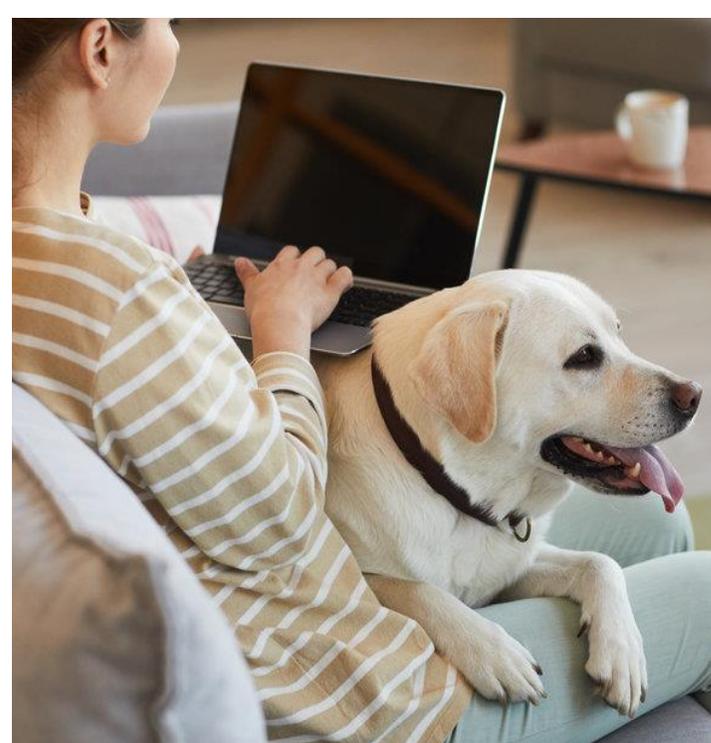


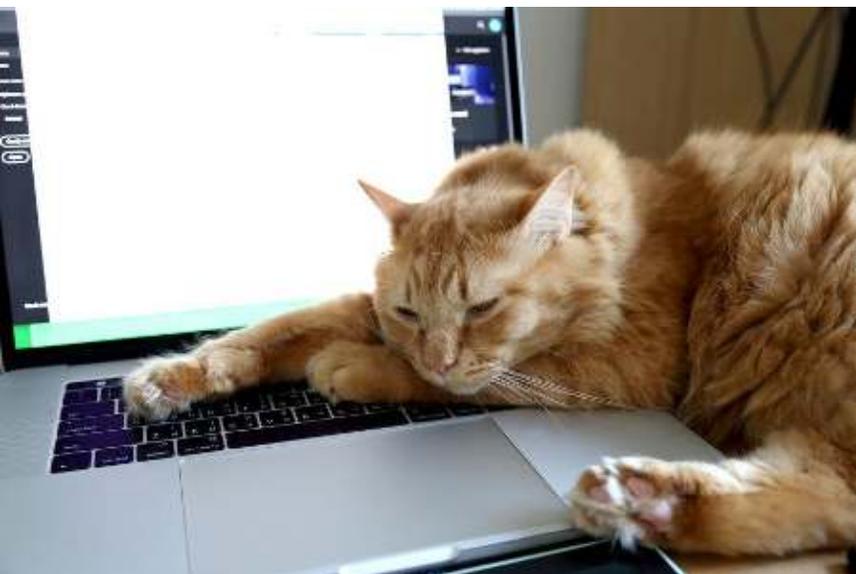


# Remote Auditing

How to be successful from behind a webcam

Maria Mylonas  
Learning & Development Director



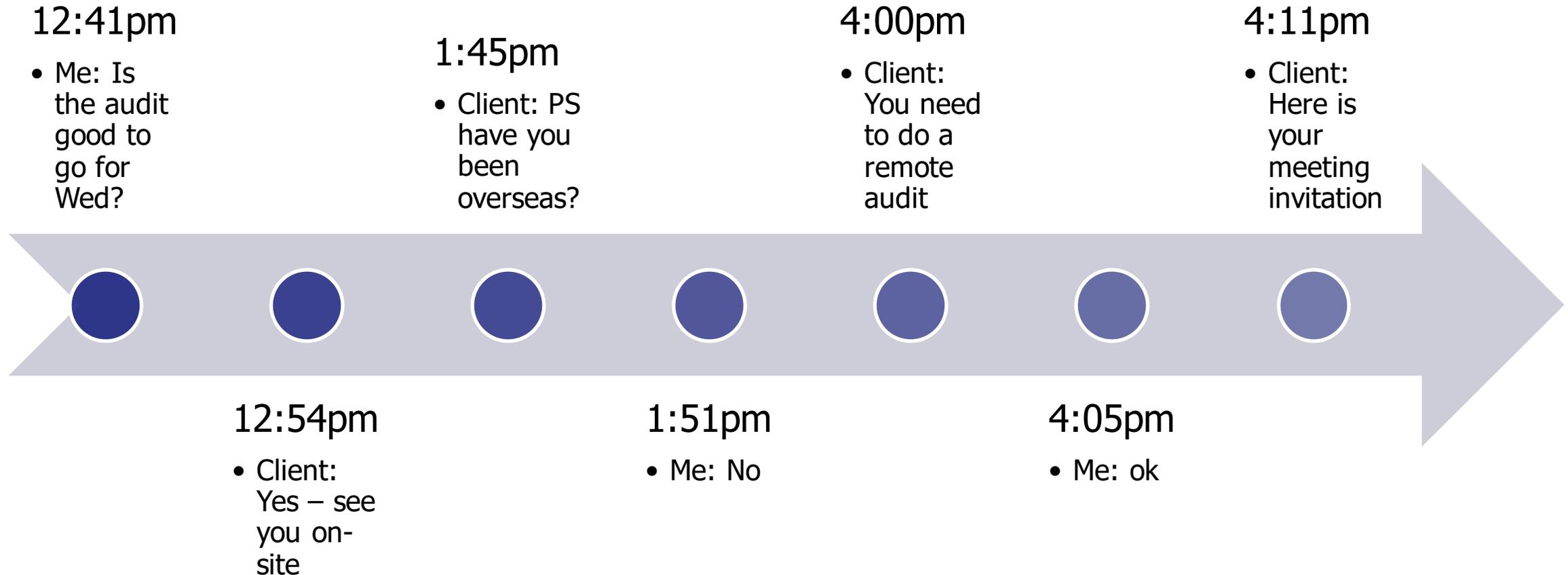


Can you relate to any of these situations?

