### Virtual Audits

Ann Hoang, CTBS StimLabs 15 OCT 2020



- What is virtual auditing?
  - Remote method of a documented review of an organization's process and/or quality system (or product) in compliance with established requirements to determine effectiveness of these areas, performed independently without bias.
- Why virtual auditing?
  - Pandemics and Health/Safety constraints
  - Travel Restrictions/Resources
  - Supplier Performance Trending
  - Communication technologies have made it possible
  - It can be performed with different business aspects such as testing laboratories, raw material suppliers, customer service, etc.
- Scope:
  - External Virtual Audits (Supplier to Supplier)
  - Internal Virtual Audits (Organization auditing its internal processes)

- External Planning
  - Communication Tools are available to both parties
    - Secured or encrypted (maintain and ensure information/health information is protected per HIPAA)
    - Both Auditor and Auditee are familiar with using the communication tools
      - When possible, test the tools to ensure accessibility
    - Provide an agenda and decide on the timeframe it will take to review materials
    - Reliable internet connection
    - Take into considerations for contingency situations where a full staff is not available if interviews are being performed or Subject Matter Experts may be needed

- Internal Planning
  - Communication Tools are available to all parties
    - Secured or encrypted Secured or encrypted (maintain and ensure information/health information is protected per HIPAA)
    - Both Auditor and Auditee are familiar with using the communication tools
      - When possible, test the tools to ensure accessibility
    - Provide an agenda and decide on the timeframe it will take to review materials
    - Reliable internet connection
    - Decide if the internal Auditor will be onsite performing a virtual audit, or offsite performing the virtual audit (employee of the organization versus a Third Party)

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- Scheduling the External and Internal Virtual Audits
  - Provide a timeline for the Audit agenda:
    - Virtual Tours, where applicable
    - Opening meeting
    - Discussions on findings
    - Closing meeting and Audit Reporting (handle nonconformances in the same manner as you would for an onsite audit)
  - Have open communication to set expectations on how long it will take to review materials
  - Set dates for requested materials
  - If performing interviews or if Subject Matter Experts are needed, request and designate a timeframe for staff availability
  - Don't forget to schedule breaks



- Tools and Resources based on your IT infrastructure and resources, examples include but are not limited to:
  - Virtual Private Network
  - Secured Controlled Tools
    - OneDrive, Box, SharePoint, Dropbox
  - Encrypted emails
  - Webinar Tools
    - Zoom
    - WebEx
    - AdobeConnect



- Some Advantages and Disadvantages:
  - Advantages:
    - Conforms to federal mandates during COVID-19 pandemic
    - Saves on distance and costs
    - Reduces audit time and minimizes disruption
  - Disadvantages
    - Some items may not be as visible as a typically seen on an onsite audit
    - An Organization is limited on technology or not having adequate resources (internet connection, webinar or videoconferencing tools, information sharing tools)
- Closing Notes
  - Determine if a virtual audit is feasible when performing as part of your organization's supplier qualification process versus using a Third Party for external and internal audits
  - Plan in advance if applicable, as you may encounter challenges, elongating the process
  - Test your communication and information sharing tools, ensure both the Auditor and Auditee are comfortable with this method.
  - Keep calm and bring the audit on!



# Questions

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