LOGFILE Feature 08/2020 – 7 Basic GMP Questions and Answers

7-9 Minuten

Questions that hardly anyone dares to ask: In which language do I have to write documents? Do I have to use a particular pen for signatures? Who has to sign GMP documents? Can I start the OQ before completing the IQ? The regulations do not provide clear answers to many fundamental questions. This dialogue provided a forum for all these issues.

Qualification/Validation of Computerized Systems (CSV): Where does one start with the qualification? What must be included in the validation?

Quality risk management is the most important instrument for the qualification and validation of computer-based systems. Risk analyses must show which areas are critical. These shall be validated. It does not make sense to validate all elements. Entire infrastructures, browsers or search engines do not need to be validated.

The manufacturer should ask himself: "What do I need and not what do you (the authority) want?"

It is important that the pharmaceutical manufacturer has a concept. He must have an overall view of his systems and their elements and their interaction. Data integrity must be guaranteed.

The quality culture of the company must also include computer technology and its employees. For example, a technician who replaces parts of the computer system must consider their quality and check whether this replacement may have consequences.

A new electronic training system does not report exceeding the due date for required training. How do I deal with this? How does the authority check the training status of staff?

A company's new electronic training system applies to all areas, not just GMP. A message when the due date is exceeded is not relevant for other areas and is therefore no longer provided for in the system. In addition, documents for the training of employees

that are not relevant to their current job will also remain allocated. The employee is not trained on these documents, so that open training courses remain in the system.

In the case described, this is a system error. The system must report if an employee works in an area for which he or she is not trained. The company cannot ensure that employees are properly trained. The additional control effort would be too high.

It would be possible to include this error as a critical deviation in the Quality Management Review. The Authority may take up this point from the review and address it in its report.

With regard to training, the authority shall verify that the production manager and the quality control manager have ensured and checked that their staff have the correct level of training. It is expected that specification documents will be trained centrally.

The manufacturing record is signed by two persons. For this activity, a small number of functionaries are defined in the associated SOPs. Is it acceptable for the qualified person (not mentioned in the SOP) to co-sign the record if none of the persons mentioned in the SOP is on site?

The case described cannot be accepted. A deviation notification must be written in which this is to be evaluated and measures are to be defined. The head of production is responsible for the authorisation of the manufacturing record. This should therefore be signed last by the head ofproduction. It is possible to include in the associated SOP a more comprehensive representation provision for the signatories. But in any case, it must be defined "what the signature performance is worth". The SOP should describe what the signatory must check before signing and what he/she is responsible for.

In some companies, numerous functionaries sign the manufacturing record, sometimes for information. This approach should be reconsidered. Because it is often true that "the quality of a GMP document is inversely proportional to the number of signatures".

How do I deal with due-date overruns in case of deviations?

The overruns of the due dates cannot be ignored. In principle, every excess is a new deviation. However, it would also be possible and pragmatic to incorporate this into the existing process, evaluate it and set a new deadline.

One has to question whether the deadlines set are reasonable or whether one is not unnecessarily trying to keep a tight corset.

Do the GDP guidelines also apply to pharmacies?

For pharmacies, the GDP guidelines only apply if the pharmacy also has a wholesale distribution authorisation.

Experience in this field has shown that it would be more effective if pharmacies were either exclusively public pharmacies or wholesalers, but did not carry out both activities in parallel.

Storage of drugs under quarantine in an external facility at a logistics company: Do employees of the marketing authorisation holder (MAH) have to work for the logistics company on site or do they even have to be employed by the logistics company?

Employees of the MAH must work at the logistics company or have access to it, e.g. for sampling. In practice, employees of the logistician can also be on the MAH payroll.

The MAH must contract with the service provider to determine which personnel have access to the external premises. The personnel must be subject to the instructions of the MAH.

Conclusion:

- *The extent of the CSV should be determined by means of QRM. Critical areas should be validated, but not entire infrastructures.*
- *Electronic training systems must be able to show the training status of employees reliably and correctly. The system should report any deviations automatically.*
- *The production management is responsible for the authorisation of the manufacturing record. The associated SOP should define practical representation arrangements and concrete responsibilities for all signatories.*
- *Due-date overruns in the case of deviations are in turn deviations. The possibility of continuing to set the deadlines should be examined in the event of frequent overruns.*
- *The GDP guidelines only apply to pharmacies with a wholesale licence.*
- *Quarantine storage of drugs in an external facility: Employees who have access to the external facility must be subject to the instructions of the MAH. This must also be stipulated in the contract.*

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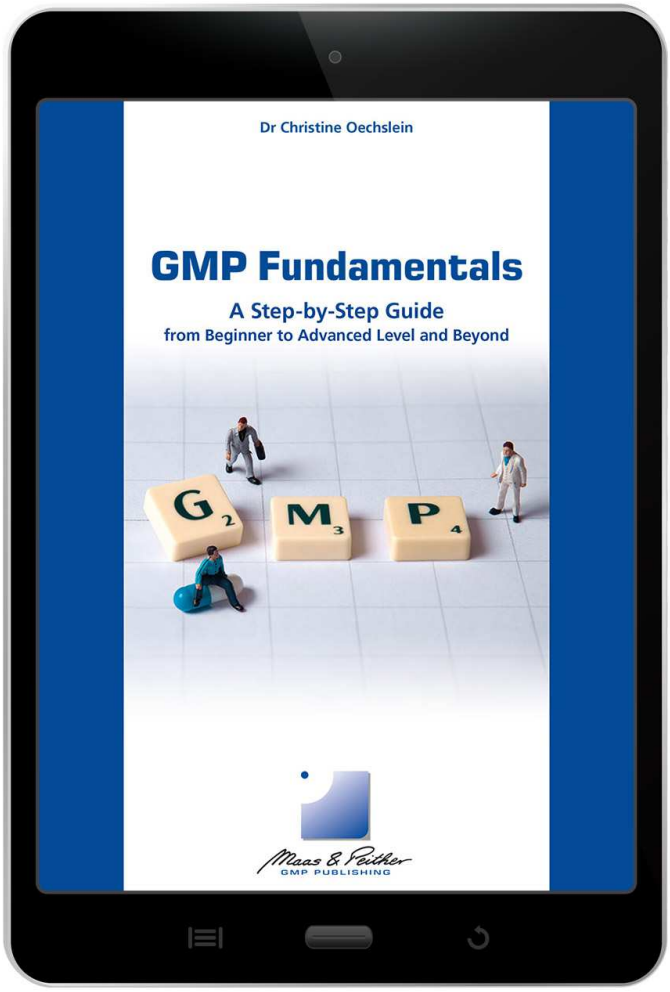

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- Standard Operating Procedures (SOP) and documentation

- Design of rooms and facilities
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