LOGFILE Feature 29/2022

Reaching the next GMP Level with Inspection Readiness Projects

Excerpt from the interview with Frank Studt, Managing Director gempex GmbH, and Thomas Peither, GMP-Verlag Peither AG, at the GMP:talk at the fair LOUNGES 2022

Thomas Peither: In my professional past, I have carried out many inspection preparations, and they were always heave-ho actions. So you were called in as a fire extinguisher or fire brigade. Has anything changed here in the last two years since the corona pandemic?

Frank Studt: No, I want to ask the opposite question: Why should anything have changed? The authorities have not personally appeared in the companies for over two years. I would even think that certain things have faded into the background a bit. I fear that nothing has changed there. On the one hand, we have the internationally positioned companies for which international inspections are daily business. That means that the process simply goes on. But for small and medium-sized enterprises, for whom an international inspection by the authorities is something very special, a one-off action that perhaps only happens every three years, a lot has changed.

I would like to mention very briefly the difference between an audit and an inspection. I think this is quite important. At the end of the day, if I, as a manufacturer of a pharmaceutical product, have certain services or intermediate productss under contract, then I go to the contract manufacturer and perform an audit at his site. That is a friendly action. My interest is that the GMP system becomes better at the contract manufacturer. When an health authority comes, we talk about inspection, that is something investigative. Look at a crime movie, there is the inspector on the way, he is searching. And he doesn't believe. He insinuates evil. He insinuates that you want to lie to him. He assumes that what you say may not be true at all. In terms of stress, this is a completely different situation compared with an audit situation.

And then, when an inspection is imminent, there are these typical rushed actions. An inspection may be announced only six, eight weeks, three months in advance. And then they say: Where do we actually stay now? Who can tell me what state our processes and documents are in, where is the qualification, where is the process validation, the cleaning validation, all the documents and proofs that have to be available?

I was recently at a company that has about 900 SOPs only in the laboratory. I found out that a good number of them are implemented differently than the documents say. Getting

clarity on this is the number one heave-ho action that comes. First of all, create an overview, carry out a gap analysis, implement actions. To support this, a hopefully qualified consultant is often hired. And the second heave-ho action, which actually always comes shortly before inspections, is *inspection management,* i.e. organising the *front office* with the inspector and the *back office* (the document room), and also quickly training the staff. What are the employees allowed to say? How far can they go out on a limb? All these topics have to be prepared. That is a lot of work.

Thomas Peither: Is there an alternative to these heave-ho actions?

Frank Studt: Yes, I think so. Just what we consultants always preach. There is a world outside and there is an ideal world. I think it's important to find a sound balance. I think it is very important to get *inspection readiness* into daily operations. The companies should not only train GMP once a year, but look where the deficiencies are in routine operations and then specifically retrain and incorporate continuous training. *Inspection readiness* should be seen as a continuous process. And this starts very early, already with the development of a pharmaceutical product, when the first data are generated. This data must be stored in a structured way and must be retrievable at any time. *Track and trace* and *data integrity* are very important here.

And you must not believe that a transfer project from development to routine is a sure-fire succes! We have seen many transfer projects in the past. Those that were not consistently set up as a project, i.e. with a schedule, cost plan and responsible persons, failed. It is a very important aspect to make sure that a positive culture of mistakes is built in. Making mistakes is something normal. And that is a good thing, because mistakes mean: I actually find something that can be done better. I think it is good and right to install a culture of failure, an open acknowledgement, so to speak.

Thomas Peither: Culture of failure has also been a topic for me for a long time. And I recently came across a sentence that is an essential one for me, comming from William Edward Deming, one of the great quality popes: *Blame the process and not the people.* And for me, that is the epitome of what quality culture actually means.
In your view, what are the success criteria for establishing a positive culture of failure?

Frank Studt: You just said it. The Harvard Conflict Theorem also assumes that the factual level should be separated from the personal level. A very important point is not to point the finger at the person who has made a mistake. I don't want to talk about the person's mistake, but I want to talk about the potential behind it, which should ultimately be raised for the production process. That is what I want to talk about. I want to talk about benefits and not about people and mistakes. It is important to establish a culture of failure or mistakes in the form of raising a finger or a hand and saying: something happened, we have to take care of it, we have to open up and then actually see to it that an important measure is implemented, not that a person is reprimanded. That is important.

I would like to give an example of a wrong understanding of GMP. If you have been on the road as much as I have as a 3rd party auditor, you have often been confronted with the sentence "We don't want to commission an audit, we just want to buy an audit report". So there is a view that audit reports have to be commodities to be bought cheaply. And that, to me, is the crux of the matter. That is a mistake that is being made that should not be made. When I qualify a supplier, I need to know what is actually going on there.

Thomas Peither: Is buying audit reports really that widespread? I hear it again and again, too.

Frank Studt: This is common because supplier qualification is a very expensive topic. As an auditor, I once heard the beautiful sentence: "A QP does not belong on the plane". And the sentence is true. You have to send people, qualified people, to an audit who are also able to inspect, who are able to ask the right questions, to cooperatively find out what is going on on the other side. Of course it costs money. A large contract manufacturer with perhaps 700 suppliers is under considerable cost pressure, so the question is obvious!

Now imagine you go to Asia, you conduct an audit at a critical supplier, who has two critical deviations, plus major and minor ones. Then you write an audit report that describes all this objectively and present the report to the supplier. The supplier will certainly not sign the report knowing that it will be sold in Europe. He will refuse. The potential buyer of the report, who has never been on site, may not buy such a report either. He would like to buy an audit report with which he has little work afterwards. The deficiencies found must therefore not be critical. Only then can I sell the report. If I start with this kind of motivation, then I write a nice prose report with beautiful photos in it. But it's not worth the money.

Conclusion

Experience from many years of inspection practice shows: *Inspection readiness* understood as a continuous process and implemented in a risk-based manner saves money and nerves! To achieve this, it is important to integrate the following aspects, among others, into the daily GMP routine: data integrity, continuous training and a positive culture of mistakes.

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