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Remote, Distance, Offsite or Virtual Audits? – What is GMP Compliant and What is Reasonable?

by Thomas Peither

Note: This is an abridged version.

The detailed version is available to the GMP Compliance Adviser customers.

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There is no standard for GMP audits that are not carried out on site at the contractor's premises. Nevertheless, these remote audits, as I call them in the following, have become routine for all those who carry out audits.

A lot of information on remote audits has been published in the last few months and I have followed and analysed some of it. I hope there is also something for your everyday GMP life. This article looks at GMP audits and not at official GMP inspections. The latter are subject to other regulations and would go beyond the scope of this article.

Every company must operate GMP compliant processes and obtain as much information as possible from the supplier in a realistic manner.

It's best to look at the task from different angles - because that's how we make ourselves aware of the different problem points. And even after that, there is no single solution, but we look at a heterogeneous landscape of solutions. I leave it up to your expertise where you locate yourself.

The regulatory view

Audits differ from inspections in that inspections are carried out by competent authorities and audits are carried out between companies. In this context, the performance of audits is also frequently transferred to third-party companies, which then act on behalf of the contract giver. Audits are carried out for

- the Review of outsourced activities and
- the Supplier qualification.

Guidelines for the review of outsourced activities (in the long version)

[…]

Supplier qualification guidelines (in the long version)

[…]

EMA Notice to Stakeholders: Q&A on Regulatory Expectations for Medicinal Products for Human Use During the Covid-19 Pandemic (in the long version)

[...]

The current regulatory position

The current guidelines only provide clear requirements for a few GMP audits. Accordingly, audits at active ingredient manufacturers are only GMP compliant if they are carried out on site. The exception is the time when the pandemic is declared and travel restrictions that make an on-site audit impossible.

For all other audits an on-site audit is not stipulated by the GMP regulations and they can be designed with a comprehensible argumentation. Clients can therefore establish alternative processes in the form of remote audits, which can be GMP compliant.

The conservative view

"Remote audits do not represent reality truthfully", could be a conservative assessment of remote audits

This opinion can be substantiated with many shortcomings, disadvantages and technical problems of remote audits (see figure 1).

Disadvantages of remote audits

- **Plant tours of manufacturing facilities, warehouses and cleanrooms are difficult.**
- **Details are lost with inadequate camera and transmission technology.**
- **Auditors lose flexibility as they are more bound to a predefined framework.**
- **Complex process flows or difficult spatial situations can only be reviewed to a limited extent.**
- **On-site documents in production, warehouse and engineering can hardly be viewed spontaneously.**
- **Sifting through documents on screen is tedious and comparisons with other documents are difficult, if not impossible.**
- **The behaviour of employees can be more difficult to observe (inconspicuously).**
- **Environmental conditions such as cleanliness, temperature, tightness, tidiness, etc. can only be tested to a limited extent or not at all.**
- **Auditors are less able to follow their intuition and experience, as an overall picture is not transmitted.**
- **IT security is only guaranteed to a limited extent for many digital systems.**
- **The IT equipment at the client's and the contractor's premises does not allow for adequate auditing.**

Figure 1 Disadvantages of remote audits

Considering all these disadvantages, one has to conclude that remote audits are insufficient. It is not compatible with GMP requirements to conduct remote audits as an alternative to on-site audits.

Consequently, all audits conducted as remote audits during the pandemic must also be repeated and confirmed by an on-site audit after the pandemic.

The progressive view

"We have seen a massive improvement in technology in recent months that allows us to evaluate companies at a distance from almost anywhere in the world," is the credo of those who would prefer not to travel at all.

[...]

The advantages are obvious for the supporters of this group and can be read in the long version of the article.

A perspective for the future (in the long version)

[...]

Thomas Peither outlines a future perspective in which combinations of different audit forms (preparation off-site, remote audit, on-site audit) will play a role.

Summary (in the long version)

[...]

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