



Online Course 12 E „Design Principles and Technical Documentation“

Belonging:	GMP for Engineers
Learning Goal:	Discover more about the aspects that need to be considered when planning and designing pharmaceutical rooms and facilities. Find everything you need to know about technical requirements, clean rooms and hygienic design in this course unit.
Target Audience:	Project managers, technicians and engineers responsible for planning, operation or for qualification, operators, quality assurance
Processing Time:	Approx. 45 min.
Personal Certificate:	After successfully completing the final test

Concept:

In this course unit, you will get to know more about the aspects that have to be considered when planning and designing pharmaceutical rooms and facilities. Important keywords that you will find here are "clean rooms" and "hygienic design". As patients, we are glad that we can rely on the quality of the pharmaceuticals. Enormous technical requirements have to be met. What these requirements are and how they can be fulfilled is explained to you in this course unit.

Content:

8 Chapters
2 Exercises
1 Summary
1 Final test

Learning Component 1: Introduction

- Welcoming address
- Everyday example
- Overview of the course unit
- Sources of contamination

Learning Component 2: Layout Principles

- Product properties and manufacturing processes
- Everyday example
- Cleanroom areas
- Design approaches for the material flow



Learning Component 3: Cleanroom Classification

- Cleanliness zone concepts
- Different work steps in the clean room Grades A to D
- Sluices
- Requirements for microbiological air purity
- Requirements for sluices
- Exercise

Learning Component 4: Walls, Ceilings, Floors

- Everyday example
- Different variants of ceiling systems
- Different variants for walls
- Execution of the floors
- Cleaning the transitions

Learning Component 5: Hygienic Design

- Everyday example
- Definitions of terms and guidelines
- The area in contact with the product
- Hygienic design of systems
- Inseparable joints
- Exercise

Learning Component 6: Materials

- Importance of materials in the GMP environment
- Stainless steel
- Synthetic materials
- Lubricants and sealing materials

Learning Component 7: Technical Documentation

- Scope and structure
- Description of contents
- Example checklist

Learning Component 8: 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 FIT² Coach.