Remote Auditing –
Technology Best Practices and Solutions

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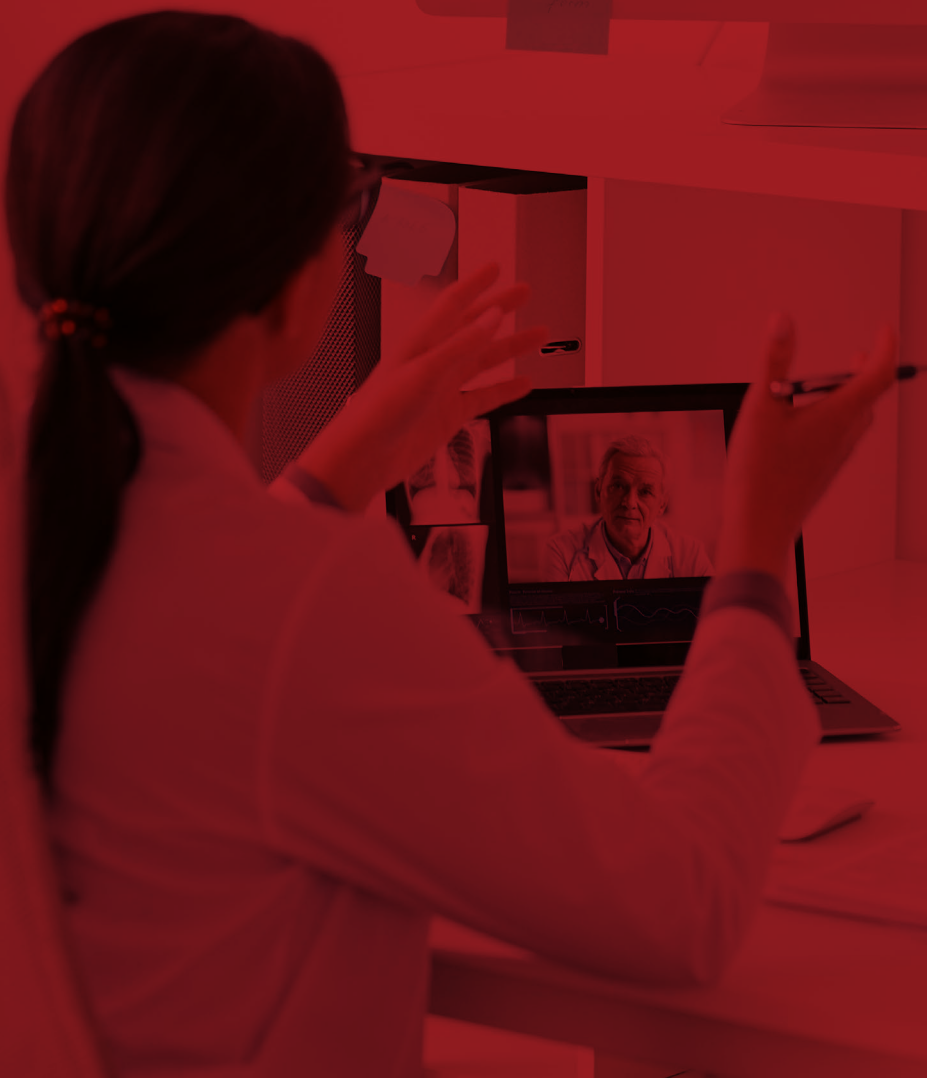
TABLE OF CONTENTS
Remote Auditing – Technology Best Practices and Solutions

Background

Definitions

Remote Auditing History

Remote Auditing Technologies

Technology Determination

Qualifications & Skillset

Remote Auditing Techniques

Special Considerations

Conclusion

References

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INTRODUCTION & BACKGROUND OF REMOTE AUDITING

Auditing to verify a process or system meets stated criteria. The audit process involves looking for objective evidence that will substantiate that the process or system under review meets the objectives of the quality management system standard. For years the standard way to perform audits was to go to the facility or location where the activity to be audited took place. As computer systems and related technology developed, the ability to look at evidence remotely came into existence.

Faxing, scanning and email technology paved the way to share information from one location to another relatively easily. Other technologies like Remote Vision Glasses and technology sharing platforms like Skype & Zoom built on top of those early technologies and created the foundation for remote audits.

Remote audits in various incarnations have been in practice for over a decade, however the gold standard was the onsite face-to-face audit where the auditor went from one location to another to exam the processes and systems firsthand. This was true for different types of audits but especially for supplier audits.

Fast forward to March 2020 and the development of the international crisis related to the spread of Covid-19 virus making almost all travel next to impossible. The regulated GMP industries still need to function, which included performing quality audits at locations outside of the organization. The concept of remote auditing was pushed front and center, and it became the focus of how to perform audits. The global pandemic did not give birth to the concept of remote auditing, but it nurtured it and accelerated its further development and growth.

Here in this paper we will take a deep dive into remote auditing. We will explore the technologies used and investigate the best practices for performing remote audits.