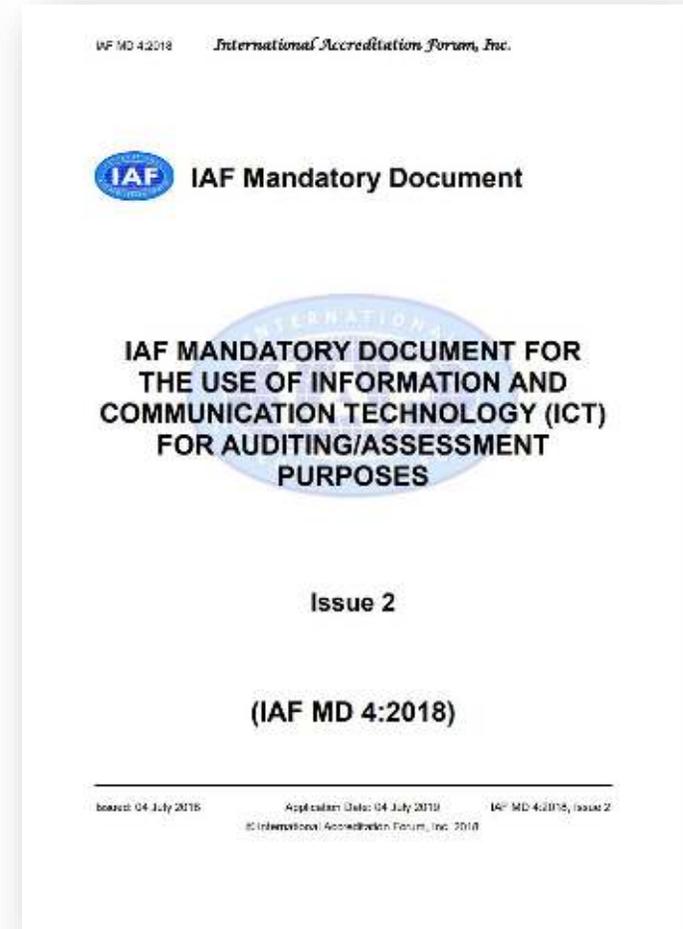
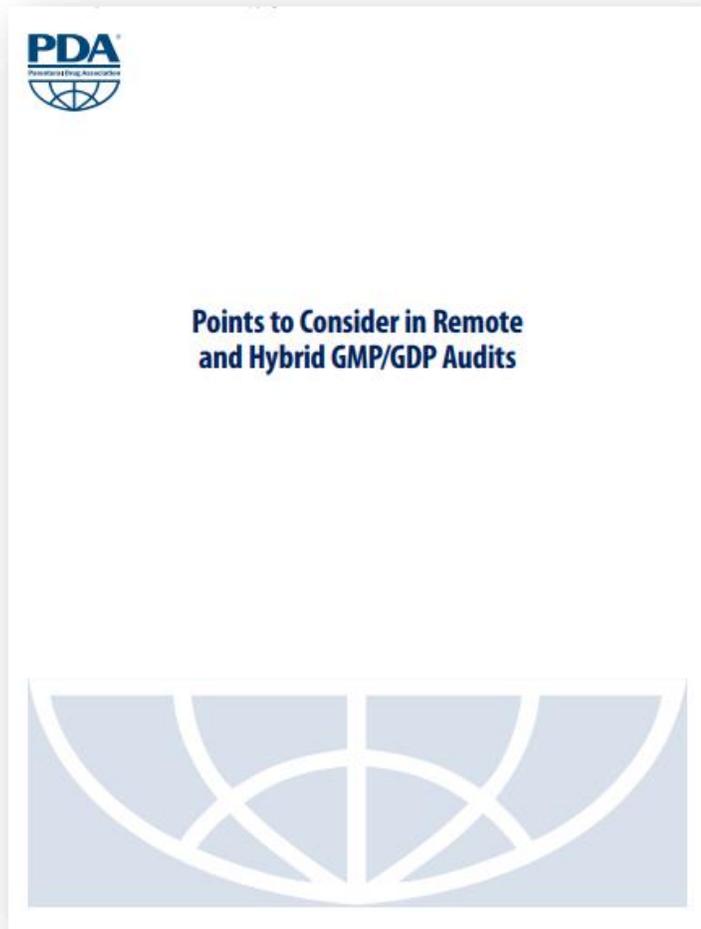


# 1<sup>st</sup> Remote Auditing Experience (Mid-March 2020)

It's Monday, on-site audit is on Wednesday (1.5 days)



# This presentation is brought to you by.....



# What will be covered?



**01** INTRODUCTION  
TO REMOTE AUDITS



**02** PLANNING THE  
REMOTE AUDIT



**03** PERFORMING  
THE REMOTE AUDIT



**04** CONCLUDING  
THE REMOTE AUDIT



## Section 01

# Introduction to Remote Audits



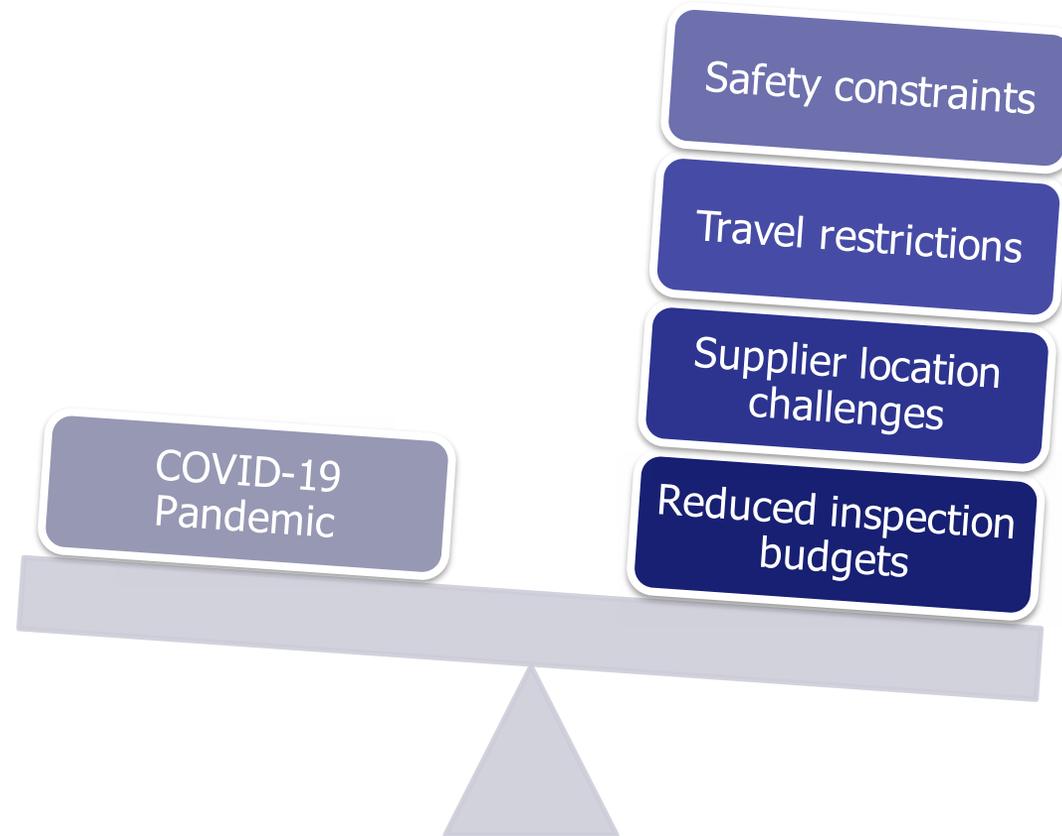
# Why Remote Audits?

