



PDA Webinar: Effectively Using Technology in Remote Audits

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LEVERAGING TECHNOLOGY IN REMOTE AUDITS

PDA Webinar: Effectively Using
Technology in Remote Audits



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Presented by

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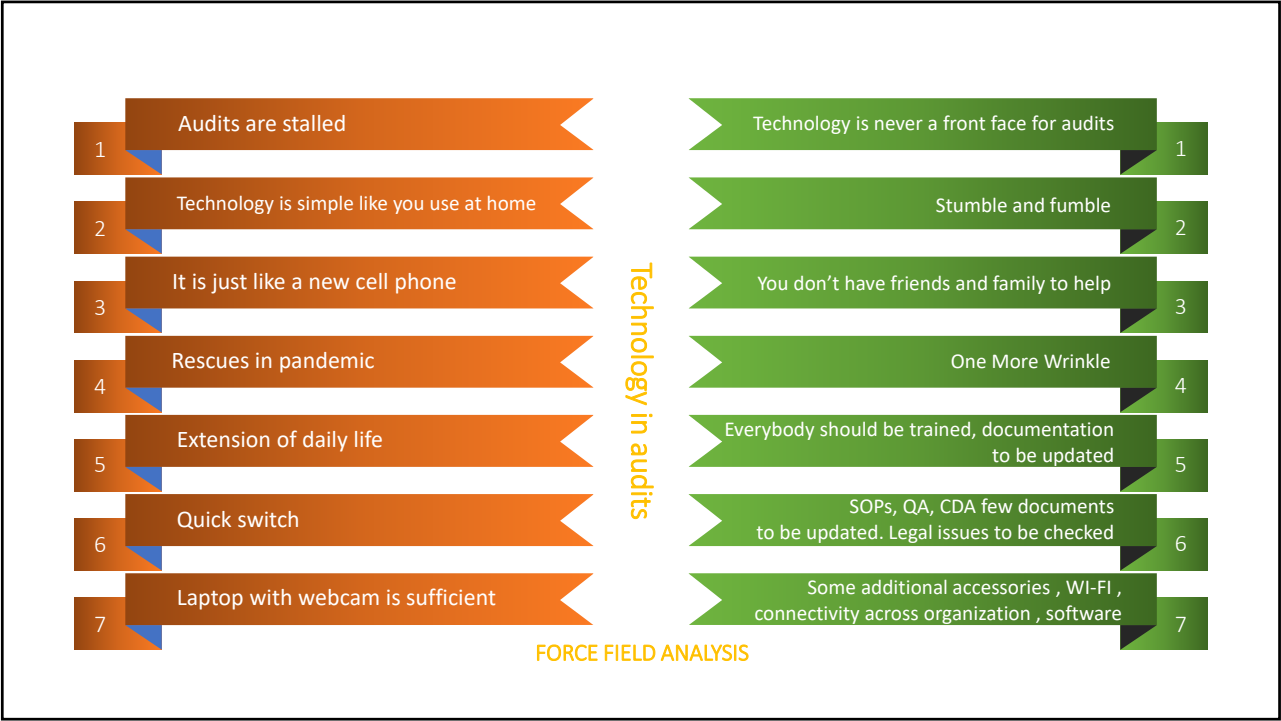
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Point of departure

- Till 2020 remote audits were very rarely practiced in Pharma
- Regulators [except WHO] never practiced remote inspections
- Confidentiality, trust and local laws are main issues to overcome
- Most of the pharma procedures were written much before the existing IT platform
- Remote audits are the best possible alternate in current pandemic and new normal


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


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Everybody in the organization involved in auditing should agree and align to the change in audits



The technologies being used should be understood and tested before being used in real time



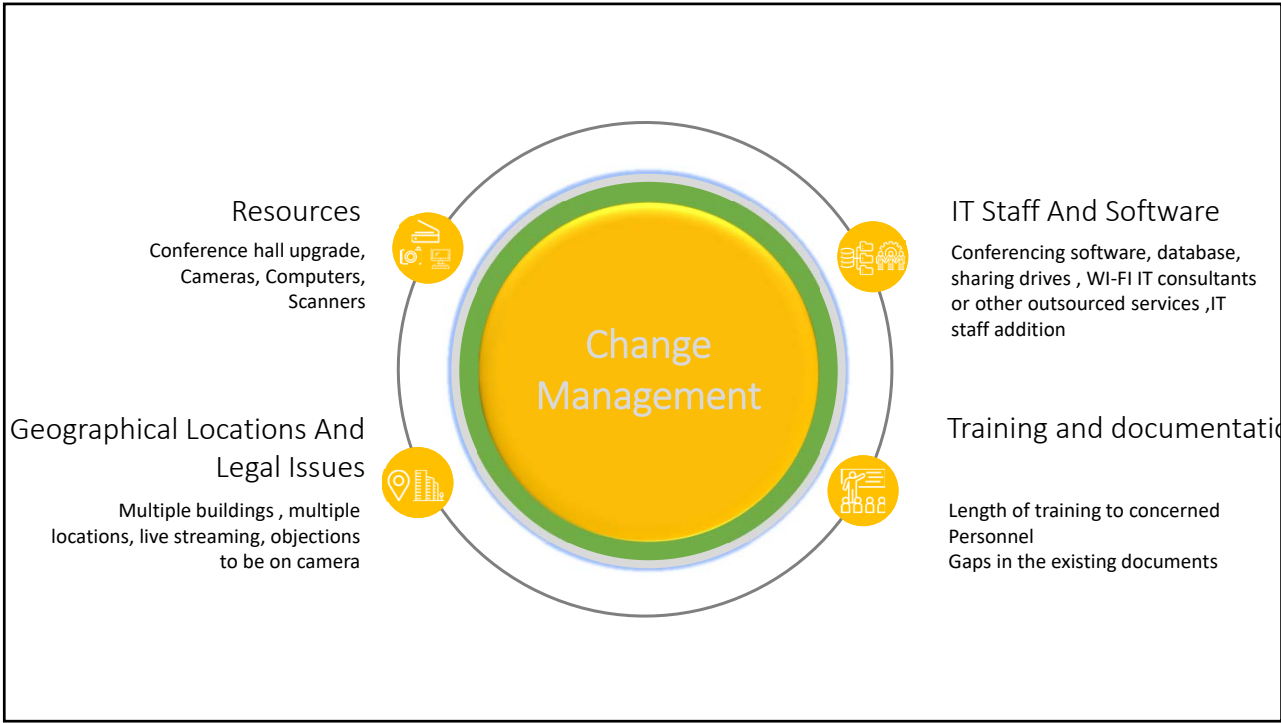
Remote audits

Doctors – Tele Medicine and remote examination | Students – remote learning | Virtual events | Watch parties


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Existing Quality agreements to be amended to

- Include usage of technology and list of technologies
- Accept scanned copies equivalent to original copies for audit purpose
- Electronic signatures or any other equivalent
- Duration of audit
- Pre-audit checklist
- Retention of documents on drive for audit prep and report prep

