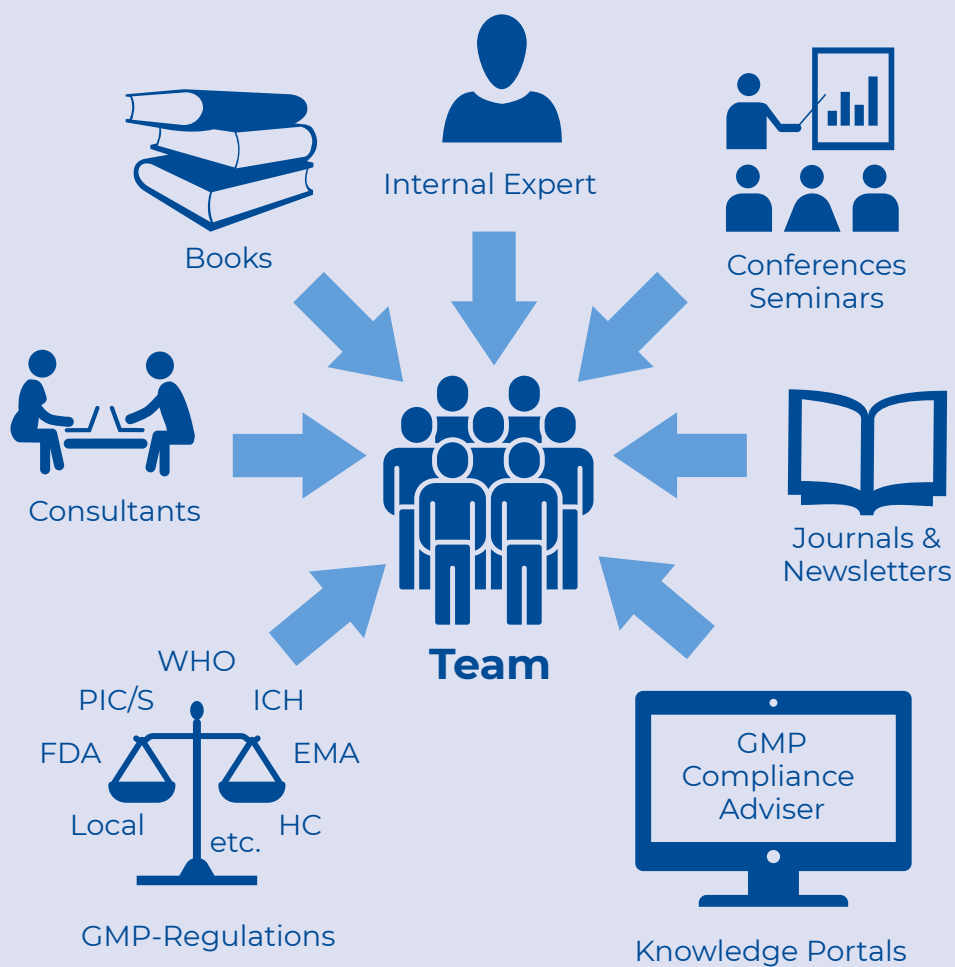


# How do you organize GMP knowledge and relevant news in your organization?

## Organizing GMP Knowledge and News



[www.gmp-publishing.com](http://www.gmp-publishing.com)

## **1. GMP requirements are very extensive, confusing and only accessible at great effort.**

You are familiar with the situation: The requirements for good manufacturing practices are constantly increasing. In some cases, new documents with new requirements appear weekly.

Every pharmaceutical manufacturer must ensure that the responsible employees are informed about current changes and new requirements. This means that resources must be available. They should check the publications of the relevant authorities at close intervals and keep an eye on them. There are more than 50 public authority websites that need to be checked regularly.

Another problem is that the information is not always presented in a prominent way. Some new publications, for example, require extensive research.

Due to the fact that official requirements are very fragmented and available on the Internet, many employees are frustrated and do not pay attention to many changes or do not do so in time. This results in GMP deficiencies and non-compliance.

It would be good if all relevant guidelines were available in one place. So one could search through them quickly and would always have access to all current guidelines.

## **2. Companies must interpret GMP requirements. This requires highly skilled employees with broad experience.**

Once a new GMP relevant guideline has been identified, the next difficulty arises. Who can interpret the changes in such a way that they do not only meet practical requirements but are also sustainable in inspections?

This requires experts with broad GMP experience. Such employees are rare and expensive and are usually needed in complex projects. Experts are therefore often unable to provide such interpretation tasks. However, experts have the great advantage that they can create interpretations specifically for the company and also take into account the specifics.

Nevertheless, less experienced employees often try to interpret new guidelines for operations. The result is all too often suboptimal.

Another difficulty is the accessibility of these interpretations for all employees. Policies, SOPs and other instruction documents are always very summarized information that must disregard many aspects of an interpretation or work aid.

