

A woman with dark hair is looking down at a tablet computer she is holding. The scene is dimly lit, with a blue color cast. In the background, there are out-of-focus lights, creating a bokeh effect. The overall mood is professional and focused.

FDA INSPECTIONS v SUMMIT

TRACK #2: MEDICAL DEVICES: MANAGING VIRTUAL MDSAP INSPECTIONS

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OVERVIEW



HOW REMOTE MDSAP ASSESSMENTS ARE BEING CONDUCTED



BEST PRACTICES FOR MANAGING REMOTE AUDITS



VIRTUAL MDSAP CHALLENGES AND HOW TO MITIGATE THEM

A person is shown from the side, working on a laptop. The image is heavily blurred and has a dark blue overlay. The person's hands are on the keyboard, and the laptop screen is visible. The overall scene is dimly lit, with the primary light source being the laptop screen.

HOW ARE REMOTE MDSAP
ASSESSMENTS BEING CONDUCTED?

MDSAP

- ④ Medical Device Single Audit Program (MDSAP)
 - Allows a single audit of a medical device manufacturer's Quality Management System (QMS), which satisfies the requirements of multiple regulatory jurisdictions
 - Australia, Brazil, Canada, Japan and US
 - May be combined with assessment for CE and ISO 13485
- ④ Audits are conducted by Auditing Organizations (AO)
 - Authorized by the participating Regulatory Authorities to audit (e.g., BSI Group America, DEKRA, Intertek, TÜV, UL)
- ④ MDSAP Certification – 3-year cycle
 - Initial Certification ➡ Surveillance (Years 1 and 2) ➡ Recertification (Year 3)
- ④ Initial Certification includes two stages, typically scheduled separately
 - **Stage 1:** Audit of documentation and procedures to evaluate readiness for Stage 2
 - **Stage 2:** Audit of compliance with all applicable QMS and regulatory requirements

REMOTE MDSAP AUDIT: ELIGIBILITY

🌐 MDSAP Published Communication on Remote Audits

- *Extension and expansion of temporary extraordinary measures related to MDSAP audits during Covid-19 quarantine orders and travel restrictions – Remote [2020-05 and 2020-07]*
 - *Available on US FDA MDSAP website*
- **Remote Audit:** Audit performed off-site through the use of information and communication technology [Synonyms: eAudit, virtual audit]

🌐 When remote audits can be conducted:

- Surveillance audits
- Recertification audits
- Significant change audits without any extension of the scope of certification
 - *Addition of activity (if activity can be successfully audited remotely)*
 - *Addition of new medical device (with similar risk profile and production methods as existing devices in scope)*
 - *Addition of a regulation*
 - *Expansion of a facility (not including addition of a new site or facility)*
 - *Change in name or ownership*
 - *Change in critical supplier (if change does not require an audit of the supplier)*

REMOTE MDSAP AUDIT: AO TRANSFER

- ⊕ Remote audits can be conducted for a **transfer between AOs** if all the following criteria are met:
 - Certification of the facility is in good standing and is still within its validity period
 - Facility has a good history of conformity
 - Facility does not require an on-site audit to verify the implementation of corrective actions
 - Transfer of certification does not expand the scope of certification or add facilities
 - All relevant audits reports and nonconformities going back to the last certification or recertification audit are available and reviewed

REMOTE MDSAP AUDIT: NOT ELIGIBLE

- ④ When remote audits **CANNOT** be conducted:
 - Initial Stage 2 audits (Regulatory Authorities are considering the possibility)
 - Special audits
 - Unannounced audits
 - For a significant change to add a new facility to the scope of a certification
 - Facilities that require an on-site visit to verify the implementation of corrective actions
 - Facilities with a high number of nonconformities suggesting a lack of operational control

REMOTE MDSAP AUDITS PROCEDURES

- ⊕ AO establishes procedures that define technology and tools required for remote audits
 - Prior to the audit, AO verifies technological capability of the facility to ensure a remote audit can be performed
 - AO considers need to adjust duration of the audit based on the effectiveness and proficiency of the audit team using this technology
 - Audit report will cite any obstacles or technical difficulties encountered during the remote audit leading to delays or difficulty in communication
 - Any mandatory elements of the MDSAP Audit Model that cannot be performed remotely will be listed as deviations in the audit report and added to the next on-site audit

REMOTE MDSAP AUDIT RECERTIFICATION

- ⊕ For MDSAP recertifications renewed with a remote audit:
 - Validity period of certification is not to exceed twelve (12) months
 - Subject to subsequent on-site verification as soon as possible to confirm remote audit and to perform any tasks that could not be completed remotely
 - Following on-site verification of recertification, AO may issue a certificate with a three-year validity
 - If an on-site audit cannot be performed within 12 months or the on-site verification is unsuccessful, the certification shall be suspended

RECENT REMOTE MDSAP AUDIT EXPERIENCE

- ⊗ AO: BSI auditors located in the U.S. (same time zone)
- ⊗ Scope and Timeline Determined by AO
 - Stage 1 audit – 1 auditor/ 3 days (similar timeline for surveillance audit ~ 1 auditor/2-3 days)
 - Stage 2/Recertification audit – 2 auditors/4 days
 - Micro audit conducted 1 week prior to recertification audit – 1 auditor/4 days
 - Corrective action implementation response – 1 auditor/0.5 day
- ⊗ Audit agenda similar to on-site audit and sent 1-2 weeks prior to remote audits
 - Auditors provided a list of requested documents by email prior to Stage 1 and micro audits, but not for the Stage 2/recertification audit
 - No facility tour – company is a specification developer and outsources manufacturing
- ⊗ Company provided:
 - Video conferencing for opening meeting, audit and closing meeting
 - File sharing site to provide documents for review