KEY TERMS

REMOTE AUDIT:

Remote audits leverage technology such as video teleconferencing and shared file folders to facilitate interviews and share documents and record, when an on-site audit is not viable or desired.

DESK AUDIT:

The desk audit is usually done remotely where the auditor sends the auditee a request of a list of questions and specific information to be sent to the auditor's location. The auditor reviews the information and writes their audit report based on the information provided. There is little interaction between the auditor and auditee in this type of audit.

DIGITAL COLLABORATION:

The practice of people working together through online means such as software-as-a-solution (SaaS) platforms. Instead of teams only communicating and working together in person, they are able to rely on digital tools to address many of their collaborative needs. Some organizations use digital collaboration to supplement their day-to-day, onsite operations.

ICT:

Information and communication technologies.

SCREEN SHARING:

The act of sharing access to a given computer screen. Screen sharing software uses many different methods to allow sharing a screen remotely with a second user for collaboration purposes or other objectives. Screen sharing is also the name of a proprietary Apple product developed for these purposes. Screen sharing is also known as desktop sharing.

VIDEO CONFERENCING:

A technology that allows users in different locations to hold face-to-face meetings without having to move to a single location together.

VIRTUAL BREAK OUT ROOMS:

Electronic rooms which allow groups of two or more participants to meet separately and collaborate during a larger live online session.

REMOTE AUDITING HISTORY
Brief Overview

Auditing, just like technology, is evolving. Previously it was a face-to-face meeting, with a site tour and review of hard copy evaluation. Then came a hybrid. Copies of documentation were shared and reviewed and then the face-to-face meeting would take place with a site tour. Moving on, audits are now virtual: a repository is opened, and all documents required are deposited. These are reviewed up-front and then follows the site tour using live streaming. There may be some more requests for documents into the repository during the virtual tour.

Not all companies allow up front access to documents. Some are very restrictive and only allow day-of viewing, controlled by the auditee. The gold standard is to have documents available ahead of time. Similarly, not all auditees will perform a site tour. Some have pictures or a video and others just say no. In cases where there is a no, a commitment to a follow-up on-site visit is best. Opening and closing meetings are limited, and more and more written communication takes place as documents are viewed. From full personal interaction to full virtual interaction.

REMOTE AUDITING TECHNOLOGIES

In this section, we will cover different technologies that can be used in remote auditing. This will include the name of the technology, a brief description, and key pros & cons regarding the use of the technology.

TECHNOLOGY	DESCRIPTION	PROS	CONS
Telephone/ Conference Call	Traditional telephony. Use of a landline or mobile phone to facilitate interactions between auditor(s) and auditee(s)	• Simple • Understood by virtually everyone • Can reduce distractions caused by live video streaming	• Results in a much less immersive experience overall • Significantly limits the ability to review operations and review documentation in a collaborative fashion
Cisco WebEx **Zoom** **Google Meet**	Video conferencing tools designed for audio, video, and screen sharing.	• Relatively simple to use. Meetings can be joined from a specific URL generated in a meeting invitation from the auditor. • Feature rich. Screen/content sharing, remote annotation and control, cloud meeting recording, breakout rooms, virtual backgrounds for video participants. • Can join from a computer, tablet, or phone	• (WebEx/Zoom) Meeting hosts require a paid account in an Enterprise environment (there is no account needed to join a meeting though) • To host a Google Meet Session a paid G Suite account is required • May not be available at your company
Microsoft Teams	Digital collaboration tool from Microsoft that encompasses chat, video conferencing, file sharing, and team boards.	• Multi-faceted collaboration possible. You can set up a "Team" for an audit and exchange messages, documents, and communicate. • Video conferencing experience has a focus on simplicity while still delivering features such as screen/document sharing, remote desktop control (useful for scrolling through documents the auditee is sharing from their computer), and virtual backgrounds	• More complicated to "just meet". To collaborate with an external person (like all supplier audits), there may be setup needed in advance to invite the person to a Team. This may also require intervention from your IT function. • The document sharing function in Teams is inferior to WebEx/Zoom. It is difficult to share successive documents without stopping and restarting sharing • Offers a fee trial, and after there is a cost. Is available with additional cost with an Office 365 Subscription
FaceTime	Proprietary video conferencing tool from Apple	• Simple to use • Can be used 1:1 or for a group	• Limited to Apple devices only (iPhone, iPad, Mac) • Only does video calling. Does not allow screen sharing and other features available with alternate options.

