Interview with Thomas Peither, Maas & Peither AG

GMP Compliance through better GMP-knowledge

Today, it is important to keep an eye on developments in Good Manufacturing Practice (GMP). However, it is not only a matter of taking note of new guidelines. New guidelines mean changed interpretations in practice and an adaptation of inspection practice to the new requirements. Keeping an overview here is a challenge for every company and responsible person. Huascar Pimentel from Azierta interviewed Thomas Peither from Maas & Peither GMP Publishing, who has advised the pharmaceutical industry on GMP issues for over 20 years and has been active as a publisher of GMP specialist literature for 18 years.

Mr. Peither, why is GMP compliance so important?
Imagine you or a close relative or acquaintance has an accident and you are taken by ambulance to the nearest hospital. You will immediately receive injections and infusions that will get directly into your body. If these medicines are contaminated, it can be life-threatening. It does not matter whether the contamination during production is caused by a faulty ventilation system, an employee, poorly cleaned rooms or contaminated active ingredients or additives. Only if everyone adheres to the specifications in the work instructions can the medicine be manufactured in such a way that it helps to become healthy.

Does this mean that we are all helping to protect patients?
This is the way to look at it - if the GMP guidelines are ignored in practice, the risk for the patients and thus for all of us increases! If, on the other hand, we adhere to quality standards, we help people to become healthy.

And what role does a specialist publisher play in this, as it does not produce any drugs at all?
We help the experts in the industry to keep the overview and to make the right decisions. More than 100 authors from industry and authorities work with us to create the contents of the world's most comprehensive GMP knowledge knowledge-portal. Our task is to give the experts direct access to exclusive knowledge. This enables them to access the best information without a long search and research. It's true that we don't manufacture drugs, but our editors also come from drug manufacturing and all our authors come from industry, consulting or government. I myself have advised the pharmaceutical industry on GMP issues for 24 years, including many well-known global companies.

How can Maas & Peither ensure that it is up to date?
Every week we check all relevant government websites worldwide and create GMP news for our customers, which are published in the weekly newsletter LOGFILE. This can even be subscribed to free of charge. Often, however, we already know in advance what is happening with the authorities, because we are optimally connected in the world of authorities. For example, we are involved in the official German translation of the EU GMP-guidelines for the German Ministry of Health.
The news serves the editorial staff to update the GMP knowledge portal, the GMP Compliance Adviser. New guidelines will immediately be incorporated into the GMP Compliance Adviser and the authors will revise their articles as soon as they have proven their worth in practice.

How often does the GMP Compliance Adviser update?
We currently update the Adviser approximately every 4-6 weeks. This depends on the changes, author contributions and guidelines. In any case, it is the most up-to-date GMP knowledge portal currently available.

Is it correct that the publisher received a prize for the publication?
Indeed, and the publishing team is very proud of that. The Specialized Information Publishers Association (SIPA), based in Washington DC, USA, awarded the GMP Compliance Adviser third place in the "Best New Success Story" category in 2016. The application with the title "Save Drugs through Better GMP

Understanding" convinced the jury and also shows the position that this work enjoys in publishing circles globally.

How do your customers benefit from the publication?
95 % of our customers will find what they are looking for in the knowledge portal. This is the result of a survey we have been conducting with our customers for months. Our users don't have to search long to find all relevant GMP guidelines, GMP laws and practical articles. You'll quickly find what you're looking for and everything in one place. A comfortable search function, a clear table of contents and an editorially edited index help the reader. Today, nobody has much time for research on the Internet - you would have to search dozens of government websites for a detailed result. And our practice contributions with several thousand pages are exclusive knowledge, which is not available in the Internet.

How extensive must one imagine the GMP Compliance Adviser?
If you printed all out, you would have about 7,000 pages. We don't know it exactly, because we offer the work only digitally as data base. About half are GMP guidelines, the other half are interpretations from practitioners. These are written in such a way that one can quickly apply the knowledge and thus improve GMP compliance in the company - checklists, sample documents and how-to-do descriptions help. Many topics are covered, such as the classic validation topics: Process validation, cleaning validation, plant qualification; technical chapters such as cleanrooms, ventilation systems, water treatment, and computer validation. But also questions about personnel or quality assurance topics such as change control, deviation management, documentation are not neglected. Quality control and microbiology are covered as well as manufacturing, packaging, shipping and transport. The range of topics is enormous and 24 chapters structure the practical part, which is why more than 100 authors are working on this enormous opus.

Which GMP guidelines or countries do you cover?
The Adviser contains the world's most important GMP guidelines: EU Directives and Guidelines, CFR and FDA Guidelines (USA), ICH-Guidelines, PIC/S Guidelines, as well as local guidelines from Canada, Japan, China, India, Australia and Brazil, but also the globally important WHO Guidelines.

That sounds like a lot of work and a high price, can a small pharmaceutical manufacturer afford it at all?
As we have customers in over 50 countries with approximately 10,000 users, every company can afford our GMP Compliance Adviser. It usually costs less than a 1 day-consulting fee per year - and you have the Adviser available 24/7, i.e. 24 hours a day, 7 days a week - that's less than 3 Euros per day for a Single User Licence.

How do customers use the working tool?
Our customers use the GMP Compliance Adviser for the preparation of inspections and audits, for the planning and renovation of production rooms, for plant planning, for the creation and revision of SOPs (Standard Operation Procedures), for the training of new employees, for the preparation of presentations and training courses, for the research of GMP requirements, for the planning of projects, etc. The application possibilities are almost endless - as long as GMP requirements have to be fulfilled.

And what if the customer has a question?
Then they can contact us as subscribers: We have been able to help every customer so far, because of our network of GMP experts of the pharmaceutical industry worldwide, and our readers are often experts themselves. We are happy to help our customers.

What is your challenge as a publisher?
As a publishing house with 20 employees, it is a challenge to sell such a product worldwide. The Internet

helps us a lot, but cooperation with local partners like Azierta in Spain cannot be replaced by anything else. Proximity to the customer is very important to us, because we want our customers to always receive a GMP-compliant answer - up-to-date, practical and inspection-tested.

The interview was conducted by Huascar Pimentel from Azierta, Madrid.

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