

Online Course 11A+B: GMP:READY Specialist Knowledge GDP Compact

Learning Goal:	Familiarizing with the significant GDP regulations
Target Audience:	Decision-makers in the field of storage and transport, lateral entrants, refresher
Personal Certificate:	After successfully completing the final test

Concept:

The transfer of the principles of the GDP regulation is the key objective.

By a variety of everyday examples, the entrance into the topic is simplified. You recognize that you bring in a lot of knowledge from your life experience in order to use it for GDP-specific aspects. By this knowledge transfer the topic is kept very simply in mind. In order to internalize the compressed knowledge, this course unit was filled with many demanding exercises. These exercises show concrete instructions that you can apply directly at the workplace.

Important aspects are the GDP regulations, qualification and validation, recording, responsibilities and way of dealing with deviations.

Technical Information:

You can easily access the e-learning tool GMP:READY – GMP for Engineers on the internet via user name/password.

Important: User name and password will be set up for the designated trainee. End-user has to be specified when placing the order!

The course is displayed on the internet via FIT² Coach.

Content:

In **Part A „Basic GDP Requirements“**, you will get in touch with the basic requirements of transport and storage of medicinal products.

Chapters:	7	Summary:	1
Exercises:	7	Final Test:	1

Learning Component 1: Introduction

- Welcoming address
- Everyday example: Careful case packing
- Transport and storage und Lagerschäden bei pharmazeutischen Produkten
- Overview of the course unit

Learning Component 2: What is GDP good for?

- Everyday example: The right preparation for an aircraft take-off
- Quality deviations for drugs
- Are today's storage and transport requirements justified?
- Exercise: Which deviations can occur and how?

Learning Component 3: Compliance, Monitoring and Responsibility

- Trust alone is not enough
- Monitoring compliance
- Who's in charge?
- Exercise: Assessment of non-compliance with internal regulations

Learning Component 4: Critical Steps in the Logistics Supply Chain

- From the drug manufacturer to the patient
- Animation: Risks of the individual steps for drug quality
- Labelling, identification and avoidance of confusion
- Influence of packaging material and storage conditions on shelf life
- Storage and transport requirements

Learning Component 5: Qualification and Calibration

- requalification
- transport validation
- calibration
- Exercise: Consequences of using equipment without qualification
- Exercise: GDP requirements for EDP systems

Learning Component 6: Procedures and Protocols

- What are SOPs for?
- Differences between regulations and protocols
- Electronic data acquisition
- Behaviour in the event of deviations
- Traceability and archiving
- Exercise: Rules for keeping minutes
- Exercise: Rules for corrections

Learning Component 7: Key points at a Glance

- Exercise
- Summary of the course unit

Final Test

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

Chapters:	7	Summary:	1
Exercises:	6	Final Test:	1

Learning Component 1: Introduction

- Welcoming address
- Everyday example: Obsolete technology
- Overview of the course unit

Learning Component 2: Why are GDP Requirements getting stricter?

- Why storage and transport requirements are becoming increasingly stringent
- Outsourcing: tasks of the client and contractor
- Delimitation of responsibility agreement
- Exercise: Obligations of contractors

Learning Component 3: Quality Management made tangible

- Everyday Example: Travel Planning
- Requirements for the quality management system
- Control of changes - Change Control
- Follow-up after changes
- Exercise: What are the considerations in quality risk management?
- Exercise: Deviation, Change, Quality Deviation or GMP Deviation

Learning Component 4: Responsible Persons and Management Responsibility

- The individual responsible persons
- Responsible Person and Qualified Person

Learning Component 5: Authorisation and Certification

- Official permission as a basis for trust
- Control is safer
- Qualification of suppliers
- Everyday example: Does the driving licence guarantee a good driving style?
- Marketing Authorization
- Exercise: Identifying differences between permits and evidence

Learning Component 6: Particular Risks in the Logistics Chain

- Control steps at goods receipt
- Requirements for the transport of medicinal products
- Outsourcing of transports
- Import and Export
- Export to third countries

- Returns, complaints and recalls
- Counterfeit drugs
- Exercise: Correct behaviour with counterfeits, returns, complaints, etc.

Learning Component 7: Key Points at a Glance

- Exercise
- Summary of the course unit

Final Test