Main  
reason

Other  
reasons

Problem?

Opportunity?



# Objective of remote GMP inspections during the COVID-19 pandemic

Reduce the potential impact of an on-site inspection to both industry and regulators

- Keep everyone safe
- Reduce the duration of on-site inspections

Ensure continued governance of GMP requirements at licenced domestic manufacturing sites

Allow the approval of new GMP licences or variations to existing licences

Maintain patient and consumer confidence in medicinal product manufacturing

# Guidelines for auditing management systems

## ISO 19011:2018

Remote auditing is one of the audit methods described in ISO 19011:2018 Annex A1.

The value of this audit method resides in its potential to provide flexibility to achieving the audit objectives.

In order to realise the benefits of this audit method, all interested parties should be aware of their role in the process, inputs, expected outputs, and risks and opportunities that will provide the basis to achieve the audit and audit program objectives.

# Who is performing virtual audits?

Everyone!

- Regulators
- Internal auditors
- External supplier auditors



# What are the inspection options?

**Remote, virtual inspection** with agreed communication tools and desktop review of information

**Hybrid** approach including a desktop review and an on-site inspection under agreed, controlled conditions

**On-site inspection** under agreed, controlled conditions where it has been evaluated as necessary and safe to undertake

Deferral of full inspections to a later date under specific conditions only.

# Selecting and determining audit methods



**On-site**



**Remote**



**Desktop**



**Hybrid**

The use of these methods should be suitably balanced, based on, among others, consideration of associated risks and opportunities.

# Risk Based Tool: New Auditable Entity

**Table AI.1-1** Criticality of Services Provided Criteria

Criteria Rank	Criticality of Services Provided Criteria <sup>†</sup>
<b>Critical</b>	Services provided have direct impact on product quality or compliance. Sterile manufacturing, sterile product, primary packaging, medical devices (inclusive of combination products), biological drug substance (API), cell banking, sterile product testing laboratory, HVAC certification services
<b>Moderate</b>	Services provided have indirect impact on product quality or compliance. API, API intermediate, nonsterile primary packaging, clinical packaging, laboratory (finished-product testing), on-site formulation (nonsterile facility), nonsterile manufacturing facilities
<b>Minor</b>	Services provided do not have impact on product quality or compliance. Laboratory in-process testing (specialty testing), secondary packaging, warehouse logistics, document storage companies, distribution centers, warehousing companies

<sup>†</sup> The criticality of a supplier that is the only available source of the material (sole source) can be determined based on the auditor's risk tolerance.

# Risk Based Tool: New Auditable Entity

**Table AI.1-2** Regulatory Compliance History Criteria and Risk Ranking

Risk Rank	Auditable Entity Regulatory Compliance History Criteria
<b>High</b>	Recent regulatory inspection yielded regulatory action (e.g., import alert, import ban, GMP certificates revoked, warning letter), or no regulatory history exists for organization
<b>Medium</b>	Health Authority findings (e.g., FDA 483) or equivalent categorization findings identified through recent inspections, but no further regulatory action expected
<b>Low</b>	Recent regulatory inspection with no findings or minor findings

		Regulatory Compliance History		
		Low	Medium	High
Criticality of Services Provided	Critical	Medium	High	High
	Moderate	Medium	Medium	High
	Minor	Low	Low	Medium

# Risk Based Tool: New Auditable Entity

**Figure AI.1-2** Risk Level Matrix (Criticality of Services Provided × Regulatory Compliance History)

**Table AI.1-3** Example Risk Assessment Worksheet for New Auditable Entity

Auditable Entity	Mfg. Type Criticality	Regulatory Compliance History	Risk Score	Justification
Company A	Critical	Low	Medium	Company A is a sterile manufacturer = Critical rating for criticality of services provided Recent regulatory inspections resulted in no findings = Low rating for regulatory compliance history
Company B	Moderate	High	High	Company B is a contract testing lab = Moderate rating for criticality of services provided No regulatory inspection history exists = High rating for lack of regulatory compliance history

# Decision?

**Table AI.1-4** Action Level based on Risk Score

Risk Score	Action Level
<b>High</b>	On-site audit recommended; external auditable entity should not be used if remote is the only audit option available
<b>Medium</b>	Hybrid audit recommended; remote audit possible with justification
<b>Low</b>	Remote audit is acceptable

These risk-based approaches should not be construed as applying solely to the determination of audit type. These approaches may also be used to assist with other risk-based decisions, such as audit frequency or scope determination.

# Rationale for decision

- While, theoretically, each type of inspection can be performed remotely, the level of scrutiny possible in a remote inspection may not always be equivalent to an on-site inspection.
- Remote inspections are heavily dependent on the technology available (e.g., use of live stream, high-resolution videos) and scope of the inspection (e.g., physical manufacturing facility versus quality system (QMS/PQS) documentation review).



# How is this decided? Risk Assessment

The risks for achieving the audit objectives are identified, assessed and managed.

Another important issue is to understand what processes, activities or sites of the organisation may be audited remotely with which ICT tool available.

IAF MD 4 makes clear that this decision should be based in the documented identification of the risks and opportunities that may impact the audit/assessment, for each ICT considered.



# Typical Questions

The following are typical questions that come up when we are thinking about remote inspections:

When watching images, are we looking at real time images or are we looking at video records?

Can we capture everything about the remote site or are we being guided by selected images?

When planning for a remote interview, will there be a stable internet connection and the person to be interviewed knows how to use it?

Can the processes and sites to be audited be realistically audited offsite?

Can you have a good overview of the facilities, equipment, operations, controls?

Can you access all the relevant information?

