LOGFILE Feature 27/2020 – Work instructions, records and documentation

6-7 Minuten

Any action related to medicinal products must be traceable, because the life and health of humans and animals are at stake.

- Specific instructions must be followed for every action: excellent qualifications and professional experience alone are not enough.
- Every completed task must be fully documented: precision work alone is not enough.

  The requirements that have to be fulfilled, in particular the multitude of regulations and meticulous documentation of all actual values and observations, are very different from the practices in other industries. Even though instructions are often read on screen and many records are entered directly into a computer system, an ironic interpretation of the acronym *GMP* still works: a **G**reat **M**ass of **P**aper.
- All work carried out in a GMP environment involves instructions, records and checklists.

How do you keep track of such a large amount of data?

Whether on paper or in electronic documents, careful handling is a prerequisite when dealing with large volumes of data. It is vital that documents or different versions of documents are not mistakenly or intentionally mixed up and data is not lost (**data integrity**). This is why a **document management system** must be in place which ensures that each member of staff can access an up-to-date approved version of a document when necessary. If an electronic system is used, the **software must be validated** (see chapter 7.C

What requirements apply to computerised systems (IT systems)?), i.e. the main functions must be tested in advance to ensure that data or documents cannot be modified or **deleted** by mistake. Companies are increasingly phasing out paper documents. Work instructions, specifications, reports and other documents are not only created using a computer system, they are also electronically approved and distributed. Anyone who needs process instructions, SOPs or other documents, must open the document in the computer system and read it directly on screen. Many of these documentation systems facilitate the printing of forms, checklists and work instructions. Staff members should only use these print-outs for the period of time specified (usually 24 or 48 hours) to ensure that older versions are not used by mistake.

Controlled documents

Informal memos are not permitted in a GMP environment. This applies to both instructions and records.

All documents must state clearly:

- Who created or edited the document?
- Who checked the document and the data entered?
- Who approved the document and when?
- What is its status? Is the document a draft, being revised, valid (since when?) or a previous version?
- What is the document and revision number? How many pages and appendices does it have?
- Is it an **authorised copy** (controlled/registered copy) or an authorised printout from a computer system?

These documents are referred to as **controlled documents**. They are only distributed to relevant persons and are subject to **version control**, i.e. they cannot be modified at random by any member of staff.

Particular care should be taken when **copying** documents: every copy, e.g. of instructions, records or printouts, must be **complete and legible** to ensure that no information is lost. The creation of uncontrolled copies is not permitted. There is a danger that

changes to the original or new versions have already been authorised, and somebody is still working with these uncontrolled copies. Errors are inevitable. Companies that use paper-based documentation must define who is authorised to make copies, how originals and authorised copies are identified (e.g. using numbers, watermarks or special paper), and how older versions are taken out of circulation.

- In a GMP environment, only up-to-date authorised instructions must be used. Drafts or uncontrolled copies must never be used.

Traceability

Some data and documents are repeatedly used during a normal working day, e.g. for evaluations and reviews. Other data will *supposedly* never be used again – until a customer files a complaint or a quality issue is discovered. Every single detail is suddenly important when the frantic search for the cause of an error commences. Even documents that have not been used in a long time are examined. It pays off if everything has been recorded and all of the required documents can be retrieved immediately.

Accurate, complete and comprehensive documentation has many advantages:

- It is a **precondition for the consistent quality** of a medicinal product. For this purpose, detailed instructions and regular reviews of the actual data are required.
- It provides **transparency of the individual work stages** for third parties, such as customers, monitoring authorities or new employees.
- This is a prerequisite for failure investigations and root cause analyses, e.g. in the case of complaints or (quality) deviations that were detected in the company. In these cases, all tasks must be **traceable in both directions:**

