Online Course 12 D „Maintenance and Operational Support“

Belonging:	GMP for Engineers
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.

Content:
9 Chapters
2 Exercises
1 Summary
1 Final test

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

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.