NEWS

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Remote Desktop GMP audits:
A future recourse

Pre COVID-19 pandemic no one could have imagined a pandemic of such magnitude could happen across the globe bringing the world to a halt. Evidently, the current sanitary situation and travelling restrictions across continents has brought onsite audits to a standstill. However, the qualification process cannot be compromised so what options do pharma companies have...

Some of the requirements to conduct on-site GMP audits are therefore clear, for example in Article 46(f) EU Directive 2001/83/EC:
"the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites..."

Some of the options incorporated by the authorities or even the marketing authorisation holders is to have a distant assessment through remote desktop audits either through video conferencing or an audio communication. In April 2020 the EMEA authorities have already devised a questionnaire (question and answer document) which broadly addresses the remote distant assessment of manufacturer's and cites examples of audits which can be conducted.

The pharmaceutical industry and marketing authorisation holders have little choice but to resort to remote desktop GMP verification. A distant assessment is therefore a possible way to assess manufacturer's or CMO's GMP compliance. The Qualified Person (QP) conducting desktop audit can clearly point out that distant assessments are not intended as a substitute for on-site inspections and that on-site inspections should be carried out as soon as circumstances permit. Decision should be based on an adequate, scientific and documented risk assessment.

For new sites too such distant assessments by the competent authorities can be an option and provisional GMP certificate can be issued based on the assessment outcome with a condition to allow the onsite GMP audits as soon as it becomes possible. Distant assessment and supplier qualification will certainly increase in the near future, but these qualifications cannot replace the onsite audit requirements.

Resources:

Notice to stakeholder's questions and answers on regulatory expectations for medicinal products for human use during the covid-19 pandemic:

https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf