AUDIT FROM ANYWHERE:
UPGRADE YOUR QUALITY SYSTEM AUDIT PROGRAMS

EVERSANA™

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For companies that manufacture or support the manufacture of pharmaceuticals and medical devices, the coronavirus pandemic has drastically impacted audits that are required for companies to maintain their ability to make and sell their products while ensuring those products are safe and effective. From supplier audits to evaluating internal or affiliated sites with the FDA, travel restrictions have made it difficult to access and be on site for audits at facilities as has been done in the past.

We've learned, however, that remote and cross-functional collaboration can be successful, and quality system audit programs are not exceptions. Here are some tips for how to continue to make your audit program a benefit to your organization:

PREPARATION FOR THE AUDIT

This concept isn't different from any other audit, but the steps to prepare for a remote audit are critical. Preparing for the review of systems, practices and processes with limited or no physical access to facilities and systems can be challenging, requiring a level of coordination that may not have been needed in the past.

Some Medical Device Single Audit Program (MDSAP) audits carried out by the USFDA involve the use of a single point person who functions as the eyes and ears of the team and supports the rest of the audit team in collecting information and transmitting documents and observations. This approach can also be adapted to a company's internal or supplier audits as applicable.

If it isn't possible for any auditors to be on site, ensure that all required documents, procedures and processes can be reviewed and that this would ensure an appropriate level of review and assessment. Shared folder systems can provide this information and access and, especially for audits of larger scope, are preferable to trying to email individual documents back and forth between the audit participants.

Strategic preparation beforehand is key to providing a successful audit process. Schedule any required experts far in advance to ensure their availability during the parts of the audit where their involvement is important. Establish arrangements ahead of time for access to documents, records, processes and points of contact, including the ability to view pertinent operations in process. Protection of intellectual property or proprietary information may require additional measures or involvement of your company's legal department.

PRO TIP:

Consider whether this is an audit that can be postponed or conducted remotely. Can audit intervals be extended based on past performance or criticality of the product or process being reviewed? Could your procedures be updated to incorporate these approaches without adversely affecting the quality of your product and processes? A side benefit is that travel and lodging costs can be reduced or eliminated.

DURING THE AUDIT

When carrying out a remote audit, the use of a body-cam or other method of allowing remote auditors on the team to view and assess processes and see them in production can be deployed. This can also allow up-close or detailed reviews of processes and equipment that are of interest to the rest of the audit team.

Provisions for addressing findings and providing/documenting corrective actions should be made before the end of the audit whenever possible. What time

frames for response/completion of audit responses are required? To whom will this documentation be provided? Is a review of corrective action at the next audit acceptable, or is a different response time needed? Are findings critical enough that corrective action and confirmation of corrective action are needed before manufacturing/processing can continue? How will corrective action be confirmed?

CLOSING OUT THE AUDIT

When concluding the audit, expect a draft of the preliminary findings of interest at the audit close-out unless other arrangements are made that are acceptable to all parties involved. As we've all experienced, physically gathering all stakeholders for a close-out meeting may be more difficult for a remote audit. Schedule an audit close-out in advance with the audience in mind and the expectation that more than one meeting needs to take place based on time zones and availability. Ensure the distribution of a final report to all interested parties, and understand that audit findings may affect other areas of the business, requiring more follow-up to provide clarity on the issues noted in the audit.

Today's dynamic and fluctuating market has made medical product audits challenging, especially in person. Planning and preparations help to meet these challenges and maintain the utility and compliance of your audit program.

OUR (REMOTE) WORK IN ACTION

CHALLENGE:

ISO-13485 recertification audit for a small orthopedics design/ manufacturing company during the COVID-19 pandemic with limited on-site access

SOLUTION:

Our team developed a strategic plan for a remote audit with:

- Shared folders for documents and records for the Notified Body performing the audit.
- Lists of required documents for review that were supplied ahead of time by the auditor to allow for access and remote review.
- A video/audio feed with the auditor able to ask pertinent questions and request additional records as needed. A portable video feed was also set up so the auditor could see and assess processes in action and communicate directly with process experts.

RESULTS:

The company was successfully recertified, and the audit was performed within the expected time frame.