

In collaboration with Acino AG

Situation

The Covid-19 pandemic forced pharmaceutical companies to postpone audits. A constantly changing environment developed in various situations and health measures in different countries. Also, fast changes were not only appearing for countries but also for certain cities as Vienna or Madrid. At the Swiss pharma company, Acino AG audits are mostly conducted by internal auditors. Due to the travel restrictions, Acino's auditors were no longer able to conduct all audits themselves.

Complication

Acino cannot conduct a third party audit in Moscow due to travel restrictions. However, the audit date is set and internal processes are depending on that date. Nevertheless, Acino employees hope for the situation to change and get better. While the audit date is getting closer, the situation doesn't improve. A local Moscow auditor is needed to conduct the audit because of hygiene regulations in Russia.

Key Question

How can Acino keep the audit date and find a suitable external auditor on short notice and therefore prevent internal processes to stop?

Answer

Acino reached out to Qualifyze, a third party auditing provider, to ask if they can conduct the third party audit on behalf of Acino with an auditor in Russia. Due to hygiene regulations, the auditor had to be a local from Moscow. Qualifyze's response came back quickly which was optimal with this urgent request. A Russian auditor was not yet qualified, but Qualifyze maintains a database of worldwide auditors' CVs. To be included in this database, auditors are screened to make sure they comply with the minimum requirements. The Qualifyze team contacted several Russian auditors, selected the most suitable one, and started the qualification process. This process includes a self-assessment questionnaire, an interview, an inspection of a reporting reference, and a final review. The qualification process was quickly applied without compromising on quality, confidentiality, and accuracy. The time this process takes depends on different factors. In this case, the process only took two weeks. Qualifyze always sets up a contractual agreement with the auditors before they conduct an audit. Additionally, the independence of the auditor is checked to assure there is no conflict of interest.

With Qualifyze adapting to the fast-changing Covid-19 environment Acino was able to keep the audit date in Moscow. The auditor conducting the audit was a former employee of a health authority and therefore could perfectly adapt to Covid-19 hygiene regulations. This was especially important since the audit covered several finished products and was therefore challenging. Keeping the audit date, also internal processes that depended on the audit could be continued.

Conclusion

Since Covid-19 will accompany the world for some time, Acinos demand for outsourced audits will last at least two to three years. Qualifyze's pool of auditors from around the world provides flexibility which is an important asset in constantly changing times. Hence, Acino will commission more audits from Qualifyze in Egypt and Dubai. Qualifyze was a help to Acino because of its fast adaptability to the situation given. The team considered all individual needs and requirements of Acino and provided excellent customer service. Finally, Acino received a high-quality audit report. The Russian audit for Acino allowed Qualifyze to extend the pool of qualified auditors who are rigorously monitored at all times. Thus, both parties could benefit and learn from the case.

” I was surprised by the speed of Qualifyze's work. We have chosen Qualifyze because they work fast and have a larger pool of auditors from around the world than other third party companies. “

– Dr. Antonios Karagiannidis, Head GMP/GDP Compliance, Acino AG