Where do you store such interpretations? Who writes them? Are they accessible to your suppliers and business partners?

## **3. Journals and Newsletters are a frequently chosen way to follow developments.**

Of course, everyone in this discussion immediately thinks of journals, trade magazines and newsletters. After all, their task is to follow current developments and report to the professional public.

*Scientific journals* are an excellent source of specialist information. Usually they are reviewed by colleagues and represent a viewpoint with broad agreement. Unfortunately, scientific journals hardly focus on GMP aspects. This topic is therefore very neglected in scientific journals.

## Pros and Cons

### 1 GMP Regulations

GMP regulations change constantly. You find fragmented regulations on 50+ websites on the Internet without interpretation guidance.



### 2 Internal Experts

Regulations have to be interpreted. Highly skilled experts with broad experience deliver adequate and specific interpretation for the company. Often they are not available.



### 3 Journals, Newsletters

Scientific journals deliver professional information with peer review, less focus on GMP or manufacturing. Trade magazines summarize discussions and trends but seldom details.



### 4 Books

Books are slow media in a fast changing environment. Sales of professional books decrease dramatically in a "digital first" world. E-Books are faster and cover specific topics.



### 5 Conferences, Seminars

Use events to interact with experts, meet people and discuss specific topics. Quality is individual and depends on speakers and program.



### 6 Consultants

First choice for handling specific tasks, getting additional resources and performing trainings. Knowledge management and transfer is often not their key competence.



### 7 Knowledge Portals

Regulations, interpretations and expert knowledge in one place. Accessible 24/7 with easy access for every employee - probably the Gold Standard for knowledge management.



[www.gmp-publishing.com](http://www.gmp-publishing.com)

*Trade magazines* are usually financed by advertisements and less by the subscriber price. In such cases, advertising aspects often hide behind articles. The reader must decide then whether it is a matter of well-founded contributions or rather public relation.

The *newsletters* that various providers often offer free of charge remain. Here one must look exactly at the sender - what is advertised in the environment? If it's training programs, then often news is placed in connection with seminars or conferences - also here often "re-cycled" news can be found in the "newsletters". Every week the reader has to decide anew - is it really new or just because the message fits into the advertising environment? If you have found the adequate newsletter, it is a good way to stay up to date - and maybe even very inexpensive!

It's really hard to find reliable neutral information paid for by the reader. Because where the reader pays, he is recognized as a customer with his needs.

Perhaps you are wondering what the situation is with *books*? Now, the production of books has a lead time of 1-2 years for many publishers. This means that a book is often outdated by the time it is published. This is why current professional publishing is usually only available in digital format and mostly online.

#### **4. Conferences and seminars are good for interaction.**

Conferences, seminars and other lecture events are great for discussions with other professionals. Events are perfect to meet people and to interact with experts. Good speakers can explain very clear current topics at such events. The listener takes home many aspects and insights. Unfortunately, a transfer to the company or to colleagues is seldom successful.

On the one hand, this is due to the wealth of information, as many lectures are often presented. On the other hand, the lecture information that participants receive is so sparse that it is almost impossible to transfer knowledge. A further problem is the archiving of such information in order to make these colleagues accessible.

But there is also the opposite, that only few lectures bring an added value and the whole event is therefore unnecessary. Such face-to-face events often cost between 1'000 - 2'000 €/ \$ or more. The travel times and the loss of time of participants are not yet included.

Events are indispensable for knowledge management, but must be integrated and managed in the framework of the overall concept with processes of knowledge transfer.

#### **5. Consultants support for specific tasks, resources and trainings.**

The classic information media are exhausted with the listing above. What about hiring external experts?

Put it to the test and ask your consultants about their training programs, participation in conferences and seminars. You may be just as surprised as I was when I asked such questions to many consultants. It turned out that training of consultants often takes place in customer projects. And one wonders who a hen or an egg is here. That's why you have to take a very

close look at what your consultant can offer you. Expert knowledge from project experience or the latest developments and the interpretation of the effects on the company.

I myself have advised pharmaceutical customers on GMP issues for over 25 years. It is a major task to attend regular conferences and seminars in addition to diverse and time-critical project tasks. In some years I have not been able to do this regularly either.

It is the first choice to ask a consultant if you have specific tasks to perform in the company, if you need additional resources or if you require special training. However, you should manage knowledge and decide who needs to know what in internal processes, supported by reliable sources.

## **6. The Gold Standard is the use of knowledge portals.**

Knowledge portals can combine many advantages of knowledge transfer and at the same time provide valuable services for the respective industry. Not every company has to reinvent the wheel. Sharing knowledge increases the efficiency and further progress of an industry.

### **News and announcements**

Isn't it enough for reliable partners to take over the weekly search for changes? This must also be delegated internally. Why not delegate to external experts? Knowledge portals inform their customers about the latest changes and important news - often faster than internal departments can.