TECHNOLOGY	DESCRIPTION	PROS	CONS
Avatour 360	Remote presence solution enabling virtual tours and physical inspections utilizing a 360 degree camera and mobile device	• Can be used for 1:1 session or for a group from a real location and in real time • Packaged in a starter mobile kit • Easy to deploy and simple to use • OneX camera enables realistic, live, high resolution video capture • Purchase costs are variable based on the agreement • Since launch, the solution has been implemented to solve several business problems	• Sessions are limited to 9 attendees • Tripod is on a stand with wheels and may not roll well on a bumpy surfaces • There may be areas or activities that are not as accessible with the 360 degree camera • Cutting edge and beta began Fall of 2019 with release in March 2020 • Requires purchasing hardware and a subscription however costs are variable based on agreement • Preplanning is needed to ensure set up is complete, batteries are charged, network or cellular access is available, and training for use is completed
Hodei Technology – GEMINI & IKASI Solutions	Remote telepresence solution enabling virtual tours and physical inspections utilizing Google Glass and delivering a first-person point of view	• Can be used for 1:1 session or for a group with unlimited participants from a real location and in real time • Packaged in a pilot mobile kit • Google Glass Enterprise Edition (EE) enables hands free, real time, high definition image quality from a first-person point of view • Easy to deploy, simple to use, and secure (fully encrypted), only those invited to sessions can attend • Purchase costs are variable based on the agreement • Feature rich ability to share data from additional devices, cloud meeting recording, and breakout rooms	• Preplanning is needed to ensure set up is complete, batteries are charged, network or cellular access is available, training complete, and profiles established • Requires a purchase however the costs are variable based on the needs • Requires Windows 10 and not available for Apple Devices

HOW TECHNOLOGY ENABLES IMPROVED REMOTE AUDIT EFFECTIVENESS

Technology has advanced and enables full support of all major activities associated with a physical audit of a facility. Now, and in the post-pandemic global economy, industry will rely more heavily on establishing and maintaining quality standards, along with managing compliance from a distance. Suppliers and audit firms alike are migrating to software, hardware, and apps that were not leveraged previously to fill the operational void. This forced change has come quickly, and with it, options for technology remedies have rapidly become available. Simply articulating an audit can be conducted remotely just as easily, and thoroughly as a face-to-face audit, does not make it true. However, it is possible when a degree of pre-audit logistical planning is executed. The purpose and context of the audit matter. Once that is firmly established, an assessment of each organization's technologies should be executed to ensure confidentiality, and all audit requirements are addressed.

Traditional audit requirements include an inspection of the supplier's building and facilities, equipment, personnel, material controls, production, and quality controls. The documentation associated with each of these areas is reviewed in order to give a full picture of the supplier's quality system. Most companies have migrated to some version of an electronic record, even if that has become a result of scanning hard copies of documents to be saved as a pdf.

SharePoint is a Microsoft Solution that can be obtained with minimal cost and is more intuitive to use. As a result, sharing documents for review is easy to do remotely, if the electronic records exist. It may take a little longer to find what you are looking for on a blueprint for example, without having the document scrolled out in front of you; however, all the required information can be made available. In this case, SharePoint serves as a document repository that can be used as an intranet for sharing information internally and externally, without going with a full-blown quality management system (QMS). As a result, this solution becomes a viable option for smaller organizations.

Quality Management Systems (QMS) with auditing modules are increasingly becoming more available and offer capabilities that improve the efficiency of performing audits. Solutions such as ClearMark and SmartSolve can be validated by suppliers, and auditing firms alike to standardize workflows along with audit reports that make the process of citing, tracking, and responding to audit findings more thorough and timelier. Late stage and commercial suppliers are more likely to have these systems, as the quality requirements governing their activities are higher. The validation of the QMS can fall under the scrutiny of the auditor as well, and training requirements tend to be higher for these powerful tools. Depending upon the size of the auditing firm or supplier, multiple and different types of audits may need to occur.

Master Control is another QMS that boasts as an integrated auditing platform. It has a collaborative audit scheduling calendar that allows audits to be scheduled internally and externally, with filters for audit type and auditor. The checklists created allow for standardized auditing processes and reports, based upon the audit requirements. Once an observation has been noted, it can be assigned to internal users or external responders, for tracking. Also, a peer review collaboration function is available, allowing the report to be shared and receive responses. Follow ups, responses, and reassignments can all be managed by the auditor in real-time.

Once conference rooms and collaborative workspaces were traded for personal home offices, all generations of auditors and quality representatives have adapted to the use of video conferencing solutions. Those most familiar are: Zoom, Google Meet, FaceTime, and Microsoft Teams. While Security has been a topic of concern, these companies have worked to address this area, and continue to do so. When kicking off an audit with a presentation, Zoom and Teams both allow for screen sharing of a presentation or agenda, as well as visual display of all participants. Integrated webcams keep the startup costs low but vary in quality. If you are already using SharePoint, Teams has been integrated as well as the remainder of the Office 365 Suite, further

improving collaborative work efforts. Both solutions are ideally suited for any audit to perform interviews of subject matter experts, review data presentations, and conduct video teleconferences to kick off and close out audit efforts.