# Risks and Opportunities for using remote audit techniques

Information and Communication Technology (ICT)	Potential Use	Risks	Opportunities
Video call (synchronous) (e.g.: Skype, WebEx, ZOOM, Hangouts)	Conducting Interviews  Guided site tours	Security and confidentiality violations; Differences in time zones; Authentication of the person; Low Quality of communication; The possibility to observe the organization in a more autonomous and free way is weakened as the auditor does not command the camera The possibility to observe reactions from several auditees to communication may be weaker	Interview with relevant personnel working remotely, e.g. home office, project teams in design and development; Opening closing meeting in multisite audits; Remote site/activities where physical observation is not critical; Travel time/costs reduction and associated environmental impacts; Greater geographical range
	Documentary review with auditee participation	Security and confidentiality violations; Potential difficulty in responding to documentation requests; Increased time required (potentially time-consuming process); Potential data manipulation; Interaction with auditees may be weakened Diminished quality of information collected	Document reviews where site travel is not feasible, e.g. first stage audits where site visit is not critical to the achievement of objectives and time/travel constraints exist; Multi-site - good for remote sites where site visit can be skipped or where annual visits within the audit program are not necessary, but some follow up is needed; Travel time/costs reduction and associated environmental impacts
Surveys, Applications	Filling out checklists and questionnaires	Guarantee of authenticity; Need to pre-develop checklist and possibly prepare respondent to answer them, which increases costs	Better knowledge of the organization, applicable at preparation stage of the audit; Allows to prepare audit work, which needs to be verified during the audit by gathering other evidence; Allows the organization to prepare to the onsite visit

# Risks and Opportunities for using remote audit techniques

Information and Communication Technology (ICT)	Potential Use	Risks	Opportunities
<b>Document and data review (asynchronous)</b> (e.g.: web document review)	Viewing records, procedures, workflows, monitors, etc.	Security and confidentiality; Procedural difficulty in document viewing (e.g. accessing remotely and navigating in the organization website); Increased time required (potentially time consuming process); Potential data manipulation; Lack of interaction with the auditees does not allow clarification of issues; Transparency - Auditee loses perception of what is being audited and the sample	Eases organization and allows for a more flexible use of time by the audit team; Allows for better, more independent from the auditee and deeper exploration of information; Possibility of integrating expertise that would not be able to travel to the site; Provides good basis for understanding the organization's QMS, and potentially provides audit trails that the auditor may utilize during interviews.
<b>Video (synchronous)</b> (e.g.: drone, live stream)	Monitoring of remote or high risk work;  Guided site visit;  Ability to view high risk processes or operations  Witnessing running processes	Risks inherent in the use and presence of equipment; e.g. drone drop, use of equipment, unfavourable weather conditions; Quality of image; Full appreciation of the site, equipment and conditions Veracity of the data	Easy monitoring of high risk tasks; Increased sampling; Ideal for auditing activities where the safety requirements do not allow the presence of the audit team, or to observe places and facilities where the ratio travel time versus audit time is high; Good for complementing field visits in outdoor activities ( e.g. forest and agricultural sites, mining)
<b>Video (asynchronous)</b> (e.g.: surveillance camera, video recordings purposely taken for audit)	Monitoring of activities that are not ongoing at the time of the audit; Process videos; Call center voice recordings.  Recorded training webinars	Security and confidentiality; Quality of image; Full appreciation of the site, equipment and conditions Veracity of the data	Higher profitability (possibility of selecting only the moments of interest of the video); Possibility of observing places, hard to reach facilities and improving sampling If the electronic record contains sensitive data that CSDP criteria considers not eligible for remote auditing, the auditor should consider reassigning that record review for onsite audit.

# Confidentiality, Security and Data Protection (CSDP)

May need additional agreements from both sides (e.g. there will be no recording of sound and images, or authorisations to using people's images or screenshots etc. Where is the line drawn?)

Auditors should not take screenshots of auditees as audit evidence. Any screenshots of documents or records or other kind of evidence should be previously authorised by the audited organization.



# Confidentiality, Security and Data Protection (CSDP)

To prepare for the use of ICT, all certification legal and customer requirements related to confidentiality, security and data protection should be identified and actions taken to ensure their effective implementation.

This implies that both the auditor and the auditee agree with the use of ICT and with the measures taken to fulfil these requirements.

Evidence of agreements related to CSDP should be available. This evidence could be records, agreed procedures, or emails. The importance resides in having these CSDP criteria acknowledged by all participants.

In some situations' security requirements will not allow for the use of ICT.

# How do I decide? Risk Assessment

FEASIBILITY AND RISK ANALYSIS FOR REMOTE AUDITS	
<b>1. Confidentiality, Security and Data Protection (CSDP)</b>	Ensure agreement between auditor and auditee about CSDP issues. Document any arrangements to ensure them.
<b>2. Use of ICT</b>	There is a stable connection with good online connection quality
	The ICT allows access to relevant documented information including software, databases, records, etc.
	It is possible to make the authentication/identification of interviewed people preferably with image
	If observation of facilities, processes, activities, etc, is relevant to achieve audit objectives, it is possible to access them by video
<b>3. People in the organization</b>	It is possible to access and interview people relevant for the QMS
<b>4. Operations</b>	If the organization is not operating regularly, due to contingency situations, the processes/activities being performed are representative and allow fulfilment of the audit objectives
<b>5 Complexity of the organization and Audit Type</b>	In case of complex organizations, processes, or products and services and where the objectives of the audit type require full assessment of the standard and wider sampling (e.g. initial assessment or reassessment) a careful analysis of feasibility of remote audits to fully evaluate the organization conformity to all requirements should be performed.
<b>6 Conclusions</b>	The audit objectives can be attained with the remote audit - proceed to remote audit
	The audit objectives can be achieved partially - a remote audit may be done partially and later complemented with a on site audit
	The audit objectives cannot be attained via remote audit

This table lists the main issues to assess feasibility and risk analysis for a remote inspection.

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[www.iaf.nu; https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html](https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html)

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# Digital quality of data

Finally, when analysing feasibility, the digital quality of the data to be reviewed should also be considered.

This is more relevant when the organisation still retains information on paper that needs to be scanned for remote review.



# General Considerations

## Virtual Meeting Software

- Zoom
- Teams
- GoToMeeting
- Others?

## Technology

- Webcam (positioning)
- Headset/Microphone
- Dual Screen – multiple monitors
- Document camera
- High-speed scanner
- File transfer and sharing
- WiFi signal

## Location

- Home or office?
- What's in the background?
- Time zone?
- Interpreter?

## Managing Interruptions

- Children/Pets
- Home Deliveries
- Colleagues
- Emails/ phone
- Internet dropout

# Documentation Considerations

- Does the audit procedure/process need to be revised?
- Does the audit schedule/plan need to be revised?
- Additional training requirements? E.g. use of technology
- Are audit checklists affected?
- Does the audit plan/report template need updating?