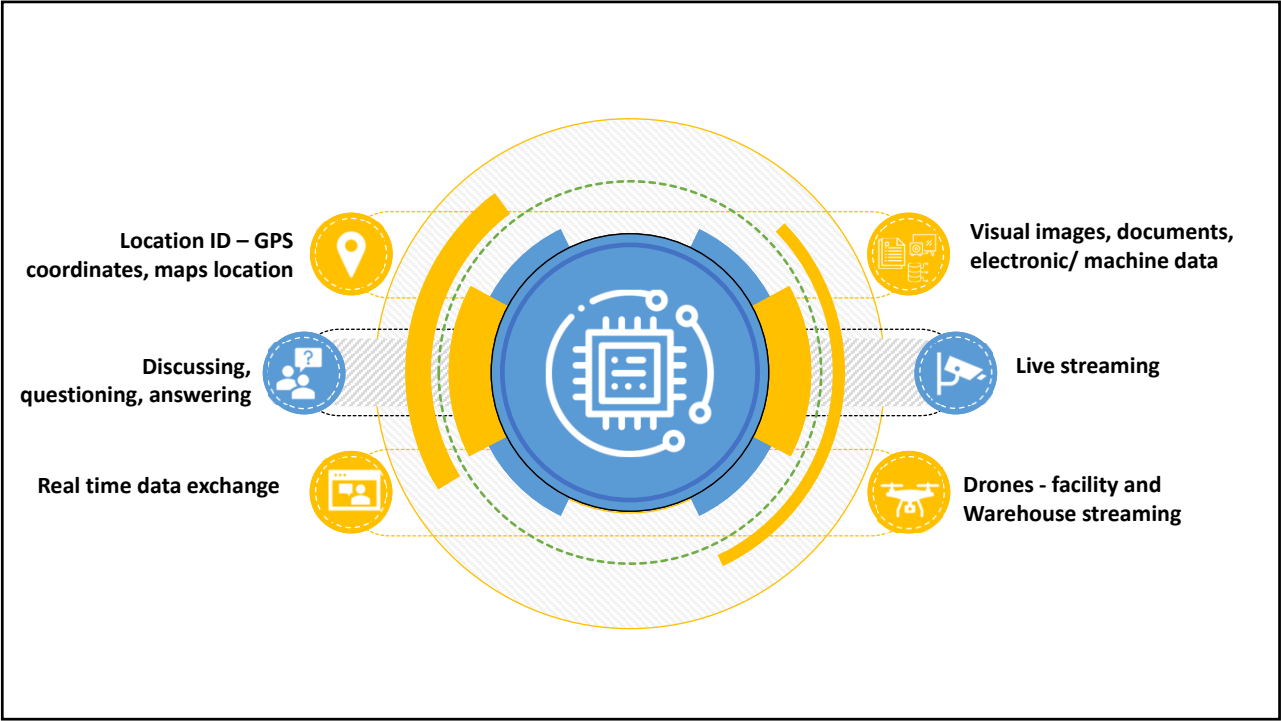


CDA and any other documents

- Confidentiality on the documents shared
- Recording or screen capturing policies



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Procuring technology needs

- Computers / laptops supporting the video conference
- Cameras and accessories (stand , trolley) suitable for indoors
- High speed scanners
- Internet upgradation
- Local intranet and internet connectivity
- Any other specifics to firm

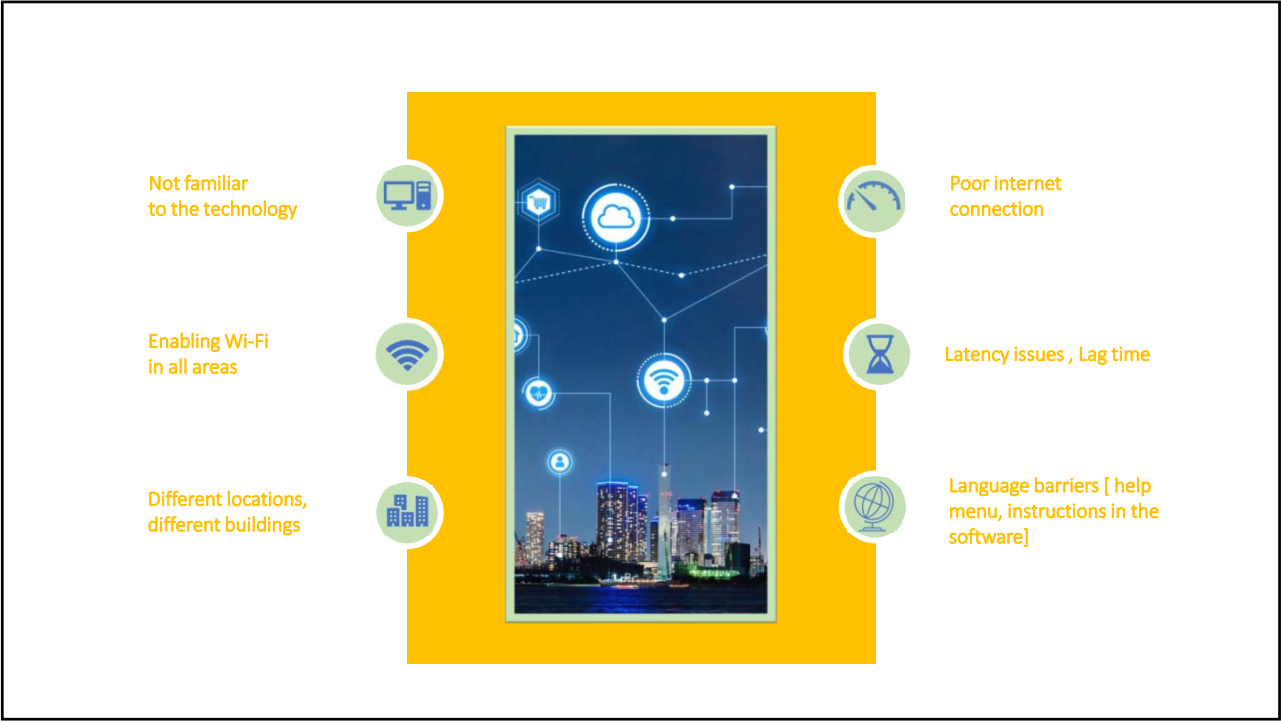
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Static in the audio – internet connection , device compatibility to software used , microphones / headset to be checked

Echo – multiple logins from the same room or closer proximity , login from phone and laptop same time and not muting one

Commotion– not muting when speaking is not required, choosing a quiet place (working from home)

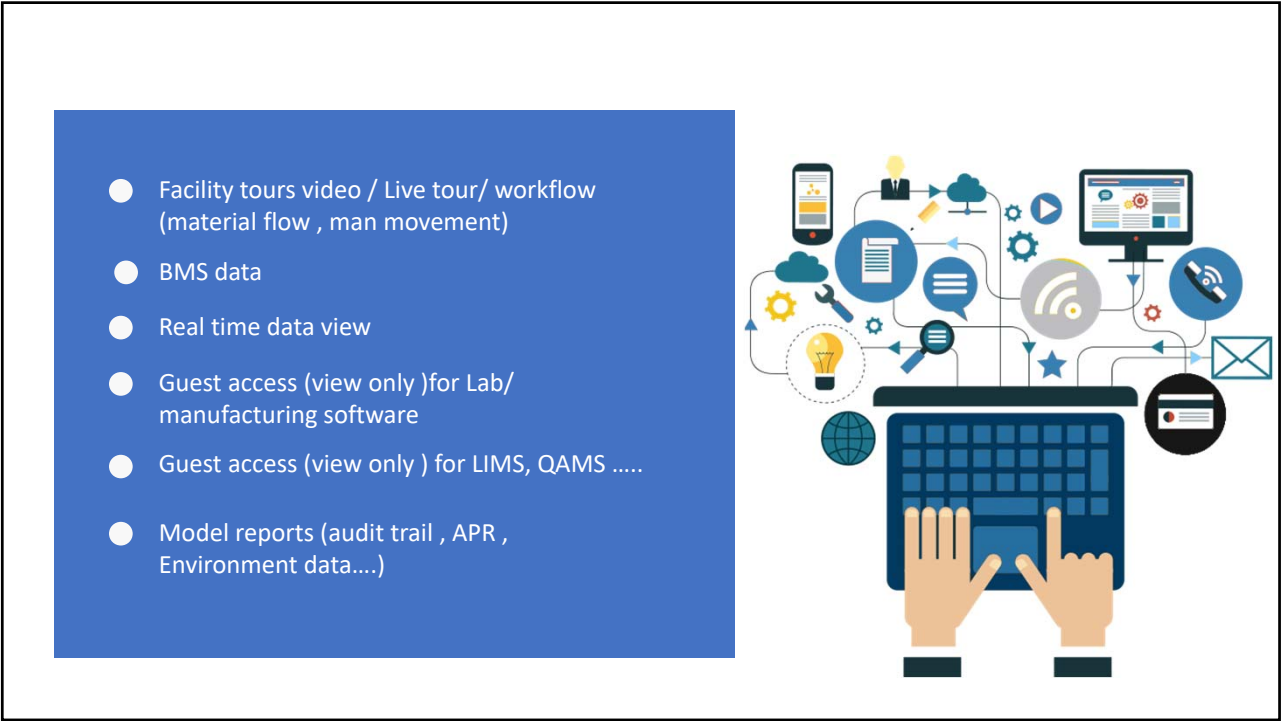
The smartphone screen displays several error messages and icons:

