Virtual Audits: Planning is Key
A NAEM webinar presented by: *convergence consulting* and Takeda Pharmaceutical Co., Ltd.
July 30, 2020

RESPONSES TO QUESTIONS AND POLL RESULTS

Leigh Leonard*,* from *convergence consulting* and Wade Miller, from Takeda Pharmaceutical Co., Ltd. have teamed up with webinar participants to address questions and lines of inquiry that were posted in the chat box during the webinar on July 30. If you have any follow up questions, please contact Leigh at lleonard@cc-global.com. Also, if you want to obtain the white paper that formed the basis for the webinar, you may download it from www.cc-global.com.

1. How do you re-create the momentary glimpses that occur during an onsite audit that lead to an unintended line of inquiry?
    A. Webinar participant: hope for over-talking and long explanations.
    A. *convergence*: Here are a few suggestions based on our experience: 1) During pre-audit preparations, ask process owners at the facility to be audited to prepare video or pictorial orientations of their areas in the facility. In reviewing this, auditors may notice closed doors, drains, or other features that they can then guide their proxy auditor to during the audit. 2) If using a live-feed camera, ask the on-site proxy auditor to occasionally (and somewhat randomly) stop and slowly pan around the scene for 360 degrees. In this way, our team actually found a small above-ground storage tank that had been overlooked by the site. 3) Consider seeking a local, third-party auditor to join and support the corporate audit at the site. They may pick up on those incidental details that lead to a new line of inquiry. If a local third-party auditor is not possible, consider appointing an internal proxy auditor who is not familiar with the area being inspected to accompany the designated escort. Any fresh pair of eyes – even if untrained in auditing – can be very helpful. 4) If possible, and if you have an open and cooperative auditee, allow more time for staff interviews to allow for less structure and a more relaxed pace that can spark incidental conversation that may lead to new lines of inquiry.
    A. Takeda: The audit evidence should provide the "glimpses" though not so much in ways that have been traditionally observed; Interview discussions could provide these insights as well as documented information. As much as is reasonable, real-time observations and inquiry should be pursued. We are building in time to go back to areas to look more in-depth using real-time video (if possible). The primary difference is that you'll have to focus your efforts to those areas/processes that pose a more significant concern.

2. [While communicating with someone can you do] site walks using the camera function in mobile Teams App?
    A. *convergence*: Yes, and Wade mentioned during the webinar that Teams has a two-way camera function so the remote auditor can simultaneously see the path ahead as well as the face of the person conducting the walk-through to facilitate interactions.

3. I'd be interested in knowing how someone is performing onsite walks through noisy environments.

    A. Webinar participant: Audit teams can utilize headset communication to talk between themselves and with onsite representatives during a walkthrough

A. Webinar participant: If those environments are noisy, there may be and auditor protection requirement, and earpieces will not fit with the required hearing protection.

A. Webinar participant: True - audit teams will need to be cognizant that they do not exceed exposures above the PEL

A. Webinar participant: Correct. something compatible with hard hats and have 30NRR rating headset/plug

A. Webinar participant: Most audit teams do not spend 8 solid hours in the noisy environment

A. Webinar participant: To clarify... when you refer to "the people onsite" are these the local site folks? if so, they should have already been included in the site's hearing conservation program

A. Webinar participant: Yes. And they are likely required to wear hearing protection. So, they cannot likely also wear headsets to communicate with the remote auditor.

A. *convergence*: There are sophisticated communications headsets that are designed to both reduce noise and convey audio communications, such as would be used in airplane cockpits. There do exist several brands of ear buds and headphones that meet OSHA noise reduction rating requirements and some are also ANSI certified. OSHA's main concern with headphones is that users may set the internal volume too high which may 1) damage hearing and 2) block out important audio information from the working environment, posing additional risks to workers. The OSHA compliant head phones have volume limiters that help address this concern. All this said, if the noisy environment is also fraught with other hazards (e.g., slip, trip fall; moving machinery; high-pressure or hazmat-containing lines; head strike; bulk chemicals), conduct a job hazard assessment to determine if a proxy auditor trying to interact remotely with another person while conducting a walk-through is a non-starter, or whether hazards can be mitigated. For example, as suggested elsewhere in the chat, could a "buddy" accompany the proxy auditor to watch for and help the proxy auditor avoid safety hazards? If necessary, you can fall back to safer alternative data gathering methods for this particular work area.