## Section 02

# Planning the Remote Audit

# AUDIT

METHODS

OPINION

REPORT

CONTROL

CONT

INVE

# Inspection Duration

- You may need to plan for more days than a typical on-site inspection but shorter hours/day (remote inspections can be more tiring than an on-site inspection).
- If there is a major or critical non-compliance, duration may be extended or it may be decided an on-site visit will be performed shortly after the inspection.



# Preparing Documents

Many sites have developed a standard list of documents that are likely to be requested in an on-site inspection. This list is equally applicable in remote inspections.

**Examples include:** site organization, size, products manufactured, list of standard operating procedures (SOP), deviation reports, site master files, out of specification results, corrective and preventive actions (CAPA), applicable Annual Product/Quality Reviews that include details on change controls, complaints, recalls, batches manufactured, aseptic process simulations with outcomes, environmental monitoring data, trends for utilities (e.g., water, steam, gas), and sterility test failures.



# Preparing Documents

In advance of a remote inspection, the inspected site should also prepare the documentation that an auditor would normally review on-site or may request at a later point. Typically, this additional documentation might include:

- Data analysis (e.g., deviation recurrence analysis, equipment failure rate, CAPA effectiveness review) and/or lists that can be searched or filtered
- Comprehensive inspection history, especially for the first remote inspection of the site and for-cause inspections
- History of or changes to key SOPs since the last inspection, along with training records
- Information related to relevant investigations.



# Options for Sharing Specific Types of Data in a Virtual Audit

**Table 1** Options for Sharing Specific Types of Data in a Virtual Audit

Type of Information	Technology Option	Advance-Planning Considerations
Standard operating procedures (SOPs) and related documents	Share through document-sharing platform.	SOP indices may be shared before the audit, which will help in reducing audit time.
Critical quality attribute (CQA) and critical process parameter (CPP) data	The auditee can navigate through specific software during the remote audit through screen-sharing during the web conference. In general, the auditee should not grant the auditor access to or direct control of the auditee's systems to avoid cybersecurity threats as well as inadvertent user error.	CQA and CPP data will be shared only as mutually agreed.
Quality metrics data such as out-of-specification log, deviations log, out-of-trend log, complaints log, change control log	If manual logs are maintained, the logs can be scanned or can be displayed live using a document camera. If quality assurance management system software is used, the software can be displayed through screen-sharing.	It may not be necessary to share quality metrics in advance of the audit.
Building management data, area qualification data, and environmental data	The most recent periodic environmental monitoring report can be scanned in OCR format or livestreamed using a document camera. Other supporting information would be provided during the course of the audit using screen-sharing or a document camera.	
Equipment calibration plan and conclusions	Livestream through a document camera.	In advance of the audit, identify the equipment used in the lab and in manufacturing for the products that are or may be within the audit scope.
Laboratory information management system (LIMS) database	Be prepared to share a report or validation, along with audit trail, by screen-sharing if requested.	It may be useful to verify in advance that LIMS software and electronic notebooks are easily retrievable from archives.
Laboratory and chromatographic software	Share via screen-sharing. Be prepared to display the raw data, metadata, and audit trail through screen-sharing as well, if requested.	
Manufacturing software	Specific records of the batches within audit scope can be extracted into PDF format along with the audit trail in preparation for the audit. The software may be demonstrated through videos or shared through screen-sharing. Be prepared to display the raw data, metadata, and audit trail through screen-sharing.	
Packaging software, track-and-trace/serialization software	Share via screen-sharing. Be prepared to display the raw data, metadata, and audit trail through screen-sharing.	

Reference: PDA – Points to consider in a Hybrid GMP/GDP Audit

# Pre- Pre-audit preparation



Auditor will prepare draft audit agenda



Confirm who will attend the pre-audit meeting



Confirm which virtual meeting platform will be used



Send/ or receive meeting invitation for pre-audit meeting

# Pre-audit meeting (30 – 60 mins)

- Confirm virtual meeting platform (this is a good time to test it out)
- Agree on audit scope
- Confirm timing and agenda, agree on contingency plan if there are ICT issues
- Confirm location of auditees (workplace? Or their homes?)
- Determine how files will be shared (Email? SharePoint? Dropbox? Other?)
- Request pre-reading materials / site video? (this will test the file sharing process)
- Confirm if an interpreter is required during the inspection period.



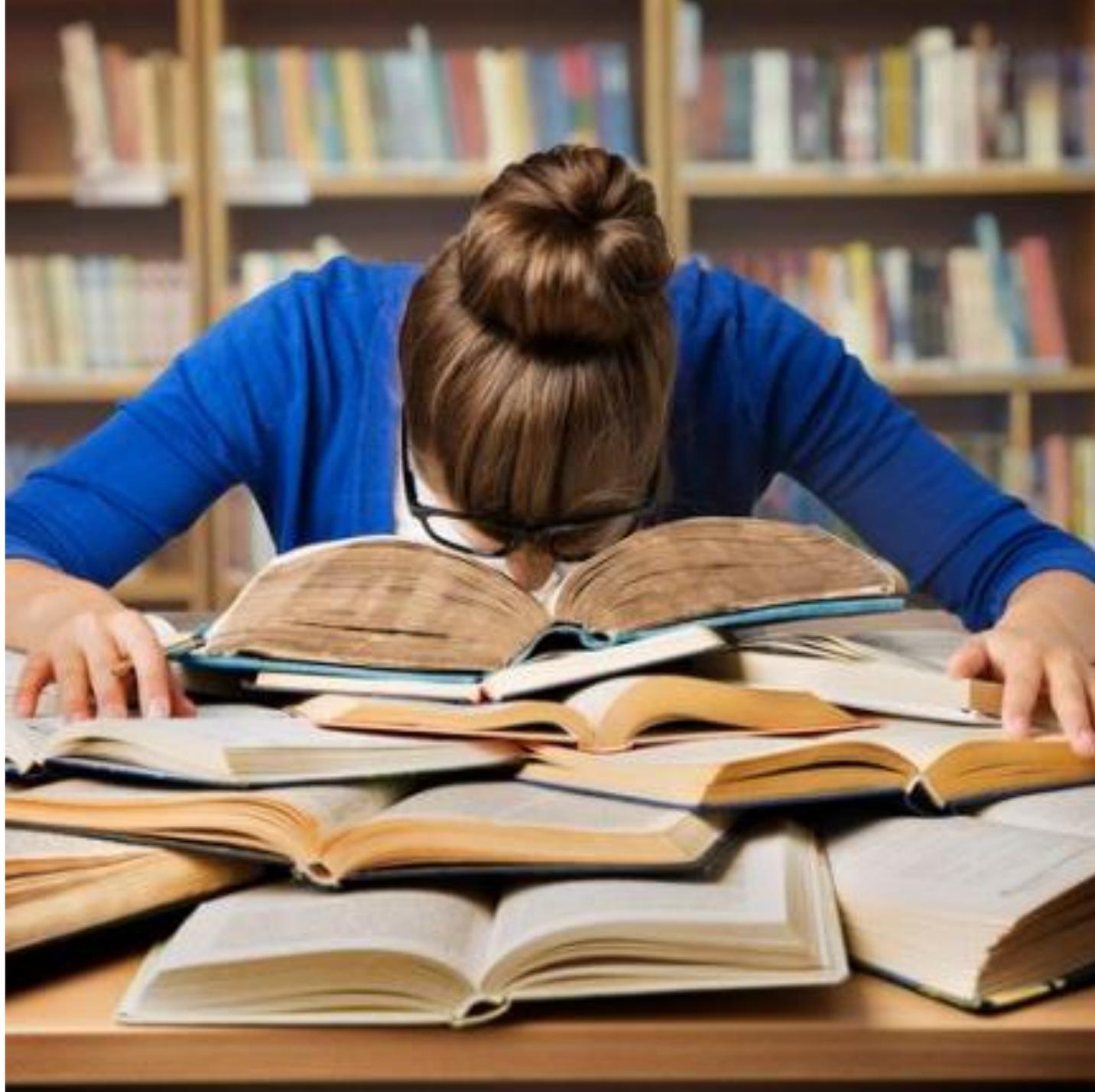
# Pre-audit meeting (30 – 60 mins)