- Pixelated** – check the camera , internet speed , check if you are operating on WI-FI
- Buffering** – internet speed , cookies to be enabled
- Buffering** (with a circular loading icon)
- internet speed**
- No picture** - enable video or switch on camera
- Poor Connection** (with a small error icon)

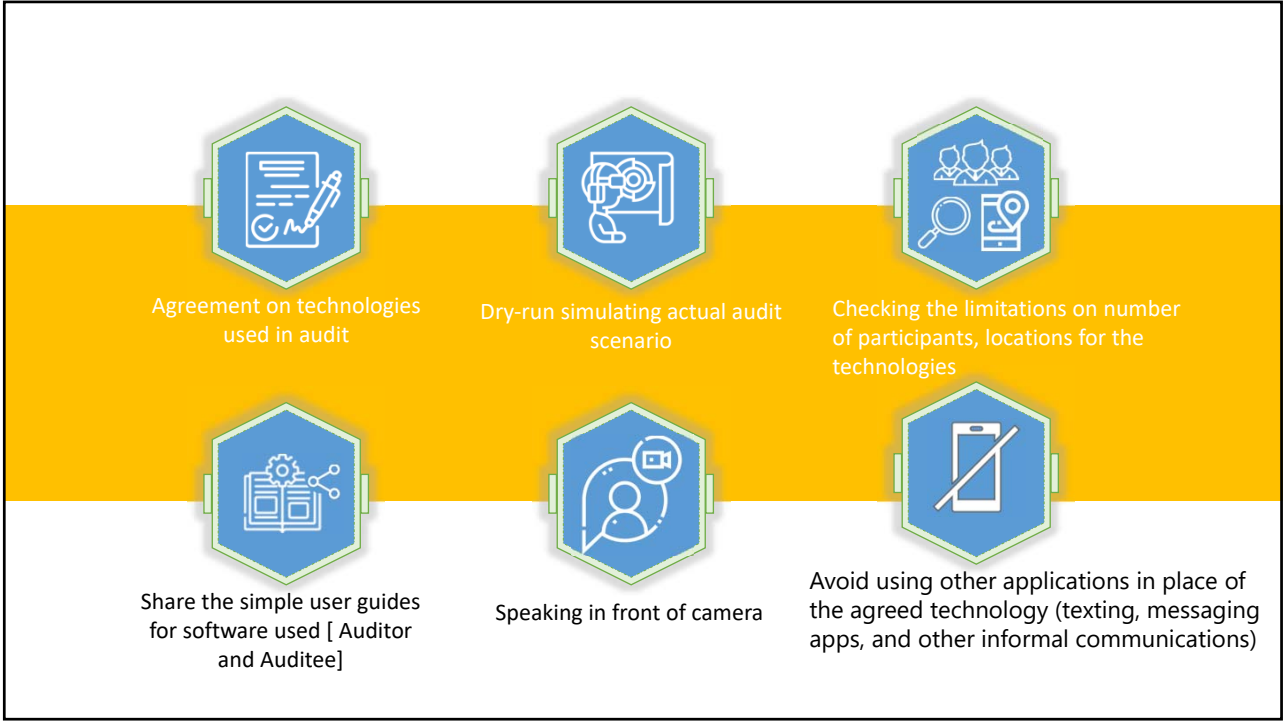
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PDA
Pharmaceutical Distributors Association

Precis

- Acknowledge the role of technology in remote audits
- Organization wide activity , Gap analysis
- Make use of existing guidance/practices [PDA , WHO , TGA , FDA]
- Upgrading resources
- Training & Trial runs
- Evolving topic and emerging situations

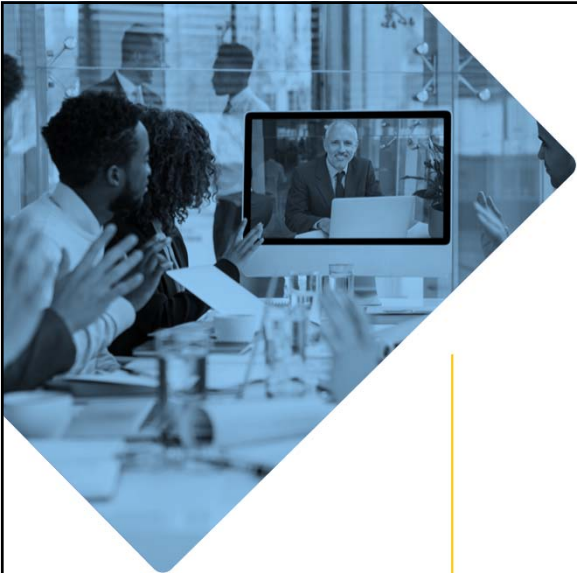
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US FDA
MDSAP Transmittal Number: AO 2020-10
<https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19>

TGA remote inspections guidance
<https://www.tga.gov.au/gmp-approach-overseas-manufacturers-medicines-and-biologicals-during-covid-19-pandemic>

MHRA UK
<https://www.gov.uk/guidance/approval-of-gxp-documents-when-working-from-home-during-the-coronavirus-covid-19-outbreak>

EMA
https://www.ema.europa.eu/en/documents/scientific-guideline/guidance-related-gmp/gdp-pmf-distant-assessments_en.pdf

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Training For All The Users On The Technologies

- Not all employees are tech savvy
- Length and mode of training should ensure users are acquainted
- Technological overkill may result in disruptions in audit
- Guide for the auditors on the technologies may be used
- Training on video conferencing expectations

Testing

- Proposed technologies need to be checked for intended usage and scope of usage.



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Ground Rules

- Video on always
- Muting the microphone when not speaking
- Alerting the other party when muting for discussions
- Staying with the agenda
- Suitable attire and behavior on camera
- Avoiding cross talking
- Not exploring new technologies on the day of audit or during audit

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Best Practices: Remote Audits

Technology that Enables an Effective Remote Audit

Best Practices you can implement today
By Pete Miller
DCS Inc.

An illustration showing two laptops connected by a globe. The left laptop displays a magnifying glass over a document, symbolizing inspection. The right laptop displays a dashboard with various charts and data, symbolizing analysis and reporting.

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- Shortages of critical drugs and devices due to pandemic restrictions
- Significant financial impact to companies awaiting inspections
- Delays in compliance auditing having a significant cost in lost revenue and opportunities
- The “new normal” clearly includes regular use of remote audits / inspections

Clear Best Practices are essential for industry and Health Care Agencies to move forward



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“Must haves” to be considered Effective

- Real-time 2 way video/audio communication
- Live stream 360°visibility during a site tour without alteration/augmentation
- Auditor must have ability to control review of content not control of systems
- Timely & secure document sharing
- No recordings of tours or dialog during the audit/inspection*

* Unless agreed to in advance by both parties

Recognizing that Technology is going to continually improve these capabilities

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Practices common to most audits:



Non-Disclosure Agreement
CNDA*



Audit Meetings



Facility Tour



Staff Interviews



Document Reviews



System Reviews


* Confidentiality Non-Disclosure Agreements (CNDA)s need no technology other than electronic signatures!
These should be automatic for all parties

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Audit Meetings

Technology

- **Web Conf. application**
Companies use different platforms
 - Secure & widely used
 - Easy to set up




Best Practices

- No recording without awareness to both *
- Audio **and** Video on for ALL parties
- Large monitors 24-27" high resolution, multiple monitors

* Unless agreed to in advance by both parties

What to avoid

- Audio only participants
- Delays in setting a date




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Facility Tour

Technology

- **360 degree camera**
 - Light weight
 - Easy to use




Best Practices

- Must be Live Stream
- Very Low/No Latency (delay) in broadcast
- NO augmentation to what is being viewed
- Real time communication with the tour guide