3.1 Do you have a good brand that's been used? We're talking 100db environments on average.

A. Webinar participant: CavComm

A. Webinar participant: It's been awhile but I remember getting the expandable set on Amazon

4. Are there trip hazards while using the mobile video?

A. Webinar participant: We are working through those issues. Walk buddies to make sure the camera man isn't put in harm's way, for example.

B. *convergence*: See answer to Question 3 regarding a job hazard assessment. The buddy system is a good idea as long as the buddy is attentive to their role.

5. How many pre audit planning meetings do you schedule as part of your planning?

A. *convergence*: This will vary depending on your base auditing protocol and how much time is typically spent on pre-audit for a site visit audit. Based on our experience and what we've been hearing, additional meetings are helpful to: orient participants to how the virtual audit procedure will differ from what they are used to; assign new roles (e.g., proxy lead auditors, technology coordinator, scheduler, records coordinator); provide a brief orientation to auditing (if non-auditors will be acting as proxy auditors); make decisions about which tech tools to use and to provide training on them; and orient remote auditors to site. While it

Responses to Questions and Poll Results
Virtual Audits: Planning is Key
A NAEM webinar presented by: *convergence consulting* and Takeda Pharmaceutical Co., Ltd. on

seems like a lot, experience is showing that investing this time prior to the audit is the key to the virtual audit having some parity with the thoroughness and effectiveness of a site visit audit.

6. How are objectives and expectations different for remote vs in person audits?
    A. *convergence*: The virtual audit procedure should establish higher-level objectives. They may be the same as or modify the overall objectives for site visit audits. For example, if a significant objective is to provide learning opportunities about compliance requirements and how to meet them, how will that be upheld during virtual auditing? There may also be additional objectives relating to piloting and then improving the virtual audit program such as to track level of effort and cost or to formally seek feedback from participants.
    A. Takeda: The audit objectives should be roughly the same, however the scope of the audit may need to be adjusted. There may be areas that cannot be reviewed using remote techniques due to constraints related to making observations. Establishing the criteria against which the audit will be conducted and then verifying the scope of what is going to be looked at during the planning portion has much more significance for VirMote audits.

7. Why do we need another program to perform this type of audits?
    A. *convergence*: You don't. Ideally, virtual audits are carried out under the authority, policy and broad procedures of the overall audit program. It is recommended, however, that the existing audit procedure be reviewed thoughtfully and adjusted/added to ahead of any audits being conducted so that virtual audits will go smoothly and options for making them more successful can be maximized. Organizations that are proceeding without making such adjustments tend to be disappointed in the results as much time is lost during the audit working out communications, technology, and roles that could have been decided prior to the audit. In addition to frustrating participants, this will result in a significant gap in thoroughness and effectiveness of the audit when compared with a site visit audit. This might be ok if the organization is doing virtual audits solely as a tactic to get through the pandemic and fully intends to return to site visit audits exclusively once the conditions allow.

8. Have you noted any changes in the findings in the VirMote audits? Either quantitative or qualitative (as compared to traditional auditing)?
    A. *convergence*: It is logical to assume that the ability to identify issues that lead to findings may be narrowed somewhat by the limitations of being remote. However, based on our experience, this should have no bearing on the quality of findings. If conducted in accordance with audit standards, virtual audit findings should be just as well developed, defensible, and valuable as a finding from a site visit audit. The white paper addresses this more extensively on page 4. Wade also makes an excellent point below; we too have found that more senior auditors with strong and versatile communications skills will get the best results (and write high quality findings) during virtual audits.
    A. Takeda: As with traditional audits, we have found that the difference in audit findings varies more around the competence of the auditors. If there is finding that is more than an opportunity for improvement, there should be enough evidence available. As noted in the presentation, we focused on using more experienced auditors for VirMote because these persons are better able to follow-up on the audit trails that create more robust findings.

