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# Optimum GMP training concept: modular and inclusive e-learning

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In Part I, Paragraph 2.11 of the EU GMP Guidelines, it is required that "approved training programmes should be available" in GMP-liable establishments.

In such a training concept (also called "training plan" or "training SOP") companies must describe their individual approach to GMP training. In particular, it is necessary to specify:

- Group of persons to be trained - divided into target groups/learning groups if necessary
- Training contents
- Training intervals
- Responsibilities
- Documentation of training
- Type and scope of retraining measures
- Type and scope of performance review

When defining the groups of persons to be trained in the training concept, the following employees should not be forgotten:

- Technical Planning
- Production scheduling
- Operating engineers
- Technical Purchasing
- Measuring and control technology
- Logistics, distribution, incl. sales force (handling of medical samples)
- Quality assurance
- Human resources department (selection of personnel!)
- Cleaning personnel
- Employees of external companies, e.g. calibration services, maintenance services, cleaning services
- Temporary employees, flexible pool of employees, etc.

## Modular structure of a GMP training plan

It has proven successful to divide the entire GMP training programme into different modules, which can then be combined with each other as required, e.g.
Module 1: Entry training for new employees or after changes from other areas
Module 2: Comprehensive basic training

Module 3 - n: Advanced and follow-up trainings
Accompanying all modules are on-the-job trainings.

## Module 1: Initial training for new employees or after changes from other areas

Goals of this training unit:

- To communicate basic customs in pharmaceutical companies
- Motivate new employees
- Arouse quality awareness

This initial training should take place a few days or weeks after a new employee joins or an employee transfers from a non-GMP area to a GMP-liable area. The aim is to provide an overview and to convey basic practices in pharmaceutical companies. Therefore, this module can be kept rather general and does not have to be specifically targeted at individual jobs or activities. This training is less about imparting factual knowledge than about awakening quality awareness and motivation for GMP. Especially in the familiarization phase, there is a danger that new employees will be deterred or frustrated by the many regulations, instructions, controls and the high documentation effort. That is why it is important to awaken an early understanding of the meaning of the detailed regulations and the multiple controls - after all, it is people's lives and health that are at stake!

Typical contents of a basic training are:

- Why GMP?
- Personal responsibility of each individual
- Hygiene in handling open products
- Binding nature of rules
- Significance of signatures
- Keeping of the minutes
- Reporting obligation for deviations, errors and changes

Such an introductory training can, for example, be carried out as classroom training in about 1.5 - 3 hours or as e-learning in several shorter learning units (together about 1.5 hours). Longer or too detailed explanations are usually neither necessary nor useful at this early stage, as GMP newcomers are overwhelmed by the abundance of regulations and cannot yet assess the significance and impact on practical work.

## Module 2: Comprehensive basic training

As a rule, a thematically broader training course only makes sense after several months of service with the company. Building on the introductory training, the aim here is to repeat and expand basic GMP knowledge. It should be possible for the employee to understand the meaning and connections of the GMP regulations already experienced in everyday work and to understand the interaction of the various "Q functions" (quality control, quality assurance, GMP department, quality circle). General quality assurance principles and legal regulations can be presented, but above all their internal

implementation must be explained in detail ("How do we specifically proceed in our company in the case ... xy ...?"). Perhaps the first "frustration" has already spread among the employees since they were hired in the GMP area. Particularly when it comes to lateral entrants from non-GMP sectors, employees feel restricted by GMP regulations and sometimes feel that they are no longer really productive. ("We hardly make any more products - instead we are busy all day long writing paper full!")

The goals of basic training are:

- Further motivation for GMP
- Awakening and maintaining quality awareness
- Creation of broad insights into GMP contexts
- Not too specialist or workstation-specific

Even a comprehensive basic training cannot deal in detail with the individual questions of each workplace. The point here is rather to convey how GMP works, why certain processes are defined in this way and not differently, and how the individual departments or groups interact. A basic training can comprise one or two half days as classroom training. Full-day training courses, on the other hand, often overtax the participants' ability to absorb and concentrate. It is also a practical and very efficient solution to convey the general learning content in the form of e-learning units and to supplement the respective company-specific implementation in the sense of blended learning in classroom training.