What to avoid


- Recording the tour *
- Inaccessible areas due to technical limitations
- Spotty connectivity during tour
- Extremely long tours
- Infractions of local privacy laws

* Unless agreed to in advance by both parties




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NO



360°


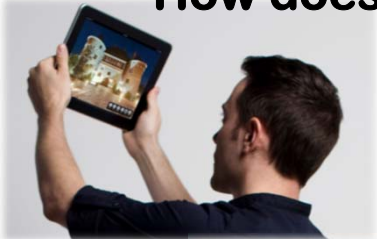
YES



No Augmentation for Remote Live Stream

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**“360° Camera” ?
How does it work**



360 camera DEMO Link
<https://youtu.be/KPNOLrkuG1A>

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Staff Interviews and Details

Technology

- Web Conf. application
- Detail camera / Smartphone
 - Light weight
 - Easy to use
 - High resolution and low/no latency



Best Practices

- Used anytime there is need for mobility to talk face to face with staff or view details (i.e. placards or equip.)
- Concurrent use with 360 Camera during site tour
- Make the Detail Camera another attendee in the web conference

What to avoid

- Different camera perspectives
- Auditor not visible
- Inadequate resolution to view details during the tour

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Document Reviews (Paper)

Technology

- Document camera for reviewing paper documents**
- High resolution
 - Creates temporary images or scans for review



Best Practices


- Adjustable to fit larger documents, binders or logbooks
- Fixed point / stationary
 - Enables Auditor to review multipage records

What to avoid

- Inadequate resolution to view documents
- Time consuming scanning if not required

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Document Reviews (Electronic Documents)

Technology	Best Practices	What to avoid
<p>Digital Rights Management (DRM) application</p> <ul style="list-style-type: none">• One way sharing• Highly secure• Easily applicable multiple files types• Enables review without security concerns	 <ul style="list-style-type: none">• Files are protected prior to sharing and expire after• View only access - No Printing, Downloading, use of watermarks in case of screen capture• Annotation capable for auditor to make temp highlight and comments	<ul style="list-style-type: none">• Direct download access<ul style="list-style-type: none">◦ Non-secure Data Rooms◦ Non-secure Cloud Storage• Collaboration platforms

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System Record Reviews

Technology	Best Practices	What to avoid
<p>Screen Share / Second Screen Software</p> <ul style="list-style-type: none">• Highly available• Easily accomplished thru web conference application• Enables review without security / access concerns	 <ul style="list-style-type: none">• PDF files are generated for any record sharing• System Subject Matter Expert is present• Keep requests within the scope of the audit	<ul style="list-style-type: none">• Auditors having actual access to system• Auditors taking screen captures• Prolonged fishing expeditions by Auditor

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Typically 3rd party auditors are engaged to bring specific technical expertise to the audit.

The parties benefit from the experience of the 3rd party.

Confidentiality and Non-Disclosure Agreements (CNDA)s protect all parties.

The parties are engaged for multiple audits in most cases and the audit sites typically have no concern for indiscriminate disclosures.



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Summary of “must haves” for effective remote audits

- Plan and agree to test technology in advance
- Real-time 2 way video / audio communication at all times
- 360° Live stream site tours, view controlled by auditor
- Timely & high resolution paper document reviews
- Auditor ability to control the review of all content
- Timely & secure document sharing
- No recordings of tours or meetings during the audit *

*Unless agreed to in advance by both parties



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Thank You!

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Remote inspections:

Current approach and challenges

Prashant Sharma

Chief Technical Officer- Zydus Cadila

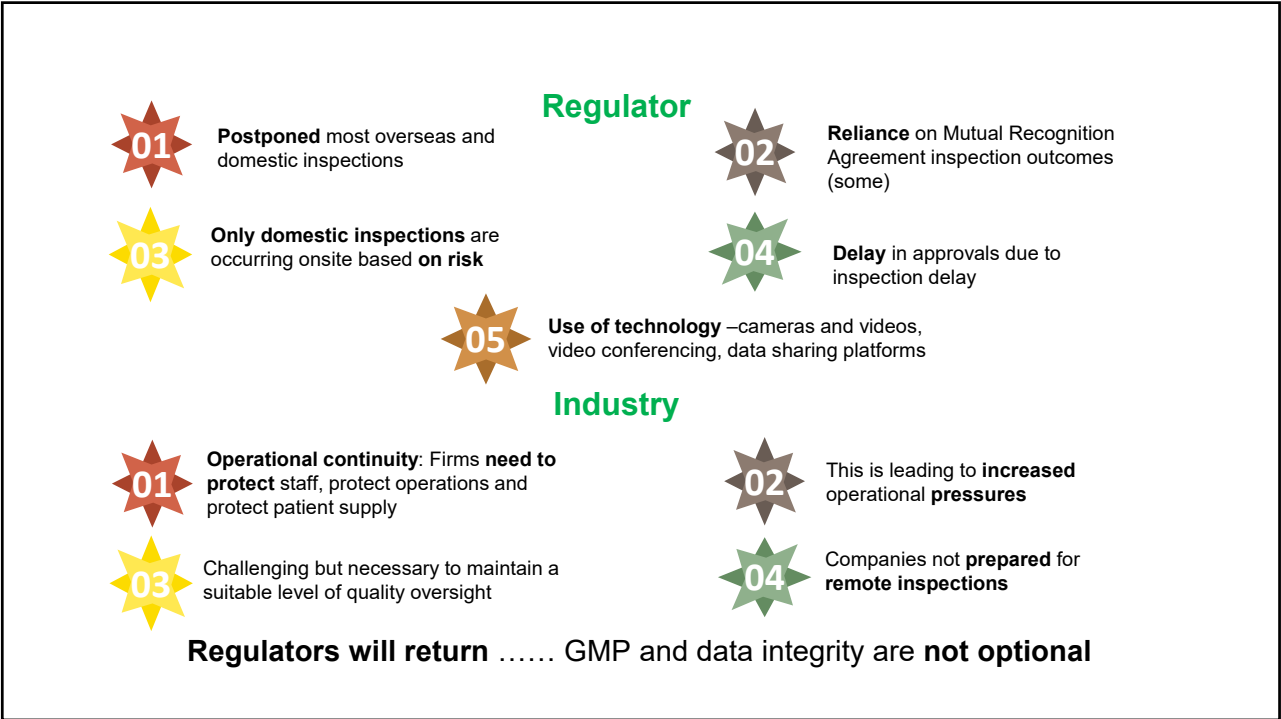
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Prashant Sharma
Chief Technical Officer
Zydus Cadila Healthcare Limited

- Prashant Sharma is a part of Zydus Senior Leadership Team and manages Group Manufacturing, Site Quality & Operations for Formulations & API at Zydus Cadila. He has been in business roles for over 2 decades and managed Global Supply Chain, Human Resources, Corporate Communications & Operations portfolios in MNCs and Global Indian organizations.
- He believes that Learning Agility & Formative Experiences shape a leader. The foundation for both is a keen desire to keep learning & challenging oneself, taking risks and building teams that perform better than oneself.

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Types of remote inspection:

- **Inter company audit** e.g. Supplier audit, service providers or vendor by a manufacturer
- **Intra company audit** e.g. Corporate audit
- **Regulatory audit** e.g. Regulatory agencies/bodies

DESKTOP AUDIT

- Auditor is not physically present at the site(s).
- Responses are shared in written form. e.g. e-mail, shared documentation platform.
- Several iterations of the request possible.
- No real time, phone calls or video conferences take place

VIRTUAL/ REAL-TIME AUDIT

- Utilize technologies e.g. live/real-time streaming video technology, screen sharing functionalities or other means of real-time communication.

