

## Online Course 12 B „From the Planning Stage to Functional Testing“

<b>Belonging:</b>	GMP for Engineers
<b>Learning Goal:</b>	Experience the GMP-relevant aspects in detail, from facility planning and design qualification to functional testing at the supplier's and on site. This enables you to set up projects correctly right from the start.
<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:**

In this course unit you will learn more about the individual steps during the planning of facilities and equipment - from design qualification to functional tests at the supplier's and on site. This allows you to set up projects correctly right from the start!

The design of machines in a GMP-regulated environment must take into account special requirements that cannot be found in any other industry.

A clear definition of responsibilities and adherence to procedures are essential if a project is to be successful regardless of its size.

### **Content:**

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

#### *Learning Component 1: Introduction*

- Welcoming address
- Everyday example
- Overview of the course unit
- Main actors / responsibilities
- Life cycle of a technical system

#### *Learning Component 2: GMP Requirements for Planning Phase*

- Steps in planning
- GMP requirements for planning
- Technical terms

#### *Learning Component 3: User Requirement Specifications (URS)*

- URS vs. specifications
- Regulatory requirements
- Exercise



*Learning Component 4: Functional Design Specification/Offer*

- From the requirements specifications to the invitation to tender
- The functional design specifications in the offer
- The functional design specification as a planning document

*Learning Component 5: GMP Risk Analysis*

- Risk-based approach
- Introduction of the QRM process
- Different types of risk analysis
- Determination of risk priority number (RPN)
- Exercise
- Analysis of the GMP status

*Learning Component 6: Design Qualification*

- Avoidance of planning errors
- Design qualification = 1st qualification step
- Development of a design qualification

*Learning Component 7: Factory Acceptance Test (FAT)*

- How, where and when does the FAT take place?

*Learning Component 8: Site Acceptance Testing (SAT)*

- Exercise

*Learning Component 9: 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.