available in Dutch.*](#)



View the agenda
and register via
this QR code

Program

Session 1

- GDP Regulations**
 - Laws and regulations
 - Licenses
 - EU Guideline 2013/C 343/01
- Personnel & Responsible Person**
 - Tasks and Responsibilities
 - Various cases
- Quality Management System**
 - The GDP quality management system
 - Outsourced activities
 - Management review
 - Complaints, recalls
 - Deviation control, CAPA, Change control
 - Self-inspections
 - Risk Management

Session 2

- Falsification of medicinal products**
 - Risks and responsibilities
 - Falsified Medicine Directive
 - Serialization and safety features
- Receipt & storage**
 - Receipt
 - Traceability, Status control, returns
 - Qualification of suppliers
- Delivery & transport**
 - Delivery requirements
 - Qualification of customers
 - Cold-chain

Test