While videoconferencing platforms have become a replacement for the conference room, they fall short when it is required to execute a facility tour, observe a production line, or view a utilities panel in a manufacturing area. Again, depending upon the requirements of the audit, this phase can be a bit more difficult to accommodate than others. However, in the current context, accomplishing an observation or tour can be one of the more important requirements to complete. Utilizing a solution like Avatour with an inexpensive 360-degree camera attached to a cell phone, the host can connect with up to nine viewers anywhere. With a selfie-stick or tripod on wheels, a real-time virtual tour can be had.

A drawback to this approach of leveraging the selfie-stick and cell phone is that it may be prohibitive in certain areas of suppliers' facilities. For instance, when trying to observe a detailed process or quality function, a 360-degree camera and streaming technology may not deliver enough image clarity and spatial dimensions needed to be successful. Also, for the individual responsible for the virtual tour, the focus can be more on the device and less on the surroundings, having safety and work effectiveness implications. AR wearables such as Google Glass Enterprise Edition (EE) and Vuzix provide a hands-free option that allows users to put on the device, provide a first-person point of view to the auditor, and maintain appropriate safety protocols.

While not as simple to use as recording a video, or taking a picture on a cell phone, these AR wearables can deliver a real-time video stream when connected to a platform such as Hodei Technology's GEMINI and IKASI Solutions. These solutions deliver high-definition video sessions to one or to an unlimited number of viewers, anywhere in the world, and in real-time. The individual onsite wearing the AR device such as Google Glass EE can be directed by the auditor to share a crystal-clear operational picture of the facility. The experience can be just like being on location and seeing it with your own eyes.

And, just as those individuals that have access to data, and the audit itself is managed in a traditional in-person inspection, access control is performed digitally with Hodei's Platform.

With the increase in functionality comes set up time. All of these come with kits, and basic start up guides, along with support teams to assist the auditor, or the supplier's IT teams. Once a simple set up is complete, and signal strength/bandwidth is tested, the auditor gains full access to a site with the best vantage point possible virtually.

HOW TO DETERMINE WHICH REMOTE AUDITING TECHNOLOGY IS BEST FOR YOUR ORGANIZATION

As can be seen from the previous section there are numerous technologies available for performing remote audits, however one size does not fit all. There are various factors to consider when choosing a remote technology for a remote audit. These can include but are not limited to, the process or system to be audited, the information technology infrastructure of the location to be audited, availability of the right equipment, required skillset and finally the cost related to the implementation and use of the specific remote auditing technology.