### **Interpretations of changes**

Knowledge portals have a broad network of experienced experts at their service. Some of them can also create reliable interpretations very quickly. An experienced editorial staff and peer reviews reduce the influence of personal preferences of authors or experts.

### **Everything in one place**

All information can be accessed via the knowledge portal. This saves many employees a lot of time because they know where to find reliable information. You save time-consuming Internet research, which is partly based on unverified opinions. Reliable information in one place make life considerably easier for employees.

### **Availability of Information and Knowledge 24/7**

Another facilitation is unrestricted access to knowledge portals. The knowledge portal does not go on holiday and does not become ill. It also does not know the end of the working day. It is always approachable and gives answers at any time. Access is also guaranteed from the home office.

## Easy access - easy handling

And last but not least, the design, functions and handling determine the frequency of use in the company. Is there a good search function? Can I copy, print or download documents? Is access with passwords complicated or simple? Is the portal also suitable for mobile devices?

# Case Studies

## 01 Training

GMP training time is often unproductive time. Transform trainings into productive time for process improvements. Use knowledge portals in your training routine and take training to a new level. [Read more in Case Study 01 ...](#)



## SOP Review 02

Standard Operation Procedures (SOPs) must be checked regularly. The author of the SOP often does this on the basis of the current processes and rarely according to a defined procedure. With the help of a knowledge portal, users have set up the process that compares the QMS with the state-of-the-art and makes QMS audit and inspection safe. [Read more in Case Study 02 ...](#)

## 03 Planning

Manufacturing areas must be designed and tested in accordance with GMP. The requirements in this area change continuously. Learn, how companies that have appropriate knowledge portals in place can reach the goal of GMP compliant planning and execution more quickly. [Read more in Case Study 03 ...](#)



© 2020 GMP-Verlag Peither AG,  
Schopfheim, Germany

[www.gmp-publishing.com](http://www.gmp-publishing.com)

## 7. Examples show the variety of use cases in the pharmaceutical industry.

A few possible examples should show how knowledge portals can be used profitably in companies.

### Case study 01: Training

A company uses a comprehensive knowledge portal for the training of new and existing employees. Certain chapters or areas of the knowledge portal are defined which the employees are to work through independently.

At a defined meeting, the employees jointly discuss the knowledge they have acquired in relation to their company. The meeting is led by a moderator. Another person minutes the findings. In the meeting, deviating ideas of the knowledge portal are discussed as well as new developments that will come to the organization in the future. Activities or proposed measures can also be worked out.

After the discussion, each participant receives a certificate for the training of the topic defined. As supplementary documentation, a questionnaire can also be answered by the participants. But even without this a proof of success is documented.

In this way several goals are achieved:

- Employees train themselves in specific topics.
- Findings can be incorporated immediately into the improvement of processes.
- New developments are recognised in good time.

In this way, training time becomes productive time for process improvements!

### Case study 02: Review of SOPs

Standard Operation Procedures (SOPs) must be checked regularly. The author of the SOP often does this on the basis of the current processes and rarely according to a defined procedure.

With the help of a knowledge portal, users have set up the process as follows.

1. The reviewer defines keywords that are important in connection with the SOP to be revised.
2. The reviewer searches the knowledge portal for changes, procedures and example documents regarding the defined keywords.
3. The reviewer checks the contents and compares them with the processes defined in the SOP.
4. In a summary, the reviewer describes significant deviations and discusses them in a meeting with the persons responsible for the SOP. The knowledge portal serves as an additional opinion that can be deviated from at any time. Decisions are documented.
5. The SOP can be revised and quickly adopted based on the meeting and the decisions made.

In this way, the QMS is regularly compared with the professional publications. In audits and inspections of the QMS, reference is made to this process.

### Case study 03: Planning for production areas

Manufacturing areas must be designed and tested in accordance with GMP. The requirements in this area also change continuously.

Both the supplier and the customer may have missed changes. And not everyone always has all possible implementation variants at hand. Thus, it helps to take a look at the relevant knowledge portals in the respective planning steps, especially within the framework of the early project phases. In this way, the planning can be compared with the state of the art.

Especially in the early project phases or during concept work, later mistakes can be avoided. If these only come to light later, then the troubleshooting usually costs many times more than an early identification. Also, possible risks, which have to be identified in the context of risk considerations, are easier to identify by looking at suitable sources.

Companies that have appropriate knowledge portals can reach the goal of GMP-compliant planning and execution more quickly.

### The next steps

You want to use knowledge portals profitably? I am happy to help you.

Send me an e-mail and I will send you further information about GMP knowledge portals:  
[thomas.peither@gmp-publishing.com](mailto:thomas.peither@gmp-publishing.com)

### Author

Thomas Peither, GMP-Verlag Peither AG, Germany,  
[Thomas.Peither@GMP-Publishing.com](mailto:Thomas.Peither@GMP-Publishing.com)