Practical Advice for Planning and Hosting Remote Life Science Quality Audits

The FDA Group **Presentation**

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Introduction

Neal Siegel, Ph.D.

A Brief Introduction

- Independent Quality/Regulatory consultant (IVD/Med Device/Pharma) with 25+ years of experience and a particular interest in quality statistics and understandable, practical application in instances of compliance shortcomings.

- Extensive, successful experience from lab bench to C-suite. Participated on assessment and remediation teams for companies with severe Warning Letters and Consent Decrees and is knowledgeable in successful recovery from these types of regulatory actions.

Agenda

1. A brief review of audit requirements

2. Advice for planning and hosting a remote audit

3. Benefits and potential pitfalls of remote auditing

4. Final questions for planning

5. Q&A

Review of Audit Requirements

- **Establish, implement, and maintain** quality audit procedures

- Ensure audits are **objective and impartial**

- Define the audit **criteria**, **scope**, **interval**, and **methods**

- Determine the necessary **competence** based on education, training, or experience

- Ensure auditors **do not have direct responsibility** for areas being audited

- Conduct internal audits considering the **status and importance of the processes** as well as the **outcomes of previous audits**

- Ensure audit results are **reviewed by managers** who have responsibilities in those areas

- Ensure corrective action(s) are initiated and, if required, **re-audit the deficient matters**

The Pandemic and FDA Inspections

Statement issued May 11, 2020:

- Postponement of domestic and foreign routine surveillance inspections

- Alternative inspection approaches and tools including remote record review

- "Mission-critical" inspections will be carried out case-by-case

- Re-affirmed that inspections are one component of robust approach to safety and quality oversight

Coronavirus (COVID-19) Update: FDA updates on surveillance inspections during COVID-19

FDA Inspections (cont.)

Statement issued July 10, 2020:

- The agency will resume routine inspections of domestic facilities during the week of July 20.

- The agency will use White House Guidelines for **Opening Up America Again**, as well as the CDC guidance for protecting workplace exposures when scheduling and conducting its field activities.

- In addition, national, state and county-level data will be evaluated when making decisions about where and when to conduct inspections.

Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system

Remote Audits for GMP Compliance

- Due to travel restrictions and workplace policies, **traditional on-site audits may not be an option**. Remote audits may offer **a viable alternative to ensure GMP compliance.**

- Remote auditing utilizes **teleconferencing** to facilitate interviews and share documents and records for viewing.

- The **appropriateness** of a remote audit should be determined via risk assessment. A prior history of compliance issues or trending quality problems should be carefully considered.
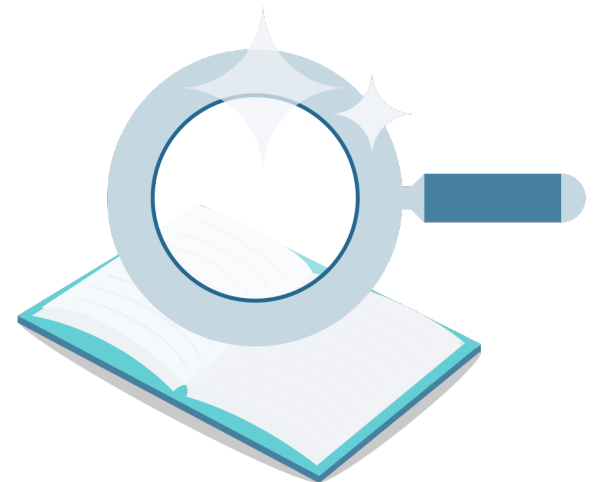
Stakeholder Planning

Stakeholder Planning

Key Considerations and Best Practices

- Fully choreograph the audit activities in detail.

- Budget additional time. Two-day audit schedules typically require an additional half day.

- Create a contractual clause barring digital recording.

- Work with IT to reveal risks and make arrangements (firewalls, software limits, security risks).

Stakeholder Planning

Key Considerations and Best Practices

- Check for potential connectivity or A/V problems ahead of time (dry run walkthrough, equipment testing).

Stakeholder Planning

A Few Important Questions

- How will both parties share information?

- Which technologies will be used to conduct or support the audit (such as cameras and teleconferencing systems)?

- What authorizations need to be obtained in advance?

- Will time zone differences complicate the concept of an "audit day"?

Document Review

Document Review

Key Considerations and Best Practices

- A remote document review largely reflects the process of a traditional on-site review with a few important differences:

  - **Time:** It may take more time to prepare and upload documents to a platform suitable for sharing materials with an auditor versus paper record storage organizers or digital database storage.

  - **Workload**: Remote auditing is rarely as efficient as on-site auditing. Consider sampling strategies if necessary.

  (Cont.)

Document Review

Key Considerations and Best Practices

- **Accessibility:** If you currently use digital database storage, determine whether the software allows the access needed for the auditor to view documents.

- **Questioning**: While a livestreamed document review should allow for live back and forth communications, auditors may need to present questions during remote interviews instead—a requirement that should be accommodated in the project schedule.