DECISION TREE DIAGRAM
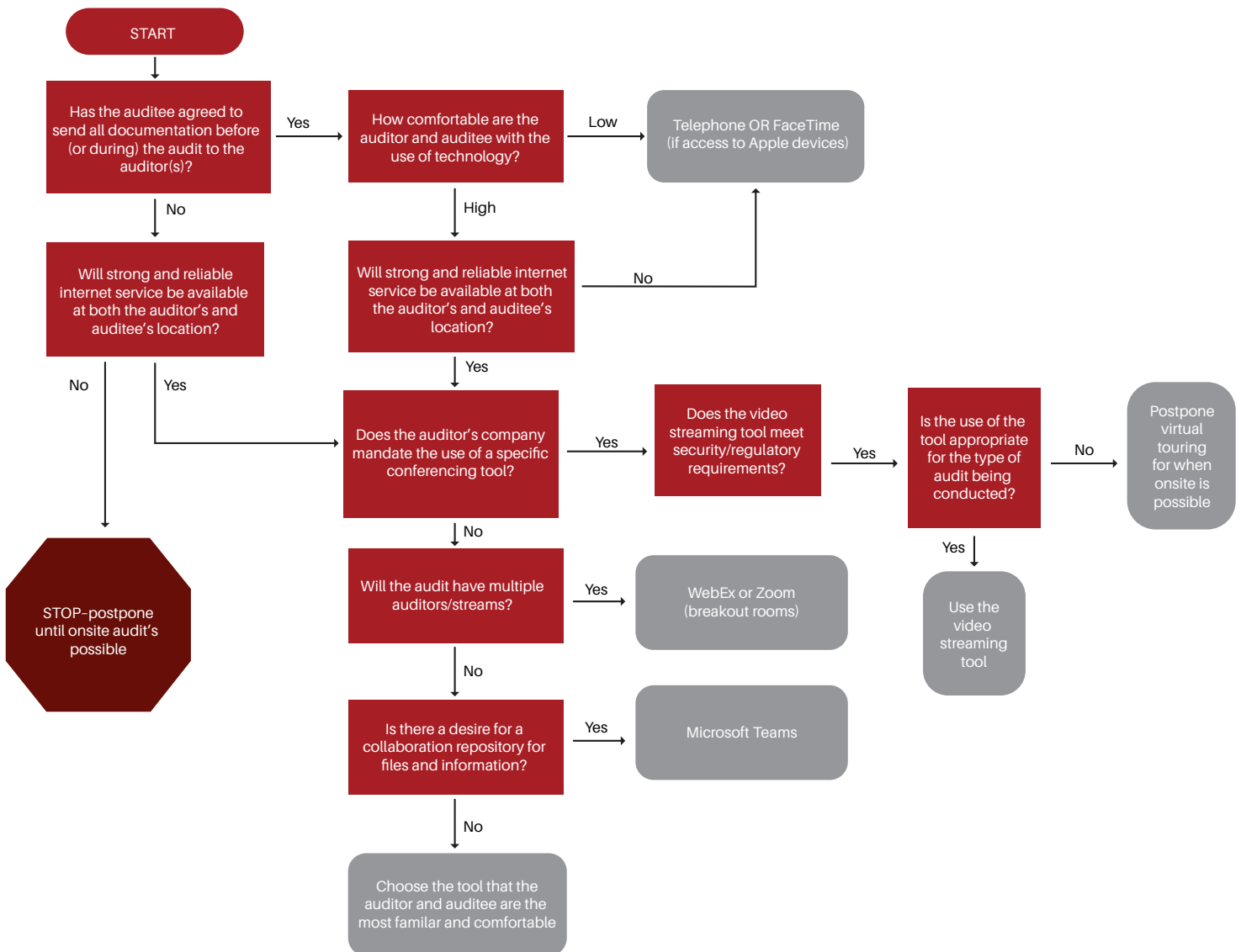
REMOTE AUDIT PROCESS STEPS

Remote audits will be conducted virtually and ensure they meet all system requirements. The audits replace current annual onsite audits and require participation from onsite quality management representative.

The audit process is detailed below:

- Schedule the dates for the audit with the quality management representative
- Perform guided interviews with auditees, using teleconferencing
- Perform review of documents and data conducted with screen or file sharing
- Records and data selected by the auditor using risk-based approach and sampling techniques
- Electronic review of all audit data collected
- Perform a risk assessment and create audit report
- Submit report electronically and review together with client in a Zoom meeting

QUALIFICATIONS & SKILLSET REQUIRED FOR REMOTE AUDITS

Auditor competency is a basic Quality Management System (QMS) requirement regardless of audit method. Each auditor must have the appropriate training and competency established, either through external certification courses or internal auditor qualification requirements. As remote auditing can bring its own unique set of challenges each auditor must have the necessary experience in managing an audit in order to be successful. While additional auditing training is not required, training and familiarity in the techniques and tools for remote auditing must be addressed.

Auditor's competency for remote auditing shall include technology fluency and communication skills. To ensure a successful remote audit, the auditor needs to be capable of both establishing meetings using the tools defined/agreed and able to trouble-shoot the tools when issues arise, such as when Internet connections are intermittent or have insufficient bandwidth to support an effective audit. The auditor must be fully trained on the capabilities of the utilized meeting, visual, audio and any other specialized technologies.

When the reliance on digital technology increases, the role of the computer professionals also becomes increasingly important for remote auditing. Staff from the information technology (IT) group may have to be included as part of the audit team to ensure that all systems used for the remote audit are properly working and that any interruptions in the transmission of information during the audit can be immediately addressed. The IT professional should also be trained on the remote audit process to aid in the smooth and efficient technology portion of the remote audit.

REMOTE AUDITING TECHNIQUES & BEST PRACTICES

With the recent onset of COVID-19 forcing entire organizations to work remotely, auditors and compliance teams have run into new challenges that require them to re-engineer their approach towards work. As an Audit Leader, you may be facing situations such as:

- Establishing or reviewing etiquette (grounding rules) for audit conducting

- Conducting walkthroughs and/or interviewing people remotely

- Collecting objective evidence on time when the auditees are swamped or distracted

- Keeping auditees and audit team members engaged during a time when people are likely distracted stresses or scared

- Providing recommendations, potential findings, issues or observations

- Auditors should be flexible and use the tool(s) that the auditee is comfortable with. This may require an auditor to ask for an exception from IT for access to things like Box, Zoom, etc. Most companies will allow these tools for specific use even if they are normally restricted.

It is normal to feel stressed and overwhelmed during these times, but there are some techniques that can be implemented and followed to make remote auditing easier and more effective.

REMOTE AUDIT ETIQUETTE RULES

During the opening meeting, it is highly recommended establish or review the etiquette rules agreed between the parties (Lead Auditor and Auditee). Examples of etiquette rules are:

- Ask to mute the microphone of the personnel that is not presenting documents, talking or asking questions.

- Agree on the sequence to present the documents. The lead auditor should explain that they will be taking notes of each document reviewed (for example: name/title, version, effective date, etc.).

- Avoid scroll down or up the document if the lead auditor has not requested it.

- Establish communication backup system in case of internet failure.

- Agree on break periods including lunch. It is recommended whenever possible to take 10 minutes breaks at least every two hours.

CONDUCTING WALKTHROUGHS

To conduct a virtual walkthrough successfully, you need to have reliable virtual meeting tools (e.g. Microsoft Teams, Zoom, GoToMeeting, etc.). Although you may have visited the auditee site before, it is always recommended to have a process flow chart on hand, where possible, to follow the process and make annotations if necessary. The Lead Auditor should communicate ahead of time to the Auditee if there are areas of specific focus that they would like to cover or emphasize during the walkthrough.