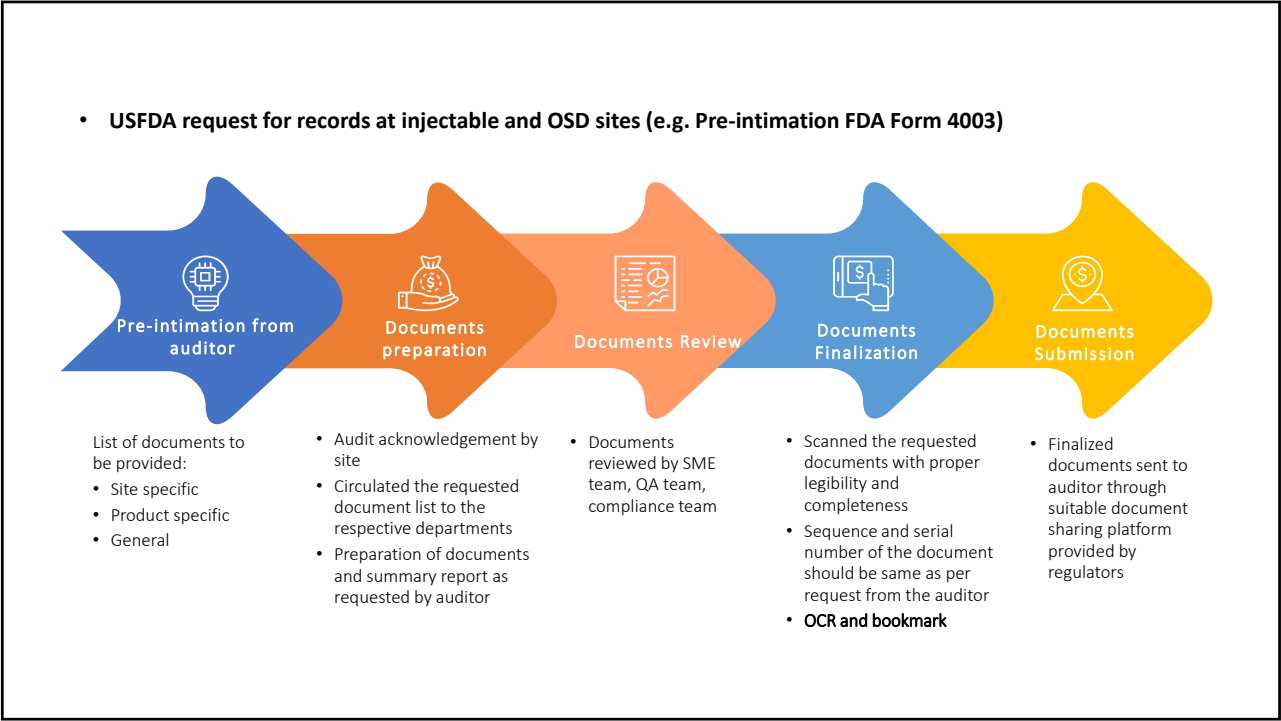
HYBRID AUDIT

- Partially remote and also includes in-person presence and on-site visit by the auditing body.
- Virtual and the in-person assessment may be concurrent or at different times e.g. a portion of audit is performed virtually or desktop, followed by a second portion on-site

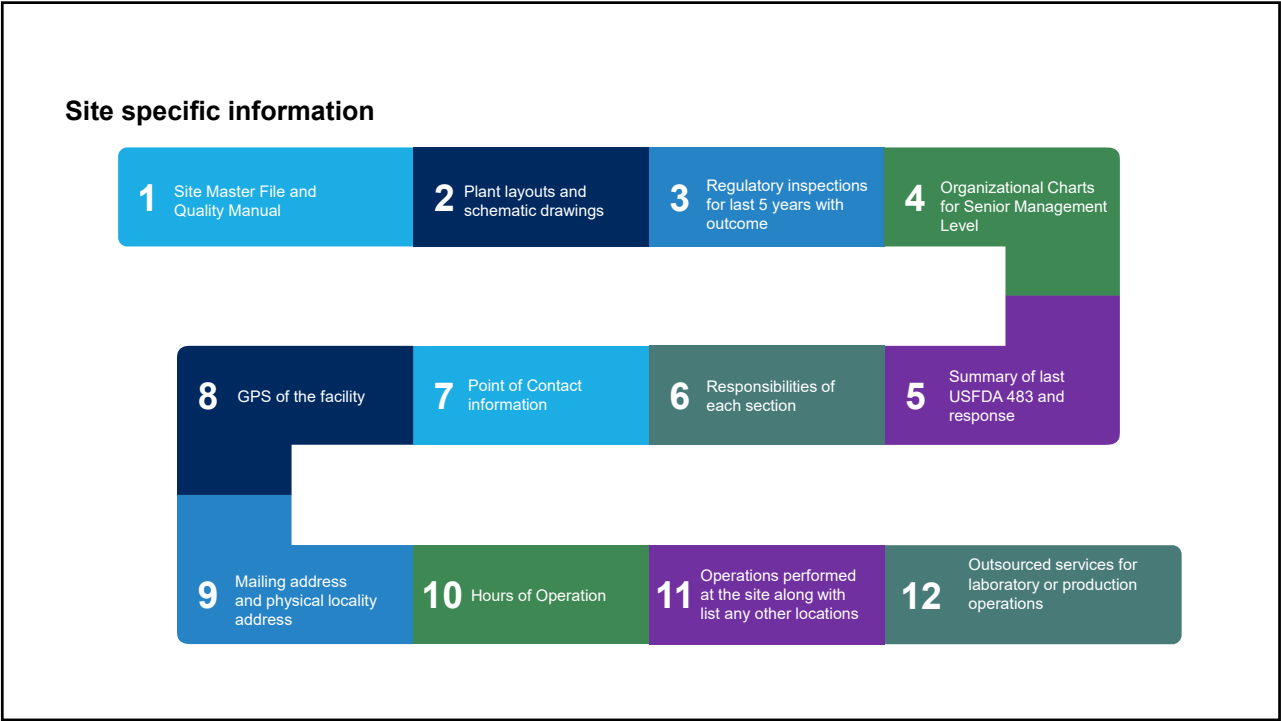
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Product specific information


List of changes to manufacturing processes


List of deviations, OOS, OOT, customer complaints, recalls, FARs

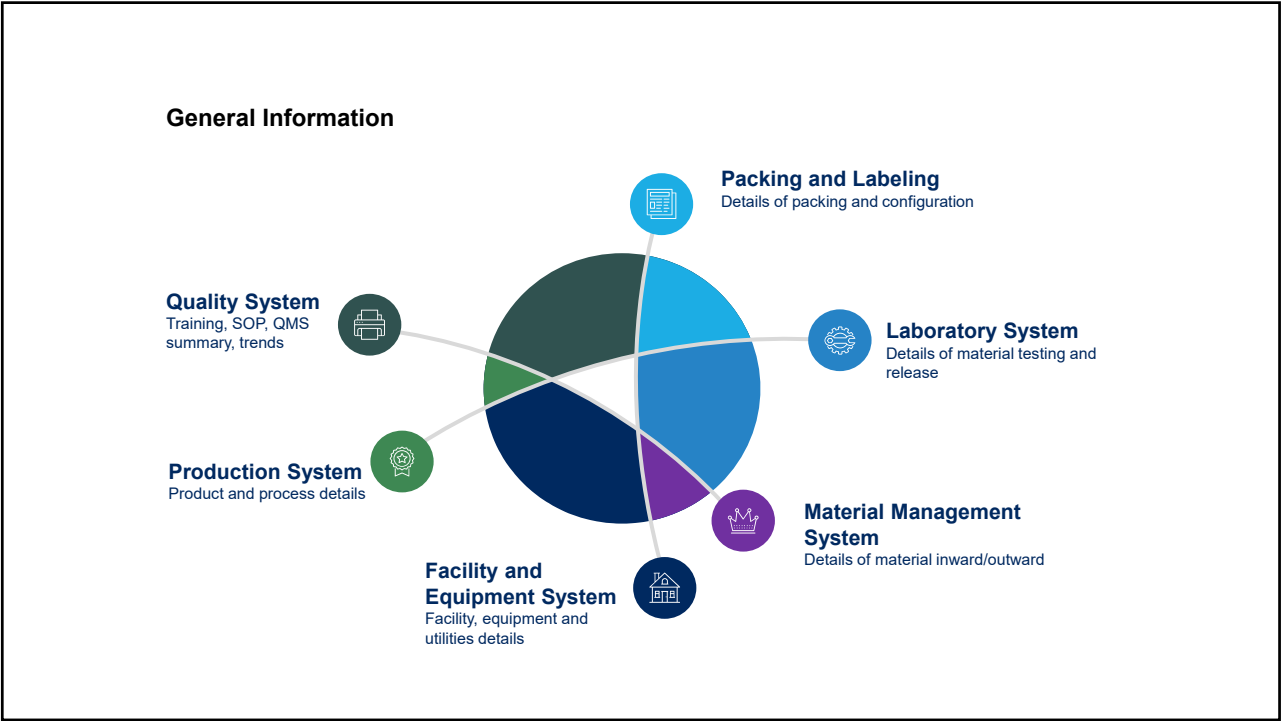
Sampling Procedure of Bulk, In-Process, Finished Product, Stability and other sample along with sampling diagrams