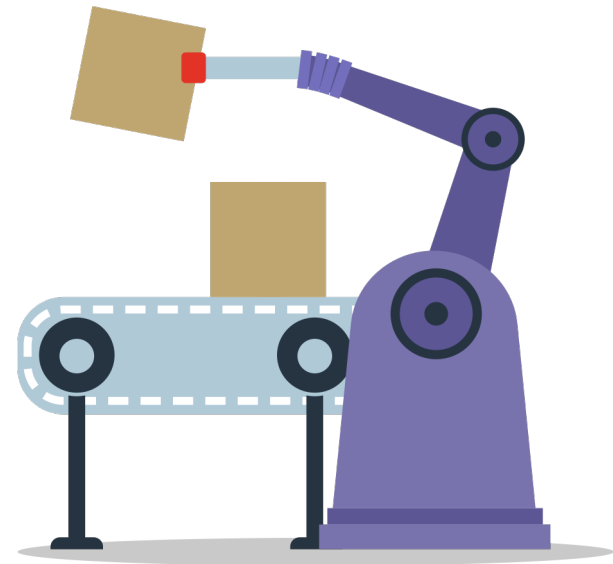# Document Review

A Few Important Questions

- Have you made copies of key documents ahead of time for remote review?

  This should likely include:

  - **Quality manual**
  - **Procedures**
  - **Complaints log**
  - **Nonconformance log**
  - **CAPA log**
  - **Deviation log**
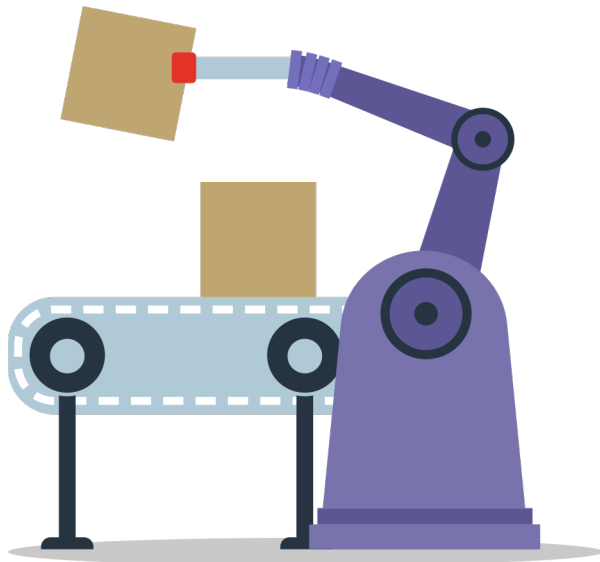 - **Validation master plan**
  - **Certificates**

Facility & Process Review

Facility & Process Review

Key Considerations and Best Practices

- Give auditors a facility map of the inside and outside areas to help plan needs and identify areas where photos, videos, or a streamed walkthrough will be necessary.

- Test for wi-fi dead spots and make arrangements for noisy environments.

- Be aware that the limitations of AV equipment can make real-time communication and peripheral observations difficult. The auditor will need to actively direct camera movements.

Facility & Process Review

A Few Important Questions

- Is a remote facility and process walkthrough feasible and appropriate given the size and complexity of your operation?

- Have you given the auditor a facility map?

- Have you conducted an equipment dry run?

- Are you prepared to perform processes and take questions during the walkthrough?

Remote Interviews

Remote Interviews

Key Considerations and Best Practices

- Video is a must. Non-verbal cues are essential.

- Interview times should largely match those of a traditional audit.

- Auditors may need additional time to prepare for interviews.

- An effective auditor will "arrive" to a virtual interview with a list of questions and discussion points to obtain additional information.

- Make arrangements to avoid people talking over one another.

Facility & Process Review

A Few Important Questions

- Are you prepared to arrange set interview times for individuals on your team?

- Have you made sure connectivity and A/V won't be an issue for those working from home?

- Have you budgeted enough time in the audit schedule?

Closing Meeting

A remote closing meeting shouldn't be substantively different from that of an in-person audit.

These should typically be scheduled a day or two following interviews—a timeframe that enables auditors to review their findings and meet as a team to gather preliminary audit results.

Benefits & Potential Pitfalls of Remote Audits

Benefits of Remote Auditing

- No travel costs!

- A larger pool of auditing professionals to choose from.

- Less operational burden.

- The potential for simultaneous assessment across sites.

- Opportunities for document reorganization.

- Opportunities to prepare for a possibly more remote future.

Pitfalls of Remote Auditing

- Technology woes.

- Awkward interpersonal rapport.

- Lack of firsthand observations and access.

- Integrity risks.

Questions for Audit Planning

Key Questions to Consider

❑ Are we confident a remote audit is feasible and appropriate?

❑ Have we planned to make any necessary contractual arrangements to mitigate risks around remote auditing, such as recording?

❑ Have we made arrangements to work with IT to review the project plan, identify risks and needs, and address them?

❑ Does our project plan include a dry run to test the technology and ensure the audit can run as smoothly as possible?

❑ Have we made electronic copies of key documents for review over the platform that will be used between our team and the auditor?

❑ Are we planning to take measures to safeguard the integrity of the audit if risks exist?

❑ Who will manage outreach to an external auditing firm that can provide access to an experienced auditor for either an internal or external audit role?

QUESTIONS?

Thank You

Contact the experts at The FDA Group

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