The videos should be live, if possible. It is preferable that the site walkthroughs should be led by a site guide/employee, knowledgeable of the entire process and familiar with the entire facility, along the planned route with smart phones, iPads, etc., with live streaming capabilities. It is important to ensure that live streaming works within the facility being audited so auditors have a clear view of site conditions. Auditors can also take advantage of any in-house surveillance cameras (e.g., security or quality systems) to provide additional footage of operations or to support objective evidence, when necessary.

When live video is not possible due to hazards or restrictions, such as a plant manufacturing flammables or explosive materials, then it may be necessary to use a pre-recorded video or photos.

INTERVIEWING PEOPLE

Interviews are an essential activity to obtain or verify objective evidence during audits. Therefore, interviews are an activity that cannot be skipped during remote auditing. Interviews are best scheduled in advance to ensure availability; however, they can be conducted on an ad hoc basis as need arises.

Virtual interviews, as well as the entire audit, should be conducted in an environment free from distractions to give your full attention. Choose a quiet room and let your housemates, if you are working from home, or your peers if working in an office, know that you are holding an interview so they can stay as quiet as possible. Your space should have a neutral background, so the interviewee is not distracted by your environment. Try to keep the environment as professional as possible to mimic the setting of an in-person interview.

Have a list of specific questions. There may be a lag when using a computer or phone to conduct an interview. Provide the interviewee with plenty of time to respond. If the interviewee cuts out during their response, ask them to repeat their answer to ensure you hear everything the interviewee has to say.

Documenting the interview. Write down everything from your interview before you forget. You can revisit your notes from the interview to ensure everything expected was covered or determine if you must go back to the interviewee.

Finally, don't forget to follow normal interviewing best practices such as break the ice, do open questions, and summarize and paraphrase.

COLLECTING OBJECTIVE EVIDENCE

Planning always has been one of the most important phases of the audit cycle. The success of an audit could be determined by the quality and efficacy of the planning performed. As in onsite audits, remote audits require careful upfront planning on the part of the auditor and the auditee.

The auditee needs to collect all documents and records prior to the audit and determine the best way to share that information remotely. Technology needs and requirements must be evaluated, and logistics and access should be tested prior to the audit. To avoid wasting time due to troubleshooting issues, it is recommended to check that all cameras, web meetings, shared document space, Wi-Fi, and other technology is working appropriately prior to the audit.

A list of procedures and documents or records can be submitted in advance to the auditee. Then, the auditee can have them ready for review by the date of the audit. Or you can start the review process prior the audit date, if the auditee has shared them with you in advance. In case of the Auditee shares the documents in advance, is recommended that the Lead Auditor check that they can open the files sent by the Auditee.

If the auditee prefers to share procedures, documents, or records on the date of the audit, prepare a list of specific questions to ask for each topic in the audit agenda. Try to avoid wasting time scrolling the entire document from top to bottom. Make specific questions and ask the auditee to go straight to the section in the procedure, document or record that can answer or provide evidence to your question.

If the auditee has shared procedures, documents or records in advance, and you have reviewed them, prepare a list containing questions, areas of concerns, concepts clarifications, etc., if applicable, for each document reviewed. Submit the list and encourage the auditee to reply to your questions before the audit date or be ready the audit date.

It is important to keep track of all your request to the auditee. Verify your list of requests periodically to ensure all topics in the audit agenda/scope have been covered.

When using a tool like Microsoft Teams the chat area can be used to add new requests or document questions as you think of them during the audit. This allows all parties involved to clearly know what is being requested.

Because it is difficult to read body language or interpret conversations auditing remotely, make sure that the communication is always clear. Summarize and paraphrase to ensure the auditee has understood your request and they are providing the correct evidence.

KEEPING PEOPLE ENGAGED

During remote auditing there are no opportunities to get together for lunch or coffee breaks; therefore, you must intentionally plan for activities to keep both parties, audit team and auditee, feeling connected and engaged.

Consider including in you opening meeting information about your company products and the impact of utilization of the auditees' products or services in your company.

Plan for short breaks, 5- 10 minutes, periodically to stand-up or talk about any topic.

PROVIDING RECOMMENDATIONS, POTENTIAL FINDINGS, ISSUES OR OBSERVATIONS

It is very important to make clear to the auditee what issues were found during the audit and allow auditee to discuss those findings during the closing meeting. Since auditor is not present at the auditee's facility, it is important that auditor visually communicate the audit result to the auditee through a presentation.

