Specialist Knowledge GMP for Engineers

The Package "Specialist Knowledge GMP for Engineers" includes:

Online Course 12A: „GMP Basics for Technology & Engineering"

Learning Goal: 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.

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:
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

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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

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

Learning Goal: 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.

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 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.

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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

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Online Course 12C: „From Functional Testing to Handover“

Learning Goal: You will gain important knowledge about the individual phases of the qualification of a facility. This includes computer validation, how tests and documentation have to be designed and what has to be considered when handing over the equipment to the operator.

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:
You will receive important information about the individual phases of the qualification of a system. This includes computer validation, how tests and documentation have to be designed and what has to be considered when handing over the system to the operator. With the help of the qualification it shall be shown that the equipment and facility used is suitable for the planned purpose. Qualification activities are therefore always associated with many tests and trials in the individual phases.

Content:
9 Chapters
2 Exercises
1 Summary
1 Final test

Learning Component 1: Introduction
- Welcoming address
- Everyday Example
- Overview of the course unit
- Qualification activities in the individual planning phases

Learning Component 2: Qualification Fundamentals
- Elements of qualification (IQ, OQ, PQ)
- Regulations
- Validation/qualification master plan (VMP/QMP)
- Risk analysis determines the scope of qualification
- Acceptance criteria

Learning Component 3: Documentation of the Qualification
- Contents of a Documentation
- The qualification report
- Variants of the four-eyes principle

Learning Component 4: Installation Qualification (IQ)
- Conformity of technical documentation and planning with reality
- Individual steps of installation qualification
- Typical Elements of an Installation Qualification

Learning Component 5: Operational Qualification (OQ)
- Conformity of the functionality with the requirements from the specification sheet
- Typical functional qualification tests
- Deviation lists and work instructions
- Initial calibration, test equipment, testing

Learning Component 6: Performance Qualification (PQ)
- Correct interaction of several systems
- Exercise
- Requirements for a performance qualification

Learning Component 7: Qualification of Computerised Systems
- Regulatory Basics
- Consideration of GMP-compliant processes
- The V-model
- Acceptance test/system test/integration test
- System environments
- Whitebox and blackbox testing

Learning Component 8: Handover to the Operations
- Procedure

Learning Component 9: Key Points at a Glance
- Exercise
- Summary of the course unit

Final Test

Online Course 12D: „Maintenance and Operational Support“

Learning Goal: Find out about preventive maintenance, the procedure for deviations, changes and CAPA as well as the topics of requalification and GMP-compliant documentation during operation.

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 learn more about preventive maintenance, the procedure for deviations, changes and CAPA and the topics of re-qualification and GMP-compliant documentation during plant operation.
Even with a pharmaceutical facility, it is necessary to take regular action to avoid wear and tear and to carry out necessary modifications and maintenance work to maintain the target condition. Only regularly maintained systems and equipment fulfil the intended purpose, i.e. are in a qualified condition.
A maintenance concept should contain an optimal mixture of failure elimination, preventive, condition-oriented, predictive and risk-based maintenance in order to ensure maximum availability.
Data integrity is also a central element of the pharmaceutical quality assurance system. The importance is reflected in regulatory documents of the WHO, MHRA, EMA and FDA and is summarized in this course unit.

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Content:
9 Chapters
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Learning Component 1: Introduction
- Welcoming address
- Everyday example
- Overview of the course unit
- Life cycle of a facility / operation of a facility during production
- External factors

Learning Component 2: Preventive Maintenance
- Maintenance measures and regulations
- SOPs
- Various areas
- Everyday Example

Learning Component 3: Calibration and Recalibration
- Definitions of terms
- Exercise
- Master SOP

Learning Component 4: Requalification
- Why does the qualification have to be repeated?
- When must the qualification be repeated?
- Interaction of different tools for maintaining the qualification status

Learning Component 5: Deviations, Changes and CAPAs
- Change management (change control)
- Divergences
- CAPA process

Learning Component 6: GMP Compliant Documentation
- Two fundamentally different types of documents
- Exercise

Learning Component 7: Traceability
- ALCOA principle
- Traceability matrix

Learning Component 8: Limitation of Liabilities
- Limitations of Liability (LLA)
- What does the LLA must include?

Learning Component 9: Key Points at a Glance
- Exercise
- Summary of the course unit

Final Test

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Online Course 12E: „Design Principles and Technical Documentation“

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 on the Internet via user name/password - whether using a desktop PC, smartphone or tablet.
User name and password are set up for the delivery recipient specified in the order.
No installation of additional programs or the use of external storage media is necessary.