‘GDP for logistic employees’

After completion of this course you can:

- describe what the term medicine contains;
- describe the applications for which medicines are used;
- name the difference between a generic medicine and a speciality medicine;
- indicate how to recognise a medicine;
- name where and how medicine is available in the Netherlands;
- explain why medicines are being registered with the government;
- describe what a counterfeit medicine is;
- indicate what measures can be taken to prevent counterfeit drugs from entering the legal circuit;
- indicate the average time it takes to develop a medicine from an active ingredient;
- explain how medicines are classified (therapy, therapeutic effect, route of administration, pharmaceutical form);
- name the differences between local and systemic effect of medicines;
- describe the route that an oral medicine (= administered by mouth) takes in order to be absorbed into the body;
- name the process steps involved in the production of tablets;
- describe which laws and regulations apply to medicine;
- name the laws and regulations that are applicable to the distribution of active substances and medicines;
- describe what is meant by GDP;
- explain whom GDP rules are designed for;
- explain why GDP is important;
- identify the risks involved in the distribution of active substances and medicines;
- describe what a counterfeit medicine is;
- describe the purpose of the quality system;
- name the steps in the deviation procedure;
- explain why changes are recorded;
- describe the aspects of Good Documentation Practices;
- name the roles and responsibilities of the Responsible Person (RP) / Designated Person (DP);
- describe the important issues when receiving active substances and medicinal products;
- describe the procedure for dealing with returned goods;
- explain the requirements for storage areas for medicines and active substances;
- identify the different storage conditions;
- describe how storage conditions can be controlled;
- indicate which different statuses we distinguish and when which status applies;
- explain what FEFO is;
- name the important issues when shipping medicines;
- identify who is responsible for the transport of medicines;
- describe the requirements for a truck transporting medicines;
- explain what is meant by Cold Chain;
- identify the factors involved in monitoring the Cold Chain;
- name two different methods of refrigeration;
- explain what a data logger is and what it is used for;
- explain the importance of medicines and active substance traceability;
- describe what a recall is;
- describe who is ultimately responsible for GDP compliance when outsourcing activities.