REAL LIFE REMOTE AUDITING EXAMPLES

VIRTUAL FACILITY TOURS:	
	DO'S
Camera	Go live if possible
Camera	At minimum some area photos should be shared, if a live tour or video is not available
Camera	Camera person should be steady and not move the camera too fast
Camera	Use panning of the of the room on first entry then narrow down to go through the process
Platform	Communicate software/platform to auditor team
Platform	Where WIFI connection does not work as good, video tape that area
Platform	Use your process flow diagrams and go through the facility as the product would
Platform	Make sure to identify areas in advance where live feed may be interrupted due to interference with WIFI.

Process	Incorporate supplier teams during normal production time
Process	Practice, practice, practice
Process	Allow auditor to lead/request areas
Process	Always follow the agenda and manage time
Process	Always get traceability in objective evidence to support any finding. Ask to focus on the objective evidence lot numbers, date, etc.
Process	Document in the audit report if a key area was not able to be seen on the tour
Process	Ensure you cover critical material storage areas
Process	Take time to give the auditor opportunities to ask questions on the tour as needed before proceeding to the next focus area
Process	Plan out the time that it will take to go through the entire process flow and critical areas and allowing extra time for questions and dialog so that the auditor understands how long the tour will take and what will be covered.
Process	Provide the auditor in advance of facility and process flow diagrams so they can follow along with what they are seeing
	DONT'S
Camera	Do not record employees directly
Camera	Take screenshots during the live tour unless you have obtained OK to do so
Process	Do not record any confidential processes or product manufacturing know-how
Process	Do not keep on looking for more information if the supplier has already told you they do not have anything implemented
DOCUMENTATION SHARING, CONTROL, ACCESSIBILITY:	
	DO'S
Platform	Use a secure platform
Platform	Research the platforms that are auditor friendly for viewing and managing the documentation
Platform	Suppliers can set a timer or 'window of accesses for the auditor to time out at a certain point. This will allow the supplier to know that there is an end point of access.
Platform	Verify selected software platform is accessible for data sharing. MS Teams does not work well with Apple computers for data sharing from a company specific access file. Recommend use of a Microsoft Computer or alternate system that is PC based.
Platform	If using platform for sharing like Microsoft Teams, allow for the auditor to take control to peruse through the documents

Platform	Ensure that documents are readable, zoom in if font is small, ensure that any scans of documents are completely legible
Process	Communicate software/platform to auditor team
Process	Organize documents as per audit agenda
Process	Provide documentation with a minimum 48 hours before the audit
Process	In preparation call the site, introduce yourself and talk about the expectations of the upcoming audit. During that call, put them at ease that they can use a secure platform to share documentation. We can put a CDA in place if needed but will need the Client/SQA to review so that needs to be decided if one is not already being discussed. Set up a short test session to assure that documents can be opened, and everyone can access the platform being used.
Process	Request access to shared documents/records post audit, if follow up questions arise or there are items that you were not able to review during the audit. This is routinely for a limited time only, e.g., 24 hours post audit.
Process	Use of shared folders to allow the auditor to navigate the documents provided
Process	Allow the auditor time to document the information needed like document titles, version numbers and effective dates
Process	Allow the auditor "quiet time" to review each document
Process	Keep audit moving in line with the agenda and announce as early as possible so that schedules can be adjusted accordingly
Process	Provide the auditor with an SOP Master List so they know what documents to request as the audit goes
Process	Be flexible. React to changes in a professional manner. Audits do not always go as planned despite everyone's best efforts. Move items around as needed
DONT'S	
Platform	If you are sharing don't scroll through the documents too fast
Process	Send documents via email is not recommended
Process	Do not share or upload in any other system that is not STEPQ
Process	Wait until the last minute to escalate that you have not received any response or documentation from the auditee
Process	Don't try to obscure information
Process	Don't rush the auditor while they are trying to review documents and records

PLATFORMS (ZOOM, SKYPE, TEAMS, GOOGLE MEETS, ETC....):	
	DO'S
Platform	Use a secure platform
Platform	Coach all teams on video conferences 101, mute/unmute button, video on/off control, etc.
Platform	Have open cameras
Platform	Ask supplier if you can record, always ask for permission.
Platform	Check your attire, visual background, and background noise
Platform	Sometimes WIFI/internet cuts out – have a backup plan (email / phone call)
Platform	It is highly recommended to have a practice run with the supplier prior to the audit to ensure all systems are functioning and data is accessible
Platform	Ensure that all computers logged in are muted unless you are the one speaking.
Platform	Ensure all who are logged in or participating are identified to the auditor and vice versus
Platform	Try to use computers that are in more private areas where common traffic areas to limit noise, distractions and overhearing conversations that would not be intended to be heard
Process	A collaborative, agreed to AGENDA is the key to a successful audit
Process	Successful audits have ALL parties/participants should attend the Kickoff meeting
Process	Pre plan with the auditor by practicing with application, platform, sharing screen, etc.
Process	Take breaks
Process	Ensure all employees know that an audit is in progress and what computers are logged in
	DONT'S
Platform	Keep track on mute button on confidential information. Ask supplier if it is ok to record for reference
Platform	Pan to quickly, shake or make fast movements
Platform	Underestimate the time needed to prepare more than an onsite audit

SPECIAL CONSIDERATIONS DATA INTEGRITY, PRIVACY & CONFIDENTIALITY CONCERNS

For remote audits, the integrity, security, and confidentiality of electronic or electronically transmitted information is key. The auditee and auditors need to understand the capabilities and limitations of the technologies planned for use in remote audits. As it is important to ensure the chosen technology will facilitate meeting the objectives of the audit, companies must ensure the chosen technology meets data integrity, privacy, and confidentiality requirements, as well.