- Agree on a logical file structure
- Agree on the naming convention for documents and records
- Confirm if live streaming will be used on the inspection day and discuss IT requirements.
- Confirm if hard copy of documents will be scanned on inspection day and ensure resources are available for this task.
- Confirm how interviewees will be managed. Who will the auditors need access to?



# Pre-audit preparation – Auditor

- Read all of the documents that have been sent
- Highlight specific sections of the SOPs that you want to verify (proof company is doing what they say that will do)
- List questions prior to the audit based on the SOPs/regulations



# Pre-audit preparation – Auditor



List the objective evidence you are going to ask for on audit day. E.g.

- CAPA register
- Deviations register
- Specific staff training records
- Change control register
- Risk assessments
- Validation documentation

# Pre-audit preparation – Auditor (~6 -8 hrs)

- Start completing your audit checklist (if you use one)
- Decide if you will print out the procedures or go paperless
- Decide how you are going to document your findings (electronically or note pad/pen)



# Pre-audit preparation - Auditee

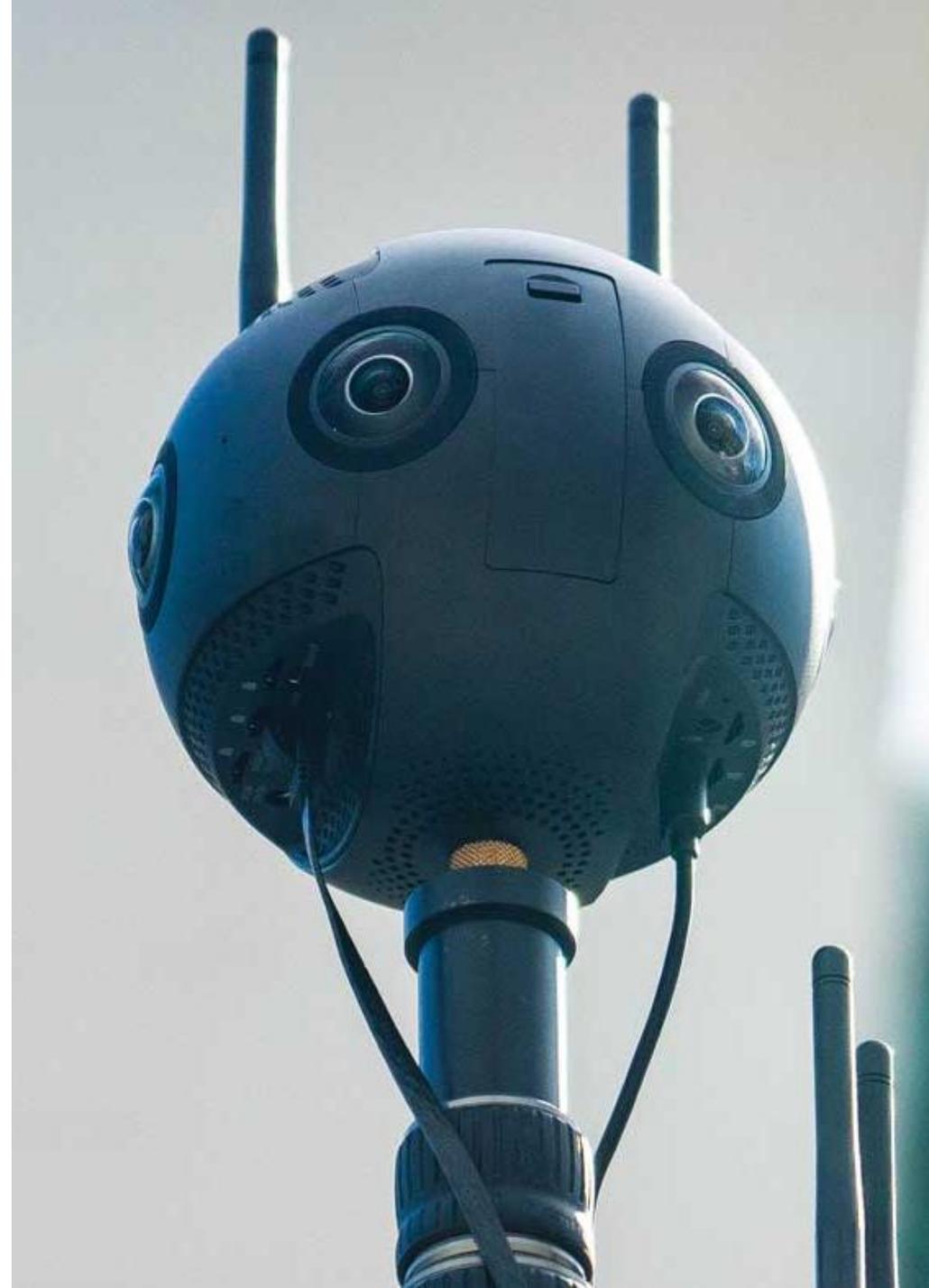
- Collate all of the pre-reading materials
- Upload/send materials
- Create site-tour video (if requested) or will this happen live?
  - Storyboard process flow
  - Phone camera? Go pro? Drone?
  - Tripod?
  - Video editing software? (nothing too fancy)