RECENT REMOTE MDSAP AUDIT EXPERIENCE

🌐 Conduct of audit:

- Documents were provided to auditors at the time of the audit using file sharing site
- Auditors requested a few documents at the beginning of the audit based on the module being audited, then requested additional documents during the audit
- Auditors reviewed documents and asked questions during scheduled time (like on-site audit)
- Auditors both reviewed documents independently and allowed company personnel to share screen to discuss specific documents
- Auditors and company personnel involved in the audit had video on most of the time
- Auditors held opening and closing meetings similar to on-site audit
- Audit report issued was similar to on-site audit



BEST PRACTICES FOR MANAGING REMOTE AUDITS

BEST PRACTICES

Prior to Audit:

- ④ Plan for more than one audit stream for a full scope audit with two auditors
 - Identify separate personnel to cover each audit stream with separate video conferences
 - Setup separate video conference meeting for each audit stream

- ④ Setup access to a video conferencing system (e.g., Zoom, Microsoft Teams, Skype)
 - Send meeting requests to the auditor(s) and company personnel
 - Use passwords and other security measures on conferencing system to limit access to meeting

- ④ Setup file sharing site
 - Setup security measures for sharing documents (e.g., use passwords, share with limited personnel, allow access for a limited duration)
 - Do not share files until the audit starts – send link to file sharing at audit initiation
 - Do not recommend emailing documents or using external storage media

BEST PRACTICES

Prior to Audit:

- ④ Prepare documents prior to audit based on agenda and requested documents, *(if a list is provided prior to the audit)*
 - Review anticipated documents to be requested based on MDSAP Audit Model
 - Setup an organized file structure based on category/type – ease of use facilitates remote audits
 - Upload a few of the common, anticipated documents on the file sharing site based on module to be audited (e.g., Quality Manual, Organizational Chart, SOPs)
 - Have other anticipated documents ready to be uploaded to file sharing after the auditor makes a request (e.g., virtual war room) – prevent delays in providing documents to facilitate remote audit
 - Consider preferred CAPAs, complaints, design projects, etc. to share if given the option to chose
 - Scan hardcopy records into electronic format
 - Share only final approved QMS documents; do not share drafts or uncontrolled copies
 - Ensure any corrective actions from prior audits have been implemented with verification of effectiveness completed – required for recertification audits

BEST PRACTICES

During the Audit:

- ④ Ensure auditor can hear you and you can hear the auditor clearly throughout the audit
- ④ Turn on video so you maintain eye contact and good communication with auditor
 - Be aware at all times when your camera and/or microphone are on
 - Assume you are in the office in front of the auditor at all times
- ④ Maintain a list of documents that are being provided or shared with the auditor
 - Do not move original files from a network location to the file sharing site - copy files from network to file sharing site
 - Copy the file share documents after the audit to a network or external media

BEST PRACTICES

During the Audit:

- ④ Use a messenger tool to communicate with other remote team members
 - Use messenger to discuss internally what is going on in the audit, request team members gather documents or have a dialog about auditor questions
 - Do not use the video conference chat for this purpose – risk auditor seeing chat
- ④ Assign one person to lead the audit and assign others to address questions
 - One person talking at a time
 - SMEs can listen in on conference line and answer questions only when needed
- ④ Try to lead the auditor through the documents, where possible
 - To address questions, open document and share your screen to explain to auditor
 - Auditor may still want to review documents independently

A hand is shown pointing towards the right side of the frame. The background is a blurred image of a person's face and hands, overlaid with a semi-transparent blue filter. The text is centered in the lower half of the image.

VIRTUAL MDSAP CHALLENGES
AND HOW TO MITIGATE THEM

CHALLENGES AND MITIGATIONS

Technology Issues:

- ④ Prior to audit, setup and test the technology to be used during the audit
 - Computer access for all participants
 - Good internet access for all participants
 - Remote access to company files
 - Quiet room with no background noise or distracting backgrounds
 - Avoid echoing if using phone and computer (turn computer mic off, mute phone)

- ④ Prior to audit, conduct a rehearsal of video conference to ensure good quality audio and video appearance
 - Audio using phone vs. computer microphone
 - Audio using headphones/earpods vs. computer speakers
 - Lighting from the front (no distracting overhead lights and stay away from windows)
 - Video set at eye level

CHALLENGES AND MITIGATIONS

Technology Issues:

- ⊕ Prior to audit, practice using video conferencing, messenger and file sharing
 - Become proficient with navigation tools (e.g., how to share screen, grant permission to others)
 - Practice navigating for efficient review of documents
 - Practice uploading and sharing documents with others including outside of the company
 - Practice using internal messenger to communicate with internal team members
- ⊕ Consider alternative options in the event that video conferencing or file sharing does not work on the day of the audit
 - Backup telephone conferencing
 - Email documents (last resort)
- ⊕ Ensure multiple personnel with familiarity on how to use the technology tools are scheduled during the audit in the event the lead person loses internet connectivity or remote access



Remote MDSAP Audits require teamwork in the same way as on-site audits

Work together and communicate using technology to manage remote audits

THANK YOU!