

GMP:READY - Specialist Knowledge GDP Compact (Bundle 11 A+B)

The screenshots are excerpts from the [Online Course GMP:READY – Specialist Knowledge GDP Compact](#)

5 min
reading
time

With this e-learning course you can get familiar with the topic of **Good Distribution Practice (GDP)**!

The aim is to explain the GDP-Regulation principles in a quick and sufficient way.

With many day-to-day examples you will get an easy access to expert knowledge: Your personal experience will be interactively linked to GDP specific aspects. This **knowledge transfer** makes it easy for trainees to remember subject matters. **Demanding exercises** improve the learning process of the concentrated knowledge. The content gives **concrete instructions** for your work.

Important aspects are the GDP regulations, qualification and validation, documentation, recording, responsibilities and behaviour at deviations.

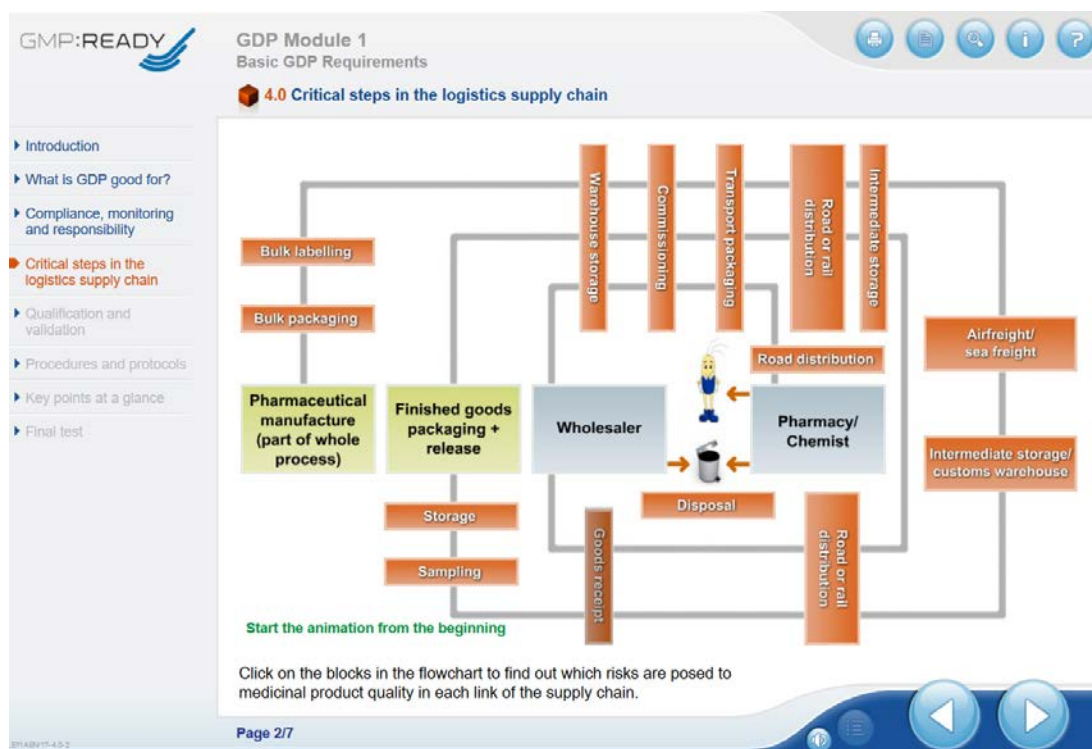
In **Part A “Basic GDP Requirements”** you will familiarise yourself with the basic requirements for the transport and storage of pharmaceuticals.

In **Part B “New Focus of the GDP Guidelines”** you will get to know the focal points of the new EU-GDP guidelines.

Today you have the exclusive chance to look at some screenshots from the e-learning course:

GMP:READY GDP Module 1

Basic GDP Requirements



Example exercise

Task: 1/1

Different events can occur during distribution and storage which may have serious consequences for the quality of medicinal products. Match the terms:


Print on label on the transport packaging illegible	Plugs are pressed out of pre-filled syringes, sterile packages burst
Maximum stacking height exceeded, impact or fall	Counterfeit, inferior material is introduced
Air freight: Pressure fluctuations in the cargo hold	Goods incorrectly booked in system, subsequent mix-up during commissioning/dispatching
Subcontractor performed interim storage of medicines at a non-qualified location	Goods exposed to uncontrolled conditions: humidity, heat, pests, unauthorized access
Return of goods from non-decipherable recipients	Excessive cooling leads to degradation of ointments and crystallisation of vaccines
Too many cool packs in the thermo transport box	Hairline cracks or rupture of ampoules, burst tubes

Learning unit 11A (GDP) OK


GMP:READY GDP Module 1 Basic GDP Requirements

5.0 Qualification and validation


Qualification



[Warehouse spaces](#)



[Transport packaging](#)



[Vehicles](#)

Warehouse spaces, [transport packaging](#) and vehicles must be qualified before they are used in the distribution of medicines – and the result must be provided in written [qualification reports](#).

At first it is necessary to define the precise area of application, such as for which products ([cool goods](#)?, which temperature range?) which minimum and maximum amounts and for which duration of storage and distribution.

Using a [risk assessment](#) it is then necessary to evaluate if detriment to quality as a result of a device or system failure or improper usage can be detected readily before patients are impacted.