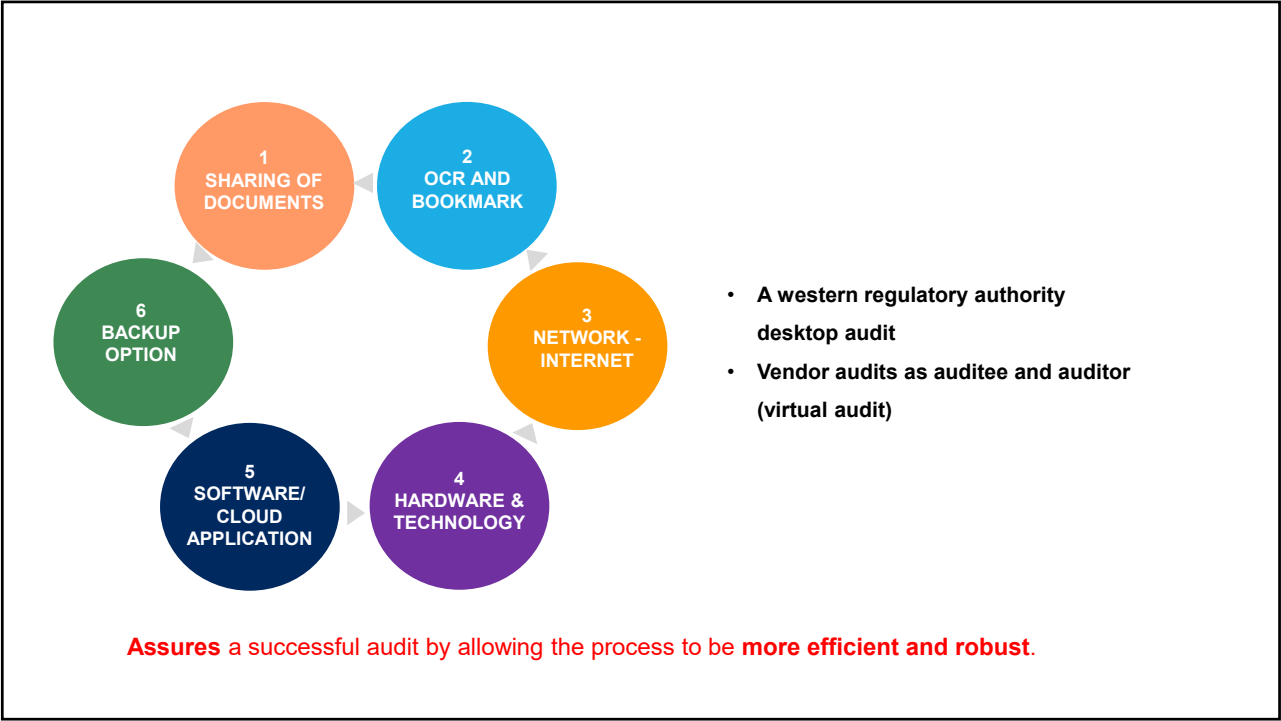
List of laboratory instrument along with last qualification and calibration dates used for in-process, release and stability testing of particular product

Equipment qualification reports for filling line

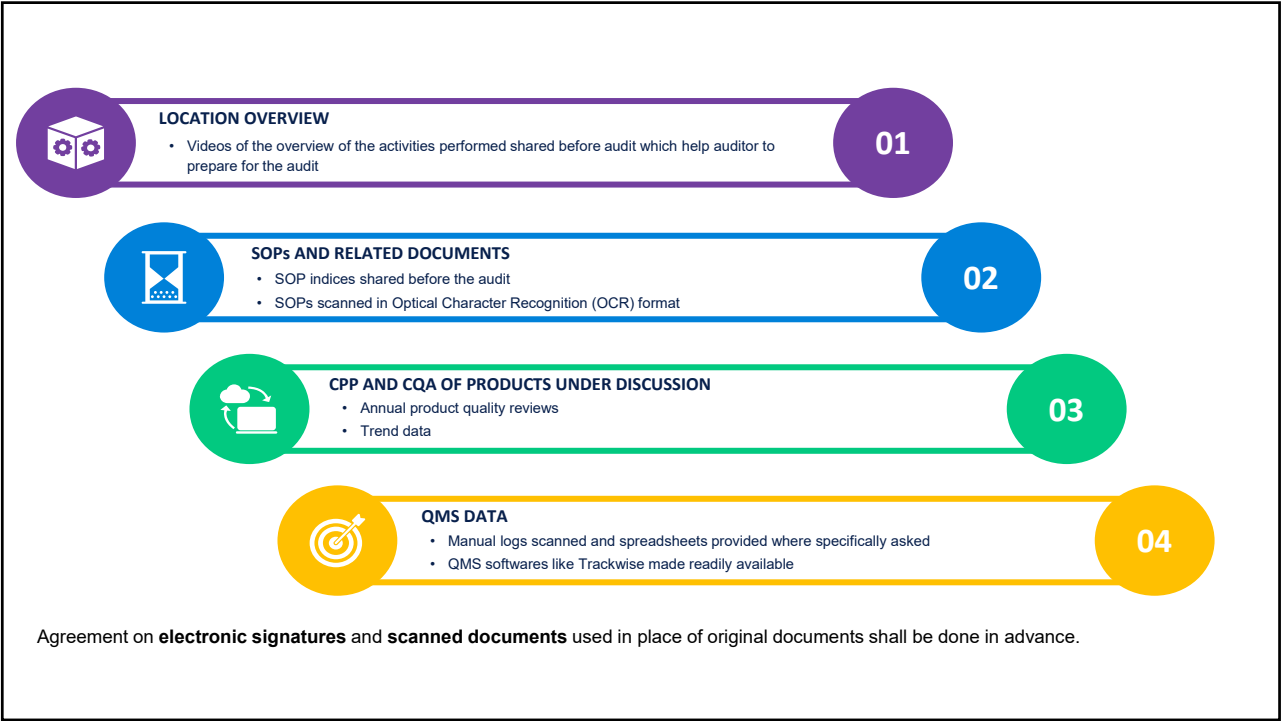
Cleaning procedures and cleaning validation protocol and report of compounding tank and filling line used for particular product

