

## Online Course 12 A „GMP Basics for Technology & Engineering“

<b>Belonging:</b>	GMP for Engineers
<b>Learning Goal:</b>	Learn the relationship between GMP requirements and the lifecycle of a technical system. You will learn about the life cycle of a system, which documents are needed, what the elements of qualification are and much more.
<b>Target Audience:</b>	Project managers, technicians and engineers responsible for planning, operation or for qualification, operators, quality assurance
<b>Processing Time:</b>	Approx. 45 min.
<b>Personal Certificate:</b>	After successfully completing the final test

### **Concept:**

The course unit gives engineers, technicians and non-technicians a good overview of the regulatory GMP requirements.

Included is a brief explanation of necessary qualification and validation activities during the equipment lifecycle. The relationship between GMP requirements and the lifecycle of a technical system is clearly illustrated.

### **Content:**

- 9 Chapters
- 2 Exercises
- 1 Summary
- 1 Final Test

#### *Learning Component 1: Introduction*

- Welcoming address
- What does GMP mean?
- Overview of the course unit

#### *Learning Component 2: Legal Fundamentals*

- When is it necessary to comply with GMP requirements?
- GMP requirements protect people and animals
- GMP is a worldwide standard!
- Everyday Example
- Regulations worldwide
- EU GMP guidelines
- Code of Federal Regulations (CFR) and FDA Guide to Inspections

#### *Learning Component 3: The Engineer's Language*

- Technical Documentation
- Worldwide requirements for technology
- Exercise

*Learning Component 4: Life Cycle*

- Life cycle phases

*Learning Component 5: Qualification and Validation*

- Definition of terms
- Qualification activities
- Four steps: DQ, IG, OQ, PQ
- Aims

*Learning Component 6: Planning*

- Everyday Example
- Important aspects
- Deviate from standard patterns of thought

*Learning Component 7: GMP-Compliant Design*

- Required documents
- Requirements
- Source

*Learning Component 8: Installation & Commissioning*

- Factory Acceptance Test (FAT)
- Exercise
- Site Acceptance Test (SAT)
- Repetition of tests
- Procedure during commissioning (IBN)
- Test points during qualification

*Learning Component 9: Production*

- Process Validation
- Quality must be produced
- Performance qualification
- Cleaning validation
- Other necessary activities
- Change control
- Decommissioning

*Learning component 10: Key Points at a Glance*

- Exercise
- Summary of the course unit

*Final Test*

**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 FIT<sup>2</sup> Coach.