9. Any hints on how to "build the trust" remotely?
    A. *convergence*: Here are some quick thoughts:

RESPONSES TO QUESTIONS AND POLL RESULTS
Virtual Audits: Planning is Key
A NAEM webinar presented by: *convergence*
consulting and Takeda Pharmaceutical Co., Ltd. on

- We've been hearing from our clients about getting "buy-in" which is related to building trust. Involve site leadership in the planning for the virtual audit program and be very transparent about virtual audit program objectives, expectations, and process.
- Giving the site clear and significant roles and responsibilities (such as deciding which tech tools to use) will help them feel more like members of a team with common objectives rather than recipients of uncomfortable scrutiny.
- Handling of interviews is key to maintaining trust. While much is being video-recorded for future reference, most clients and colleagues we've talked to are NOT recording interviews. Strongly encourage the use of video cameras on both sides to keep visual non-verbal communication intact to some extent. Auditors should strive to focus on the quality of the communication with the interviewee in addition to working through their questions/agenda. For short interviews, the auditor might consider making notes immediately following the interview rather than during. (See also Wade's suggestion about note taking for Question 17.)
- For meetings during all stages of the audit, the remote lead auditor should be proactive in noting who is not speaking and find a way to invite them into the conversation or check in with them after the meeting. If the lead auditor senses the site team is losing confidence, don't delay in addressing it. Pull everyone into a quick huddle to ask the site team how the process is working for them and subtly remind them of the shared objectives.

B. Takeda: Lots of talking. Generally, trust takes time whether the audit is onsite or VirMote. But there may be some sites that may be too challenging to build the trust before and during the audit, and it may be better to start with a smaller scope.

10. Which of the operational approaches do you use most?
    A. *convergence*: Some of our clients are initially using the Trusted Actor approach with Technology Enhancement where technology tools are readily available/familiar. Several of our clients, some with their initial virtual audits completed, are adding a 3rd party Local Auditor to be onsite if pandemic conditions allow. In a few cases, our Global Alliance partners (country experts) are being engaged to attend the audit remotely with the corporate audit team to help with national and local requirements and language.

11. When you use Teams for information exchange, how was the audit setup? A channel in an existing Teams space, a new space for each audit, etc.?
    A. Webinar participant: We use a new Teams group for each audit.
    A. Takeda: We use a new Team for each audit. Typically, we have two channels: one for everybody participating and one just for the audit team (for audit trail notes, draft findings, etc.).

12. Any recommendations of technologies to use in combustible dust hazardous areas? Technology that is intrinsically safe and explosion proof for Class 1 Division 1?
    A. Webinar participant: how do you audit XP areas, where electronics are not permitted
    A. Webinar participant: Same question regarding C1D1/D2 and C2/D1/D2 process areas.
    A. Webinar participant: We audited a gas power plant yesterday. The technology was not intrinsically safe. So, they had to carry gas monitors with them to use the technology.
    A. Webinar participant: That's a good short-term solution

A. convergence: It sounds like another webinar on types of technologies that work in different environments would be helpful
A. Webinar participant: I like that idea

13. One of the challenges we've had lately is auditing outdoors in the south. Phones have been overheating in short periods and turning off.
    A. Webinar participant: A recorded video of operations can be viewed by audit team.

14. What was that tech again that had front and back cameras?
    A. Takeda: MS Teams

15. A traditional element of a site audit is the opening 'tour' to identify priority area of focus, which might differ from those originally intended. Thoughts on how to approach this?
    A. Webinar participant: I also use CCTV at a site to view the various areas; the site manager typically has access then shares their screen
    A. *convergence*: This is an important question because auditors can definitely feel "lost" in the site details during a virtual audit if time was not taken to help get them oriented ahead of time. Remote auditors can be oriented to the site layout and processes through site maps, floor plans, and process descriptions augmented by an illustrated presentation by the site team that would be provided prior to the audit.
    A. Takeda: We use a collaborative approach with the site leadership, local experts and regional EHS lead input to establish the priorities. We are asking each site to complete virtual tours of the areas with an emphasis looking at these priorities during the planning, creating video recordings that the audit team can review before the audit week. If during a review of the virtual tours or even interviews during the audit, we need to adjust the scope, the lead will review and make any necessary changes in the audit.

16. Do you find that your findings from Virtual Audits are more "clear and robust" or less?
    A. Webinar participant: it's more document based rather than supported from observations
    A. *convergence*: Please see answer to Question 8. If we follow our audit standards, we should generally have more than one source of corroborating evidence (and preferably at least three) to support a finding. While it is true that documents are more readily available to the remote auditor, impressions can be confirmed through interviews (maybe more than one to be sure) and also through remote visualization of the site. One strategy a remote auditor can use to interrogate potential findings is to send a proxy auditor on a focused, spontaneous site check to confirm conditions. With the right technology, the auditor can "go along." For example: spot check labels here, view the weekly hazardous waste inspection log for accumulation area F that should have been completed yesterday, or view the secondary containments of Tanks A and F. We will no doubt get more creative as we adapt our inquiring auditing minds to virtual audits.
    A. Takeda: Clear and robust findings are a challenge whether or not the audit is onsite or VirMote. The most significant difference is that it can be more difficult to resolve a difference of opinion between the audit team and the site. The other challenge is that the audit lead has to push the auditors to collect additional evidence for a more robust audit finding, rather than doing the work themselves.

