Qualifyze
Case Study

in collaboration with

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▶ SITUATION

Travel restrictions and social distancing due to COVID-19 have forced pharmaceutical companies to look for alternatives to keep supply chains safe and compliant, without the possibility to conduct onsite supplier audits. Looking at the scope of possibilities that especially modern, digital technologies allow, the discussion of remote / video audits has gained a new momentum. Not only do these remote audits offer the possibility to improve audit efficiency and reduce costs, they can also contribute to more carbon-efficient operations, thus helping the planet. But moreover, a combination of frequent remote audits and occasional onsite inspections, can even improve current auditing effectivities.

▶ COMPLICATION

If we look closely at what is said in Article 8 of EU-Directive 2001/83/EC, the application of a marketing authorization shall be accompanied by a "written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practice by conducting audits". Besides, other critical suppliers or service providers might be entailed to regular onsite audits according to internal procedures.
Also, guidance for QP declaration and batch release laid down in Annex 16 of the EU-GMP guidelines, includes the confirmation of onsite audits performance in the declaration.

▶ KEY QUESTION

How can remote audits be integrated into the supplier qualification procedure to ensure a compliant, safe and adequate results?

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▶ ANSWER

EMA has published a Q&A document that provides some light in this alternative, at least for the time being.
The aim of all these "opinions" is to keep protecting human health.
It is the responsibility of the Marketing Authorization Holders to carefully assess the risk to decide if it is appropriate to move to virtual audits. This can be done in parallel to or as a part of each company's supplier management program. This assessment should be done taking into consideration multiple factors such as company profile and background (location, activities performed, size), regulatory oversight and certifications, inspection history, cross-contamination risk, recalls and complaints, nature of material or service, product development stage.

Even though the viability of remote audits can be confirmed depending on the associated risks, their actual execution poses an interesting challenge for most companies. Based on the experience gained by doing onsite audits and the expertise and skills of our qualified auditors, Qualifyze developed an open and efficient method for the execution of remote audits where efforts are always commensurate to the level of risk associated to the supplier or service provider.
A successful example of the application of this strategy was the audit to Transco Berlin Brandenburg GmbH (TBB), a carrier, freight forwarder and logistics provider based in Germany, that was perfomed in May 2020. During the planning stage, the benefits and challenges of the remote audit were broadly discussed. On one hand, this approach has more flexibility, a reduced participation time, reduced cost, lower environmental impact and increased efficiency, but on the other hand doubts on information security and confidentiality, suitable work environment, quality of objective evidence, insufficient or unreliable technology, personnel flexibility, also raised in our minds.

Despite the uncertainty, the collaborative efforts of all interested parties ended up in a detailed and comprehensive agenda and TBB provided relevant documentation in advance to facilitate the execution of the remote audit. Qualifyze and TBB also discussed which was the most suitable and secure videoconferencing platform and file sharing tool and a dry run of the technology was performed to confirm the audit objective was feasible and it was comfortable for everybody. From the many platforms available, it is important to select the simplest videoconferencing platform which guarantees the audit objective and security, as more complexity can lead to more problems. It is also highly recommended to think of have a backup or "Plan B" options.
The availability of video connection between the audit participants helped in keeping the human connection during the audit, which progressed very smoothly. Periodic breaks were agreed in advance to allow the auditor and the auditee moments of refreshment which are recommended to prevent the stress from a tightened posture and focus on the screens. In this case, the documents were presented using the screen sharing option as all of them were available in electronic format. TBB provided a clear explanation in all the processes and representative examples were also shown virtually.

The facilities tour was not applicable for this auditee (reinforcing the applicability of the remote audit approach); however, recordings of the facilities, bespoke videos of how the operations work, photographs, facilities layouts, and so on, can be used to evaluate the compliance of the facilities in other cases. Proof of accuracy would need to be done.

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▸ CONCLUSION

The complex situation caused by the COVID-19 pandemic has forced companies in all sectors to adapt their processes and operations, and onsite audits at suppliers of the pharmaceutical industry are not the exception. Qualifyze's approach and strategy for remote audits allows keeping supply chains safe and compliant, even in times when mobility is restricted.

▸ AUDITEE TESTIMONIAL

"For us at Transco (TBB) it was the first audit with Qualifyze and the first WEB audit as an auditee. The selected platform for the WEB audit worked very well and smooth. The purpose and objective of the audit were made clear and understandable. Audit agenda and required documents were announced in sufficient time in advance to the audit date.
Although Qualifyze would have it´s main focus on GMP related audits, the GDP requirements were well addressed. The questions asked were most often understandable.
When observation were made, sufficient room for explanation and discussion was given. The auditors provided enough suggestions for improvement. They understood and were able to gap the tension between compliance and operational requirements of daily business and considered those for realistic measures for improvement. The suggested measures will contribute well to improve Transco´s QM - System. The auditors did act professional, very precise but fair. The documentation of the audit was smooth and fast. The utilization of time during the audit was well managed and the audit had not to be prolonged in order to address all points of the agenda. In summary it was a very professional and open minded audit, which took place in a friendly manner. We at Transco consider this WEB based, remote audit as a very valuable experience. It will offer a new and efficient tool to our Vendor qualification management."

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ABOUT US

Enabled by new digital technologies, Qualifyze sees great potential in creating one single digital network, in which customers, suppliers, auditors, subcontractors and official authorities are connected and continuously exchange quality data in a secure way. A global pool of independent and accredited auditors, who audit suppliers around the globe on a regular and demand-driven basis, publish their results on our platform. This enables customers to continuously receive qualification-relevant information without having to conduct extensive audits themselves. They have access to a customized supplier monitoring dashboard, and receive the most recent and relevant quality data on their suppliers. Due to higher re-use of quality data, the overall number of supplier audits is reduced. This leads to significant cost reduction for all industry stakeholders.