# Virtual Tour

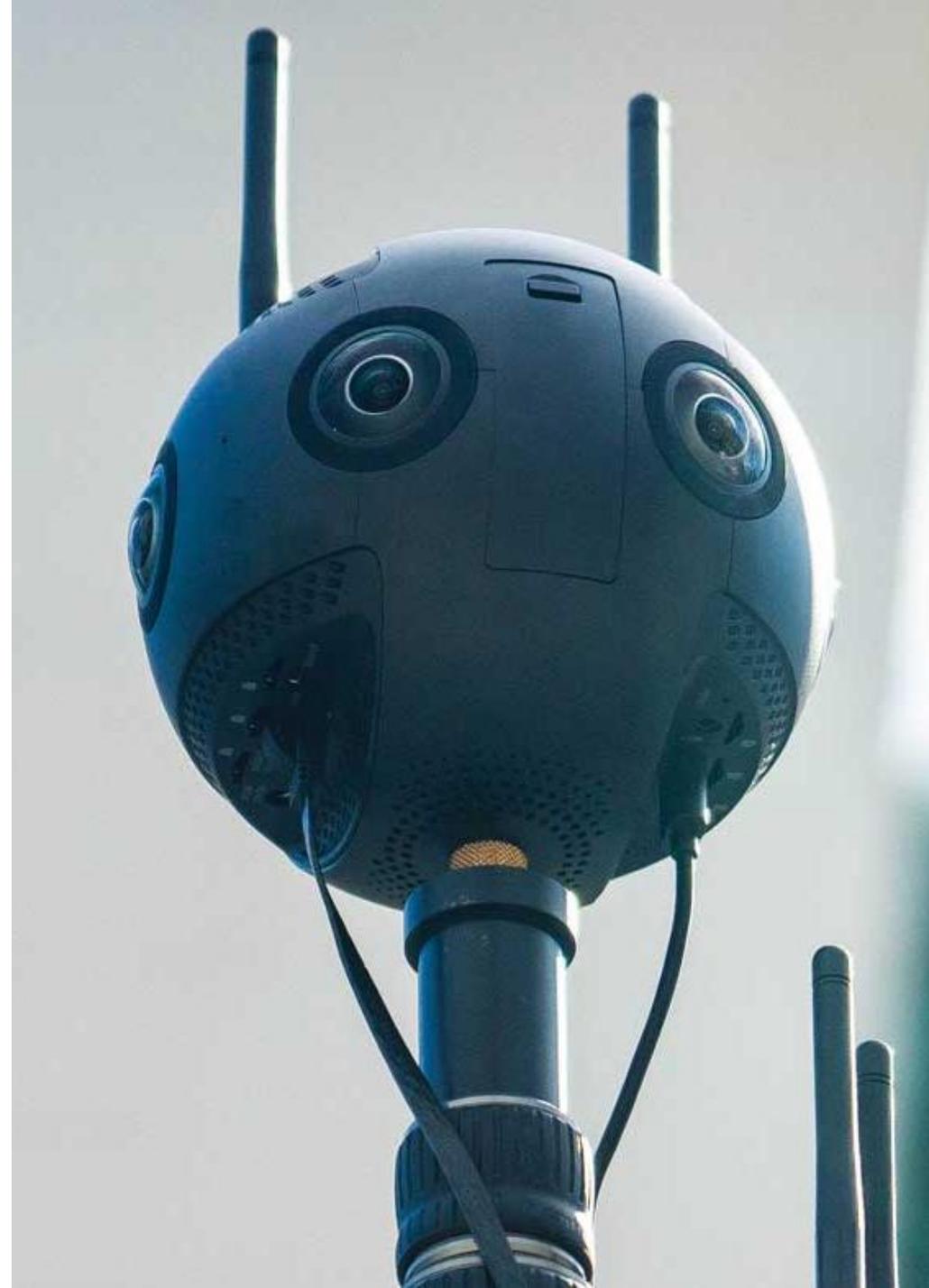
If a virtual tour will be provided as part of the virtual inspection, the following points should be considered:

- Virtual view tools such as 360° cameras or virtual reality goggles may be used. Other companies may use a laptop or mobile device.
- The device must be appropriate for the area being shown (e.g., manufacturing area or laboratory) and to provide the requested information.