    • reconstruction of **origin and use**

    • determination of **all affected products**, batches and dosages

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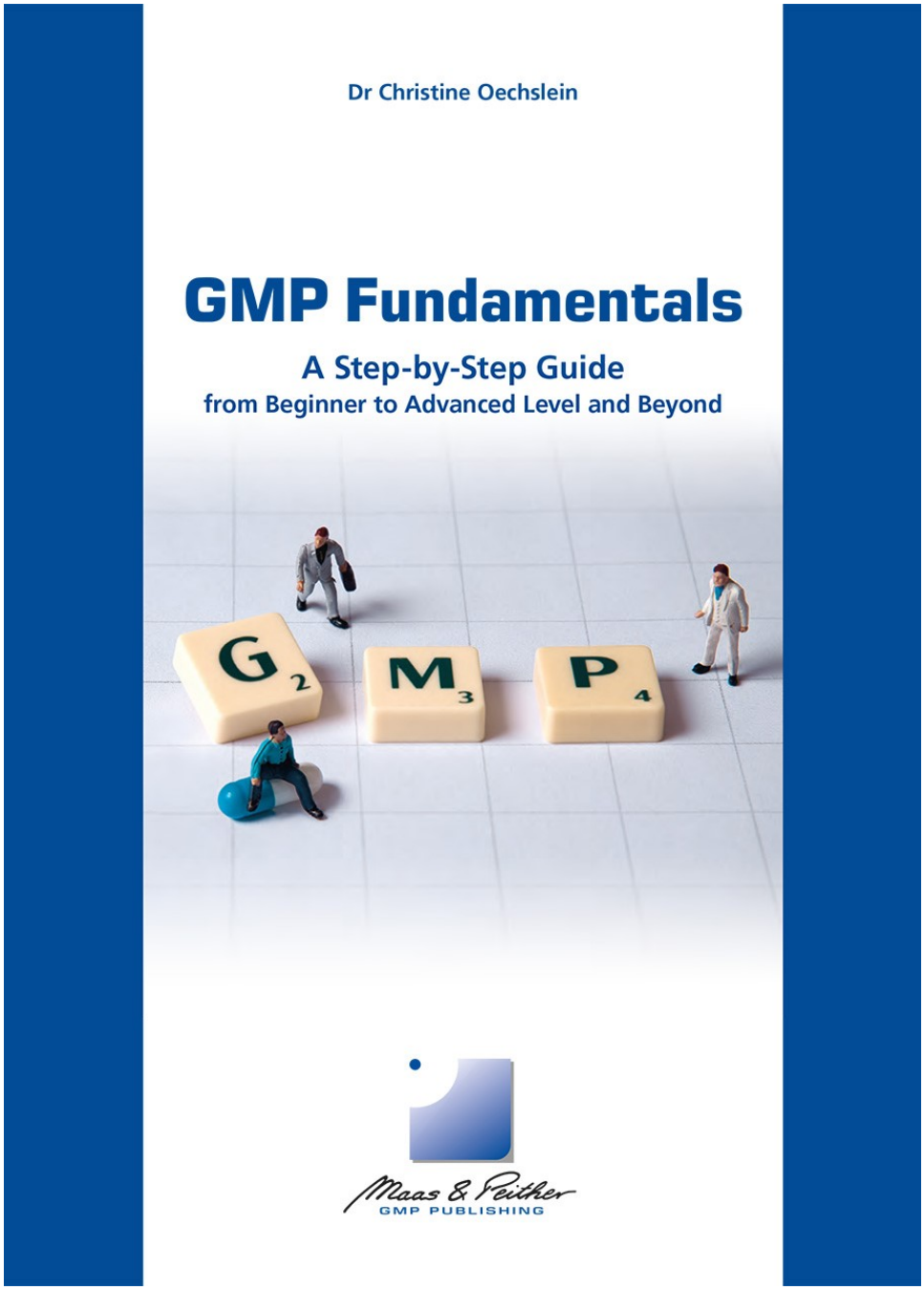
This text is an excerpt from the Step-by-Step Guide GMP Fundamentals.



GMP Fundamentals

What is GMP? Why do we need GMP?
You will find answers to these and many more questions on GMP in this easy-to-read guideline. It gives you a **quick and comprehensive overview of the complex world** of Good Manufacturing Practice (GMP). Some topics are:

- GMP: Purpose and basic pharmaceutical terms
- Laws, licenses and inspections

- Personnel: Responsibility and hygiene
- Standard Operating Procedures (SOP) and documentation
- and many more

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