What exactly needs to be tested as part of a specific qualification depends on this risk assessment.

You can see typical test items for a qualification by clicking on the pictures.

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GMP:READY GDP Module 2

New Focus of the GDP Guidelines





GDP Module 2
New Focus of the GDP Guidelines

2.0 Why are GDP requirements getting stricter?

- ▶ Introduction
- ▶ Why are GDP requirements getting stricter?
- ▶ Quality management made tangible
- ▶ Responsible Persons and management responsibility
- ▶ Authorisation and certification
- ▶ Particular risks in the logistics chain
- ▶ Key points at a glance
- ▶ Final test



Additional information

Why are the requirements placed on the warehouse storage and distribution of medicines getting stricter all the time?


Today it is completely normal that goods of all types are produced in completely different places, are then processed further somewhere else and then distributed and sold around the entire globe. The potential resulting loss in quality is often condoned for the sake of low prices.

Cost pressure in the field of health care has led to the spread of pharmaceutical intermediates and finished products manufacturing to different locations by third parties locally and abroad. By the time they make it to the patient, the medicines often have a convoluted distribution route behind them.


Many of the people involved in this chain do not know how sensitive medicines can be and they treat them like any other standard goods.


Unfortunately as a result in recent times, patient's health has suffered again and again, even fatally, as a result.


Outsourcing and globalisation make it necessary to know exactly how the supply chain for medicines is set up and to check it regularly in both directions (sourcing, traceability).



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GDP Module 2
New Focus of the GDP Guidelines

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Outsourcing: Why do it yourself if there are specialists available?


Activities which are outsourced to contractors can also influence the quality of medicines directly or indirectly.




Consultants




IT-Services




HVAC




Shipping



Office and Archiving Services



Calibrations




Facility Cleaning, Pest Control

That is why the GDP Guidelines make it clear:

The buyer of the services remains responsible for the outsourced activities.

Click on each of the persons to find out how the various contractor takers can influence the quality of medicines.

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Example exercise

Task: 1/1 LE11B, U01.2

When outsourcing activities in the field of GDP, contract giver and contract taker have clear responsibilities. Which responsibilities belong to which party?


	Contract giver	Contract taker
Activities are performed and documented precisely according to contract and all deviations reported.	✓	✓
Provide appropriate rooms, qualified equipment and trained personnel.	✓	✓
Collect and store all the incident information regarding the task and product during the contract period.	✓	✓
Responsibility for the outsourced activity.	✓	✓
Inspect to ensure that the contractor provides technical expertise, qualification and applicable authorisations.	✓	✓
Before an order is placed all the necessary information is provided about the task and the product.	✓	✓


LE11B - GDP Guidelines TP OK


GMP:READY GDP Module 2
New Focus of the GDP Guidelines

3.0 Quality management made tangible

Change Control

Define and implement actions  Whether there are plans for a new building or for leasing additional warehouse space, whether customer's desires or new legal requirements are to be met – upgrades to facilities and equipment or modifications to defined work processes are necessary time and again. What is important is that all of these **changes**, modernisations and optimisations are registered and documented without exception.

Assess changes  Every change must be assessed with regard to potential impact on medicine quality – according to internally defined procedures (**SOP**), optimally by a team and with the support of a **risk assessment**. For **planned changes** the assessment must be made **before implementation** of the change!

Register all changes  Small changes often result in large amounts of effort, but sometimes it "only" requires an update to an SOP or work instruction. In any case, an action plan including all the required measures must be defined and implemented before the change is approved.

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GMP:READY GDP Module 2
New Focus of the GDP Guidelines

4.0 Responsible Persons and management responsibility

Leaders in the field of pharma-logistics

Managing directors Responsible Person Every individual employee

For each site or warehouse a **Responsible Person** is to be named by the **wholesale distributor**, who bears personal responsibility for the fulfilment of **GDP** principles.

The precise tasks and responsibilities assigned to a **Responsible Person** must be documented in writing (job description) by the company. The person performing this role must be able to prove they are in possession of the necessary competence and experience and must also have a competent deputy.

A Responsible Person is allowed to delegate tasks, but not the ultimate responsibility.

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GMP:READY GDP Module 2
New Focus of the GDP Guidelines

6.0 Particular risks in the logistics chain

Distribution of medicinal products: out of sight for just a moment... damaged forever?

Although distribution time periods are relatively short compared to medicinal product shelf lives, these short periods are adequate to cause sufficient damage which can lead to premature spoilage of the medicine before the printed date of expiration – without the patient being able to know!

That is why the requirements for the distribution of medicinal products have gotten much more stringent:

Regular calibration of temperature monitoring devices	Delivery exclusively at the recipient address to the actual addressee	Special security measures for service providers or interim storage
Transport deviations must be reported to the originator and the recipient and must be investigated	Handling of temperature deviations always according to SOP	Qualification, maintenance and cleaning of vehicles and equipment
Transport conditions = storage conditions!	Risk based distribution planning, assessment of distribution routes	Proof that medicinal products were not exposed to harmful conditions

The wholesale distributor delivering the product bears responsibility for the prevention of harm to the medicinal product during transport, i.e. prevention of breakage, adverse effects, theft and conditions beyond the limits given by the manufacturer on the package.

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