## Module 3: Regular advanced and follow-up training

After completing the basic training, the basic principles of GMP must be regularly repeated, refreshed and supplemented with new, up-to-date aspects. The GMP regulations therefore require that every employee in the GMP area must "regularly" attend GMP training courses. It is not specified in which intervals these instructions must take place. There is therefore room for manoeuvre here which makes it possible, depending on the product range, level of training and specific requirements, to repeat individual topic complexes more frequently for certain target groups or less frequently in other target groups.

Depending on the framework conditions, monthly, semi-annual or annual build-up training can be justifiable. Much longer intervals are neither forbidden nor unthinkable - against the background of rapidly changing regulatory requirements and internal procedures (new processes, new SOPs, reorganisations, mergers, outsourcing of production steps, etc.), however, they can only be justified in rare cases. Finally, an advanced training course not only offers the opportunity to recall the forgotten, but also to introduce innovations, analyse weaknesses or devote oneself to current events or difficulties in practical implementation.

Examples of objectives of GMP advanced and follow-up training courses:

- Further motivation for GMP
- Maintaining quality awareness
- Deepen your knowledge
- Improve skills

- Avoidance of "compliance erosion"!
- Error correction
- Introduction of new processes
- Analysis of weak points

Interestingly, the same topics are on the list for GMP advanced training courses in practically all companies every year:

Whether carelessness in the handling of raw data, in the keeping of minutes, or in reporting deviations, backdated signatures, "forgotten" hygiene rules, neglected logbooks, materials "in stock" in corridors or rooms, or workarounds for cumbersome, but valid work regulations: all struggle with similar weaknesses and problems.

Internal GMP trainers, who every year are faced with the challenging task of preparing new, exciting and memorable learning content for these already "worn out" and general learning contents, can make use of commercial e-learning offers here. This leaves more capacity to concentrate on things that are actually specific to the process or workplace, as well as internal company innovations, which are then taught in classroom training.

## On-the-job training

The more or less theoretical efforts of modules 1 to 3 must usually be accompanied by workplace-specific training measures, such as the practical development and practice of behaviour (e.g. putting on cleanroom clothing), practical practice of (new) working methods, equipment demonstrations, machine instructions, cleanroom instructions, sampling demonstrations or hygiene exercises. These trainings usually take place at the workplace or nearby and are conducted in small groups so that every participant really gets his or her chance.

The prerequisite here is also that already documented procedures and rules (i.e. SOPs) for practical implementation exist.

The duration of these practical training courses can vary greatly. In some cases 15 minutes may be sufficient, but for other practice exercises two hours may be required.

As with theoretical training, careful documentation must be ensured for all practical training courses:

- Date and duration of training
- Training contents
- Signatures of the participants
- Name of the trainer

Especially the few company-specific GMP trainings, such as the general introductory training, the broad basic training and the regular refresher trainings often require a great deal of organizational effort:

- Initial training courses must be offered throughout the year, because every new employee must complete such training within his or her first working weeks - because only those who are trained are allowed to work in the GMP area. Under certain circumstances, this means that an introductory training course must be organised for individual persons.

- Although basic training courses can be scheduled for the long term, despite the best planning it will happen again and again that some employees will not be able to participate. This results in the need for additional training.
- Follow-up / refresher training: Sometimes, for operational reasons, it is not at all possible for entire groups to be absent at the same time in order to take part in a training course. In this case, several training sessions are necessary. In addition, in most cases, additional training courses must be carried out for all persons who were unable to attend any of the appointments.

In all three cases, the companies are free to communicate the essential learning content more advantageously in other ways, e.g. with the help of e-learning or as blended learning.

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