LOGFILE Feature 45/2023

GMP Question of the Week: Top 15 in 2023

Every week we publish interesting questions and answers about GMP in our column GMP Question of the Week. Today we have compiled the most clicked questions of this year (as of November 2023).

Browse the Top 15 and refresh your knowledge!

Detailed information on each topic can be found in the GMP Compliance Adviser, the world's largest reference work on quality management in the pharmaceutical industry.

1. Which persons are responsible for storage in the GMP or GDP area?

In a GMP environment, the responsibility for storage and the definition of the storage conditions, together with the Head of Quality control, lies with the Head of Production, whereas in the GDP environment it is the responsibility of the Responsible Person for GDP.

(GMP Compliance Adviser, Chapter 16.A)

2. What do inspectors of premises and rooms pay particular attention to?

The proper condition of the operating premises is subject to regular inspection by the competent GMP supervising authority. During the plant inspection, attention is paid to plant hygiene, labelling, storage conditions, and personnel and material flows. The utility systems essential for rooms are also regularly examined during the site inspection.

(GMP Compliance Adviser, Chapter 3.A)

3. What is an alert limit?

Alert limit: A pre-determined parameter value slightly outside the usual tolerance band. As soon as it is exceeded, monitoring must be intensified according to a predefined action plan.

(GMP Compliance Adviser, Chapter 3.K)

4. What is the difference between the clean up period according to Annex 1 and the recovery time according to ISO 14644-3?

The clean up period corresponds to the time required to get from the "in operation" state to the "at rest" state. The recovery time is the time required to reduce the (artificially introduced) particle concentration down to 1% of the starting value.

(GMP Compliance Adviser, Chapter 3.I)

5. In outsourcing, who is responsible for the quality of the medicinal products produced?

In principle, a marketing authorisation holder (MAH) may delegate all obligations under pharmaceutical law to third parties. However, the commissioning of third parties with certain activities does not release the MAH from his final responsibility for these activities: He remains responsible for the quality of the manufactured medicinal products even if he has them manufactured or tested in whole or in part under contract.

(GMP Compliance Adviser, Chapter 1.L)

6. When is a determination of the conductivity useful in cleaning validation?

Ionic components are detected using conductivity tests. The method is therefore suitable for the detection of alkaline or acidic detergent residues and is performed as a limit value test.

(GMP Compliance Adviser, Chapter 8.G)

7. What is the difference between cleanroom class and air cleanliness grade?

A cleanroom class is not only defined by the air cleanliness grade. For the definition of a cleanroom, several points have to be considered already in the design.

(GMP Compliance Adviser, Chapter 3.D)

8. What is the purpose of a responsibility matrix?

A responsibility matrix is used to delineate the duties of the contract giver and the contract acceptor in outsourcing. It is important that a responsibility is assigned to one party only, to avoid overlapping and confusion about who is responsible for what. If a task is assigned to both sides, it is possible for the responsible party to blame the other side. In

addition, a task should not be specified if it has not been assigned to one of the two parties as this would lead to responsibility gaps.

(GMP Compliance Adviser, Chapter 1.L)

9. What is the validation of a computerised system?

Validation is the documented evidence that the computerised system to be validated meets the requirements for the specified purpose in the operational business, with the specified reliability, and under the specified conditions (environment, processes, people).

(GMP Compliance Adviser, Chapter 9.E)

10. What are the elements of a computerised system?

A computerised system consists of the hardware, software, and network components, together with the controlled functions and associated documentation.

(GMP Compliance Adviser, Chapter 9.E)

11. What is the qualification of a computerised system?

Qualification is the documented proof that the computerised system to be qualified is suitable for the specified tasks in the company's infrastructure.

(GMP Compliance Adviser, Chapter 9.E)

12. When is qualification required for rooms and air handling units and when is technical acceptance testing sufficient?

The qualification should be limited to aspects and parameters which have significant impact to product and personal safety according to the risk assessment; for all others, which are required for proper technical functioning of the premises and air handling units, technical acceptance testing according to GEP is sufficient.

(GMP Compliance Adviser, Chapter 3.J)

13. What is rouging and how do you deal with the problem?

Rouging is a surface phenomenon that occurs frequently in water treatment plants. Moderate rouging has no adverse effect on water quality, but appropriate monitoring measures should be established. Various chemical and electrochemical methods are available to remove rouge deposits.

(GMP Compliance Adviser, Chapter 5.E)

14. What are the concepts for protecting clean work areas?

Clean areas must be protected from contamination by adjacent, less clean areas. This can be done by physical barriers (e.g. air locks), air displacement concepts or differential pressure concepts. Careful planning of layout, personnel and material flow is also important in this context.

(GMP Compliance Adviser, Chapter 3.I)

15. What are the risks associated with microbiological monitoring?

Microbiological data acquisition is mostly done manually and can thus become a process risk itself. The informative value of the established microbial detection methods is limited; however, the results cannot be directly correlated with those of more modern measuring methods.

(GMP Compliance Adviser, Chapter 3.K)