Below is a list of potential concerns related to data integrity, security, and confidentiality with suggestions to alleviate or address the concerns for executing remote audits:

CONCERN(S):	SUGGESTION(S):
Risks of the remote auditing technologies used.	• Understand the capabilities and limitations of different remote auditing tools. • Use company-approved software tools and/or services aligned with security and confidentiality requirements. • Leverage the expertise of compliance and IT personnel in the assessment and selection of remote auditing technology. • Ensure site procedures, and/or company policies are updated, as appropriate. • Ensure the audit host, audit team, and participants are properly trained on the remote auditing tools. • Provide limited/read-only access for auditor for any data that may be accessed.
Sharing confidential documents / information during remote audits.	• Review and update non-disclosure agreements (NDAs) / confidentiality agreements (CDAs) to ensure remote auditing aspects are incorporated. • Document any restrictions on copying, photographing, recording, or screenshotting information during the remote audit in the NDA/CDA. • Ensure the security of the document / information sharing technology used. • Use controlled-access software rather than email for sharing documents. • Ensure access to documents / shared folders is terminated at the end of the audit. • Ensure documents sent to an auditor are securely destroyed / discarded.
Validity and objectivity of the information provided / reviewed.	• Live / real-time demonstrations of controlled access / unique user logins, etc. • Live / real-time review of electronic system audit trail(s), metadata, site tour(s), data storage, etc. • Same-day photos / video of the site or process.

CONCLUSION

Remote auditing is another tool for auditors to use instead of an onsite audit. The reasons to use remote auditing may be varied—from pandemics to safety or security reasons. The use of a remote audit should be justified and documented.

Remote audits may be appropriate for auditees that require no physical site review and may be used in rotation with physical audits for those auditees with good compliance and quality histories.

Remote auditing existed well before the time of the current pandemic. It was not a widely used process and when it was used, it was used at the convenience to the company or companies involved for usually some type of cost or resource savings. Fast forward to 2020 and because of the inability to easily travel remote auditing raised through the ranks as the best if not only way to review quality management and product compliance adherence.

As the saying goes, necessity is the mother of invention, the coronavirus pandemic was the mother to the further development of existing remote auditing practices and technologies. Almost overnight, redeployment of existing technologies and development of totally new ones arrived on the scene.

Prior to the pandemic, the requirements for remote auditing were strict in order to comply with existing interpretations of global GMPs. Regulated companies had to comply with the requirements and expectations of regulators with respect to remote auditing GMP requirements.

Today, the industry is in a totally different situation. With the choice to use existing remote audit technologies or no audit at all, the choice has gone to using exiting and newly developed technologies with a mindset of GMP compliance.

As the GMP regulated industry matured, it has learned to become more flexible. Years ago, a huge emphasis was placed on product QC testing and QA inspection. This has now evolved to process qualification/validation and a risk-based approach. New ways to approach remote auditing have been developed to work in step with the remote auditing technologies. This includes creation of related processes, development of required instructions and training as well as creative ways to stay compliant with GMPs.

It is up to every organization to determine if they will entertain remote auditing and if so which technology is best for their situation. Researching best practices from other organizations use of remote auditing technology will go along way to make the transition more efficient and effective. Each auditor and auditee need to perform a risk assessment to determine when it is appropriate to use the remote auditing process.

With no well-defined end to the pandemic, the industry has no choice but to continue to adapt and develop ways to ensure remote auditing grows into a recognized and accepted way to ensure quality system and product compliance going forward. This will be achieved through further development of remote auditing technologies based on good quality and regulatory practices along with a risk-based approach.

References:

- https://www.ema.europa.eu/en/documents/scientific-guideline/guidance-related-gmp/gdp-pmf-distant-assessments_en.pdf
- ISO 9001 Auditing Practices Group Guidance on Remote Audits ISO/IAF Date: 2020-04-16
- GUIDELINES FOR CONDUCTING REMOTE AUDITS Rainforest Alliance April 2020

At Rx-360, our mission is to protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and quality of its materials. For information on becoming a member and membership benefits:

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"Now, and in the post-pandemic global economy, companies have been forced to rely more heavily on establishing and managing quality standards from a distance. Digital technologies have progressed enough to enable a comprehensive audit, including the ability to be present anytime and anywhere. While there was business value prior to the pandemic, it is now essential."

Emily Butler
Director, Business Development
Hodei Technology