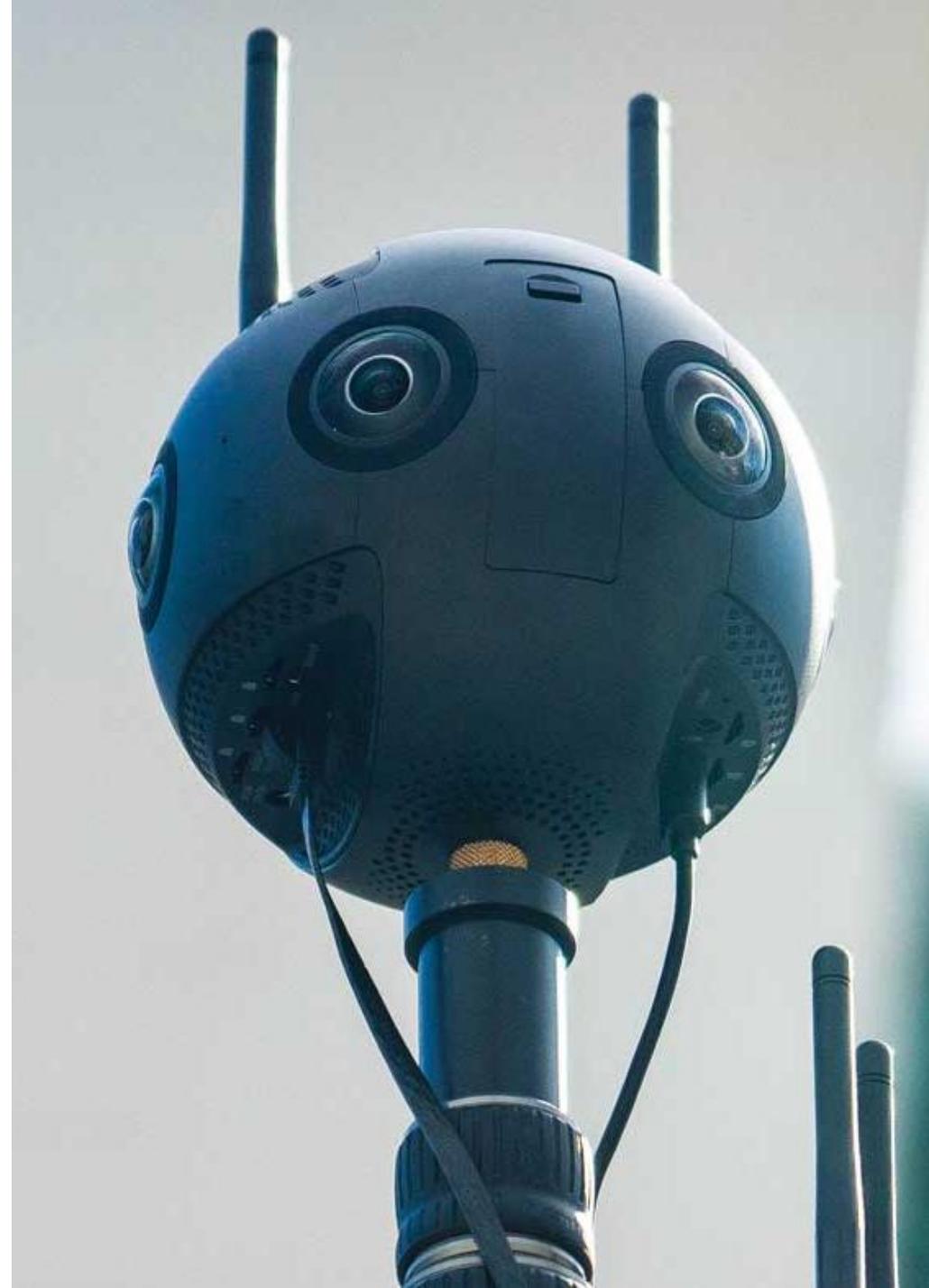
# Virtual Tour

- Care should be taken to ensure that the camera produces a stable picture that is easy to view. For this purpose, the camera can be mounted on a movable trolley or gimbal.
- The site should be prepared to remove the camera from any mounting to allow show equipment and facilities from all angles requested by the auditor.
- Unstable, wobbly pictures that occur when a camera is hand- or body-mounted, or when a trolley rolls over uneven floors or stairs, are difficult for auditors to view and can induce nausea and, in some viewers, vertigo.



# Virtual Tour

- Additional audio tools may be necessary for the person operating the camera during the virtual tour.
- The camera operator needs to be able to hear the auditor's directions on where to move or point the camera, even in areas with significant background noise.
- The camera operator also must be able to hear and respond to questions from the auditor during the virtual tour.
- In areas of the facility where the Wi-Fi signal may not be strong enough to broadcast a live virtual tour, consider whether it might be useful to install devices to amplify the signal.





## Section 03

# Performing the Remote Audit



# It's Inspection Day!

## Technology preparation

Log in early (~15 mins)

Check internet connectivity (have a back-up plan e.g. hotspot off phone)

Set your "out of office" on

Put your Teams status on "Do Not Disturb" (if required)

Phone on Do Not Disturb (DND)

Switch off pop up notifications (you will be sharing your screen)

Leave "waiting room on" in Zoom until you are ready to start the audit

Turn on your video and audio (check camera angles and sound)

# It's Inspection Day!

## Technology preparation

- Enable multiple host/screen share function (the auditee will need to share screen at times)
- Use breakout rooms if there are multiple auditors/auditees and a private conversation is needed
- Use chat panel for conversations (if required) especially if multiple people online (be careful who you are sending the message to)



Warn the family, pets,  
colleagues, delivery  
drivers etc.



# Inspection activities/challenges

- Auditors should ask for objective evidence early
  - It will take time for auditee to collect the evidence (longer than usual)
  - Physical evidence may not be able to be produced (document 'not seen' in audit report)
- Ask auditee to place any objective evidence shown into the shared folder for reference post-audit
- Turn off your audio/video during break times
- Time goes fast! Suggest taking great notes for easy wrap-up meeting preparation



# Inspection activities/challenges



- Measures to ensure confidentiality and security should be confirmed during the opening meeting.
- Keep on track
- Interviewing people other than the chosen auditees attending the virtual audit is a challenge (usually doesn't happen unless people are on-site)

# Responding to Requests



- Responses should be provided as soon as possible (same as on-site inspection).
- Ensure you SME's are ready and available for the duration of the inspection.
- When it is necessary to retrieve archived documents, or when the team at the inspected site is working completely or partially remotely, the response time could be slightly longer.
- Communicate proactively and transparently with the auditor if some responses could take additional time to access, and agree on acceptable timing.

# Responding to Requests



- Have sufficient personnel standing by to facilitate the handling of documents during the entire inspection, starting from the first request for documentation and records.
- Based on the types of requests received, personnel and resources may need to be shifted to ensure timely fulfilment of requests.
- When sharing documents during an inspection, consideration should be given to the size of the electronic files.
- It may be necessary to split documentation into multiple electronic “shipments” to ensure its delivery, depending on the method used for sharing.



## Section 04

# Concluding the Remote Audit



# Knowing an Inspection Has Ended



- The auditor and inspected site should discuss the starting and ending dates for the inspection early in the process.
- Remote inspections should end with a closing meeting via video communication platform, teleconference, or other communication method.
- If the auditors do not clearly state that the inspection has ended, the inspected site should ask for confirmation.
- Because remote inspections may include people from different locations, it may not be obvious to all auditees that the inspection is complete. Therefore, it is best to explicitly ask the auditors and make it clear to all involved.

# Inspection Report

The report for a remote inspection does not differ from that of an on-site inspection

- This report is likely to describe, at a minimum:
  - The documentation that was reviewed and by whom
  - Whether physical aspects of the facility were assessed, and the methods used
  - Inspection outcome
  - Rationale for the decision



# Inspection Report

- The inspection report also should indicate the processes that could not be assessed remotely and whether they will be assessed on-site to allow for completion of the inspection in a hybrid format.
- The report also may explain the need for an on-site inspection.



# Secrets for success

The secrets to success of a remote audit includes:

- Being well prepared
- Providing a good first impression
- Having good audit management
- Ensuring that personnel who front the auditors have the require technical knowledge and expertise, confidence and presentation skills
- Manage time effectively
- Know how to work the technology / train your staff
- Have a back-up plan for ICT issues
- Establishing an SOP and training personnel.



# Questions?

## **Maria Mylonas**

Learning & Development Director

[maria.mylonas@pharmout.net](mailto:maria.mylonas@pharmout.net)

[www.pharmout.net](http://www.pharmout.net)



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