HEPA filter qualification protocol and report

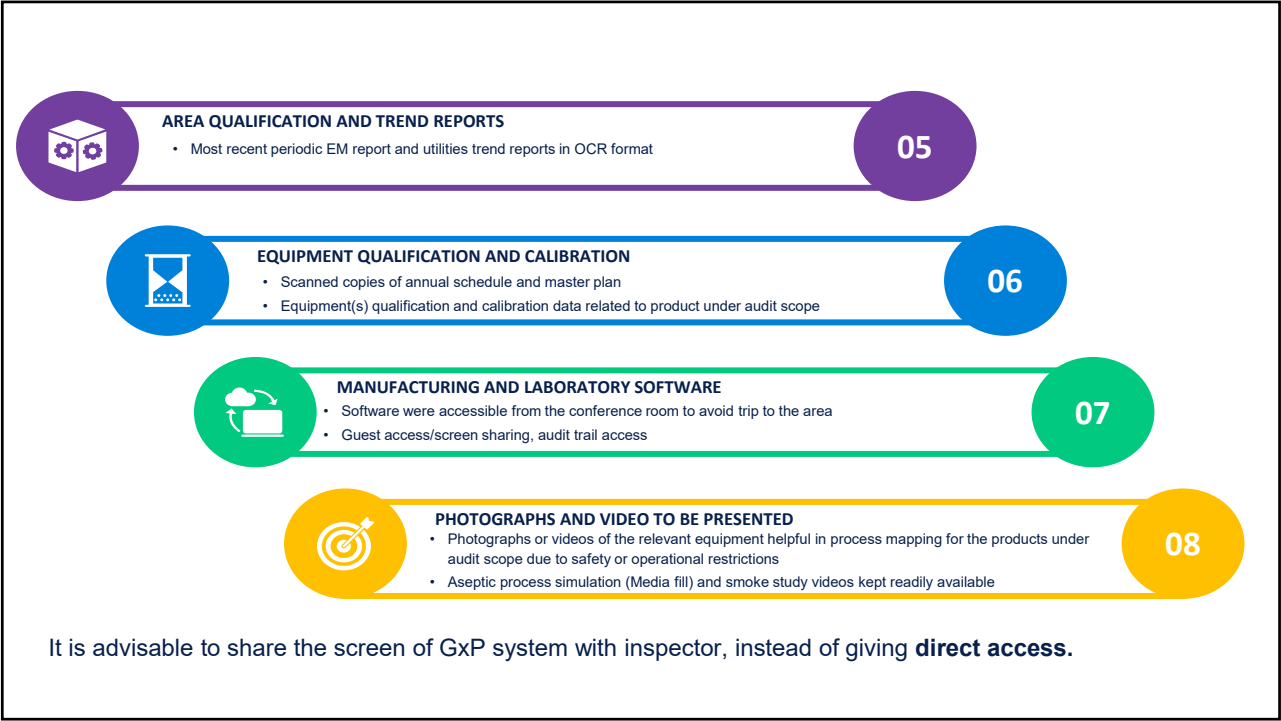




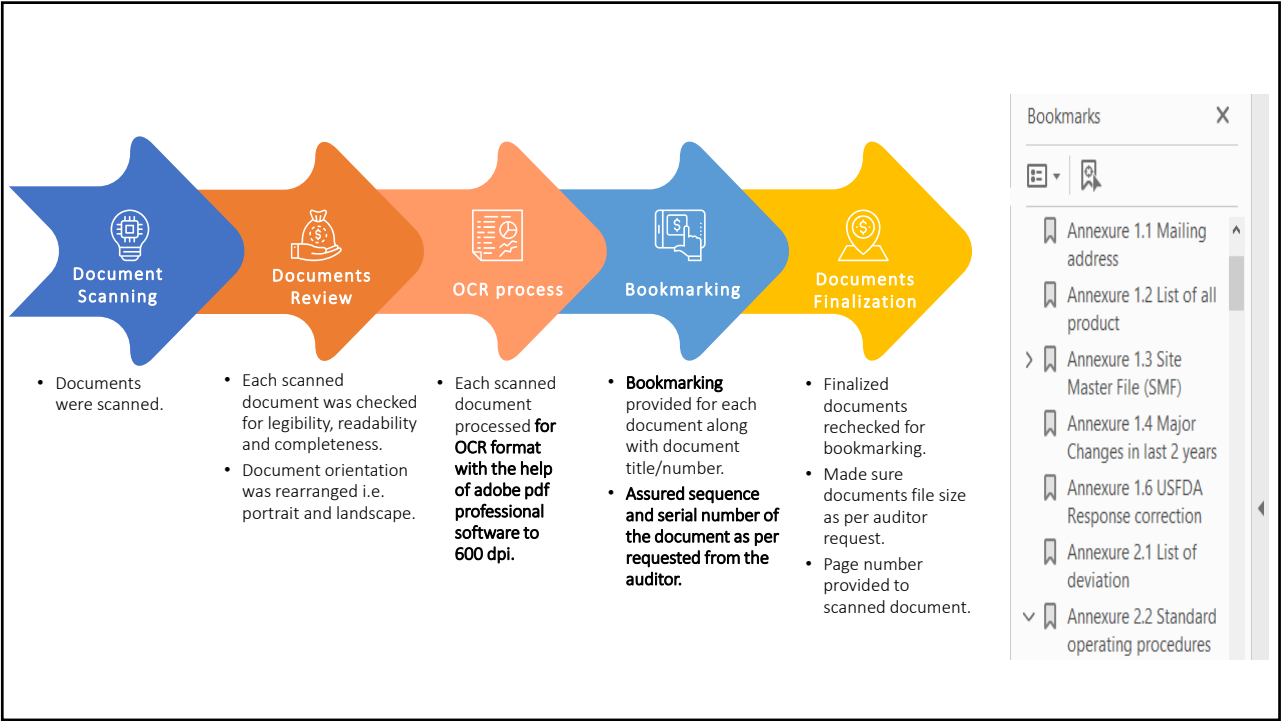
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Select the right internet and networking speed that meets bandwidth requirements for streaming video, voice over internet protocol (VoIP) and sharing documents in virtual meeting rooms




While livestreaming, wireless internet coverage can be used to avoid wired network limitation.




The minimum internet speed shall be mutually agreed



If virtual facility tour is conducted, be sure to test your technology on the route beforehand through a dry run to ensure the risks identified which don't pose problems (remember, difficult to guess where the inspector wants you to go!)



Secondary backup needs to be kept ready to handle any Internet or Network failure



Internet and network shall be arranged to get access to all software(s) from the conference room to avoid unwanted trip to the manufacturing / laboratory area

Poor network can pose challenges in core manufacturing areas. In that case pre-recorded video recording is the suggested option.

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COMPUTER

- Minimum specification of computer system (RAM)
- High speed internet
- Agreement on the hardware and technology well in advance of the inspection



DEDICATED TELEPHONE LINE

- Separate telephone line as a backup in case of an internet or computer software outage.
- Speakerphone option available



WEBCAM OR CONFERENCE CAMERA

- It is built within the computer
- Smart glasses use for real-time interaction



LARGER MONITOR

- Quicker review of documents and possibly reviewing multiple pages or documents at a time



INTRANET OR VPN CONNECTIVITY

- Connectivity shall be tested in advance from all locations that will be involved in the audit to ensure software application will be accessible



SECOND LAPTOP OR MOBILE DEVICE AND HIGH SPEED SCANNER

- To live stream the area and/ or requested data
- Scanner is helpful in preparing documents for sharing

All devices should be **approved** for use within the particular area of intended use, including classified cleanrooms and hazardous areas, from a **quality and safety perspective**.

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BROWSER TO BE USED

- Specific browser used which are compatible with software

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ANTIVIRUS SOFTWARE

- To prevent, detect and remove malware

2



DOCUMENT SHARING PLATFORM

- Scanned copies, word copy or spreadsheets, machine generated documents and video shared via sharable drive

3



COMMUNICATION PLATFORM

- Web conferencing application shall be used
- Have good signal and video enabled all time

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STREAMING AND SHARING

- Web conferencing applications shall be used
- Camera to be focused on point of interest

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All software must be **tested before audit** and, if possible, **via dry run or test run** before the day of audit

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TRIAL RUN AND CHECKLIST

- Execute and acknowledge each software/ technology prior to audit



TECHNOLOGY EXPLORATION

- Don't explore new technologies or options during the audit which may need time to implement



QA TESTING

- All software/ technology should be tested and validated for the fitness for intended use by quality and IT



DISCIPLINE

- On-camera discipline and microphone discipline shall be followed during audit



LIMITATIONS OF TECHNOLOGY

- Run a test case scenario with all possible number of participants or check the specifications

