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Adjusting Audit Philosophy For GMP Success

An industry insight by ADAMAS Consulting

In the Good Manufacturing Practice (GMP) audit world, the idea of remote or virtual audits is a fairly new concept. In the past, typical audit options included questionnaires, surveys, desk audits, purchase of independent audit reports (i.e. Rx 360), and on-site audits. There were companies looking into the idea of virtual audits but very few.

Since March 2020, many companies have had to adopt and adjust their audit philosophy to allow auditors to conduct virtual or remote audits. The complexity on the GMP side has come in the form of a key portion of the audit, the tour. Some auditees have addressed this by either not allowing a **tour** to be conducted, by use of a video tour already prepared providing a general overview of the entire facility (more of a promotional material video than the actual process), pictures of the facility, or in some cases an actual tour with the auditee moving throughout departments allowing the department head to present their area on camera. The best option for the virtual tour is actually having the auditee walk through the facility, similar to how it would be conducted during an on-site audit. There could be other options, for instance if manufacturing is live streamed, then the auditor could view the activities in the manufacturing suite through the secure portal in real-time.

The second form of complexity is paper. Some sites are currently a completely paper-based system. There are still many legacy validation, maintenance, and calibration records that are captured on paper. When hosting a virtual or remote audit, all of these records have to be scanned to allow the auditor to review them. Additionally, if there are questions during the audit, these records may need to be scanned urgently to provide an answer to the auditor's questions.

When companies have hosted the audits, due to confidentiality in the GMP space, we have had several different options that we have experienced. We have had vendors that cannot provide documentation prior to the audit; therefore, the audit is a meeting where the auditee will scroll through documentation on screen as the auditor reads it. We have had a hybrid approach, where the company will provide

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documentation through a secure portal the day before the audit, set up meetings the day of the audit with the virtual tour, and then allow the auditee to have access to the portal the day after the audit to complete documentation. In some cases, documents may not be available based on auditee resources and capabilities. During this set up, the meeting is typically active the entire audit day, allowing the auditor to instant message or speak to the audit host in real-time. We have also had a very hands-off approach to the audit, in the sense that the auditee has the opening and closing meeting scheduled. We have found the hands-off approach made the audit process a little tougher for the auditor since questions are not always answered efficiently or there are delays in responsiveness from the auditee.

Our team has successfully conducted virtual audits in the GMP space since March 2020. Our virtual audit experience includes everything that has been listed previously. Success factors really depend on the site that you are auditing. If a site is still paper based, the move to virtual or remote auditing is a difficult one. For some companies that have electronic systems, electronic records, and video tour options; the change and shift to remote auditing has been pretty seamless. Our team provides the auditee feedback on how the virtual or remote audit was hosted and the audit process. In general, the virtual or remote audit option is becoming more streamlined as companies embrace more technology and have experience in the audit hosting environment.

For many of our clients, depending on how much we can actually see during the virtual audit and the relationship with the auditee, the virtual audit is viewed as an initial assessment with the idea that a follow-up on-site audit be conducted when restrictions are lifted. This approach is especially seen in the case of qualification audits. For requalification audits, the virtual remote option is fulfilling our client's needs. Moving forward, we feel that the virtual audit will be an option in the GMP space, typically best used for surveillance or routine audits. It will be a new tool allowing us to ensure compliance throughout the supply chain and throughout the GMP process.

The ADAMAS team