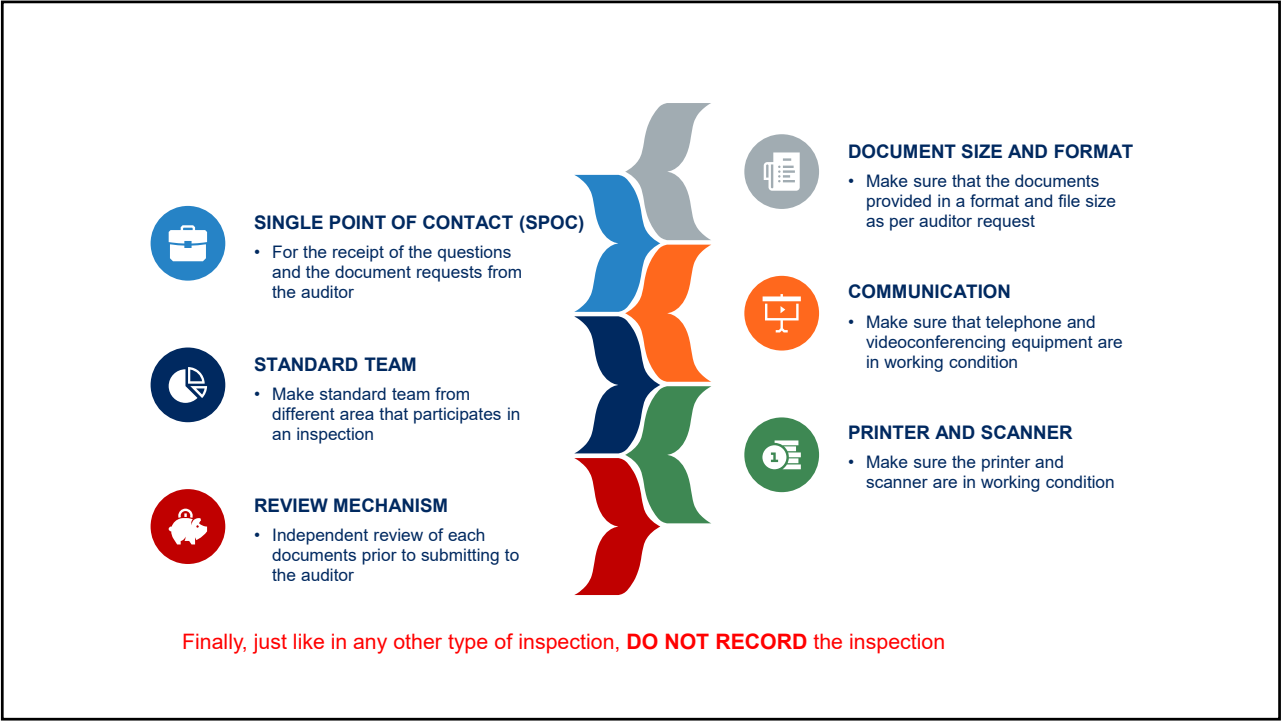


MUTUAL CONSENT

- Record mutual consent on each day of audit regarding the technologies being used that day

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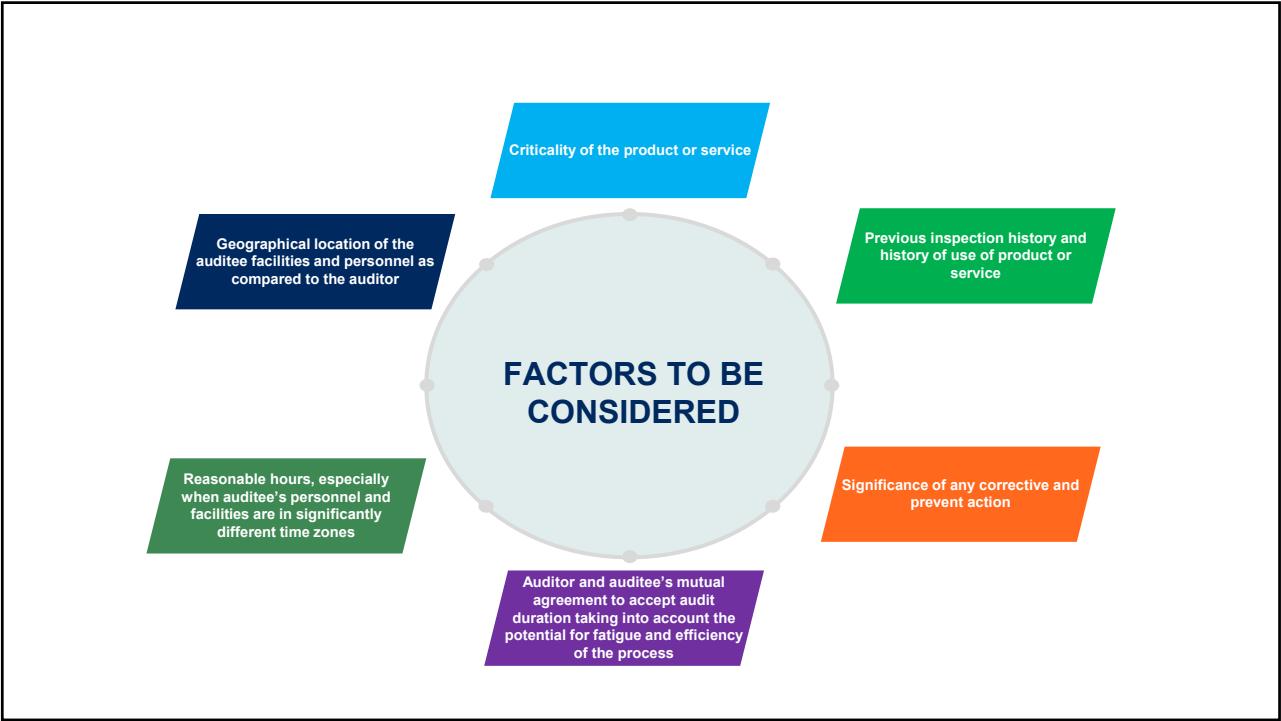


- Secondary backup needs to be kept ready to handle any **technology failure (Server)**
- Limited Wi-Fi network coverage and/or mobile phone cannot be used in areas with **risk of explosion** and **aseptic area**
- If inspector insists to inspect aseptic or risk of explosion area then
 - Wide angle camera shall be used for aseptic area
 - Fireproof camera can be used for risk of explosion area
 - Virtual tour during non production hours in explosion sensitive area
- The level of **scrutiny possible** in a remote inspection may not always be equivalent to an on-site inspection
- It is **highly dependent** on the technology available (e.g. use of live stream, high resolution video etc.)

Case Study:

In late 2009 the FDA issued a press release warning of an impersonation scam. By impersonating an inspector, a person could gain access to records, trade secret and confidential information and engage in industrial espionage.

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Opening Meeting

- Time should be specifically scheduled for introductions for everyone on the call
- Consider pre-recording videos for the facility overview
- Discuss contingency planning for technological or other issues
- Make it clear that it is acceptable for beverages to be sipped as necessary and appropriate


Daily close-out Meeting







- Plan for the daily close out meetings to be a reiteration of findings shared during the day
- It should be concise, short in duration and scheduled following the completion of the daily audit
- Discuss auditor need to allow the auditee to prepare for the next day of the audit

Wrap-up Meeting


- A high level overview of the compliance issues identified with specific checks for understanding
- Provide verbal feedback on positive aspects of the audit
- Auditee may request clarification of findings
- Inspector should communicate the path forward for the inspection response process


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-  Use an **IT platform** that allows video streaming or videoconferencing
-  Establish **one meeting link/** connection for the **entire day**, which all attendees may use, rather than creating a separate meeting link for each sub topic to be addressed during the day
-  **One or two inspectors** ask questions and **one or two people** coordinate the process
-  **SMEs** from the inspected company could join the live session to **support ongoing discussion**
-  **Written conversation** shall be done in IT platform which can be used also for sharing documents and data
-  A **live chat** channel with the inspectors also may be used to facilitate real-time questions and answers if needed

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Consider whether additional time may be required to provide evidence of correction of findings and observations



Tracking and Follow-up for compliance



On site inspection may be required if it is not possible to verify compliance status remotely

Post audit activities are generally similar to on site audit process

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Team of teams approach shall always prevail

Contact:
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Thank you

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