17. How have employees reacted to virtual interviews?

A. *convergence*: Please see answer to Question 8. In addition, how interviewees react is influenced by their comfort or discomfort with the technology being used to communicate in addition to how they feel about the audit. This is one reason why orienting all participants to how to use all of the tech tools they may engage with during the audit is helpful.

A. Takeda: Mixed.... It can be challenging to get people to relax talking into a computer screen. Some people are better at it than others. I've found it helpful to explain the silences as I am taking notes and to read back the notes as we go along so that they know what is being typed/written down. And always try to look into the camera – even if their image is off to the side of your screen.

18. Are you shipping the tech tools to different sites or do they all have the selected system? system?

A. Takeda: We are looking to the sites to get their tech because they should be able to use it for other operational needs. We haven't ruled out shipping, but shipping costs can be high, plus you have to train the site people... Not much time left for audit planning.

A. Webinar participant: @Wade we are doing the same....tolls can be used in support of other operational functions...inventory, engineering

19. Why avoid "resistant" sites? I would think those are the ones that need auditing. Perhaps engaging them in the process will tear down the walls.

A. Doreen Parrish: We are Not skipping resistant sites. We are prioritizing which ones we need to build rTDA relationships with

A. *convergence*: First, this is a decision that is very unique to each organization and we completely respect the perspective that you don't want to ignore sites that may be most in need of an audit and compliance support. Second, to be clear, we were suggesting that you don't <u>begin </u>with resistant sites during your first few virtual audits. Eventually, you would want to engage all sites where there is a duty to audit with virtual audits in accordance with your audit program and procedure. Further context from Leigh's experience: In a large, multi-site organization where sites have a lot of autonomy, there are those site teams that lead and those that resist and watch what everyone else is doing before they get on board. By investing your energy in your leading sites initially, you can concentrate on testing and working out your virtual auditing procedure without a "headwind" that will steal time and energy. Then you can engage the sites that are more reluctant later with a proven approach.

20. How do you measure program effectiveness if there is not a "boot" on the ground?

A. *convergence*: The question implies that the auditor on the ground is in the best position to measure audit effectiveness and that effectiveness can be determined during the site visit. Consider what the organization is trying to accomplish with the audit program. Leading organizations will evaluate long term effectiveness by performance over time – whether there are repeat findings or persistent systematic gaps in the same program over a number of audits. Within that context, begin by looking at the objectives and metrics for your overall audit program effectiveness and consider their suitability for virtual audits. Make adjustments and add to those as necessary to properly evaluate virtual audit effectiveness over time. It is also worthwhile to formally evaluate the satisfaction of participants with the virtual audit and their impression of the audit results as one of several indicators of the effectiveness of virtual audits.

A. Takeda: For all of our audits we solicit feedback from the sites and the audit team. We are always looking for ways to make the program more effective as part of our continual

improvement efforts in the program itself. We consider the auditee an integral part of the success of the audit and have to trust them as our "boots on the ground." Ultimately, the sites are the ones that need to get value from the audit and we try to create a value-add approach through the scoping and planning and that should be reflected in the feedback we receive. We do have objectives around meeting deadlines for audit deliverables and completion of total number of audits, but those would exist regardless of the audit format. And, if we were to get substantially different results from our internal audit verses the external audit (e.g. certification bodies or regulatory inspections), we would have to evaluate for effectiveness – we haven't seen that yet, though.

21. What can most companies/facilities use that they have on

hand now to implement a virtual audit process if purchasing new technology is not an option? What about secure areas where electronics are not authorized?

   A. *convergence*: See discussion of Question 12 re: electronics above. Where live-streaming or video is not permitted investigate whether a photo log may be created. Secure areas may also have security camera coverage that might be leveraged for the audit. This is also where you fall back to the other two approaches: Trusted Actor and Local Auditor. Consider spontaneous spot checks by your proxy auditor as described in Question 16.

   A. Takeda: Our program uses the Site's (Auditee's) technology for visualizing the site so it is the corporate audit team that must adapt and learn that technology. For communications and document repository we are using MS Teams. I've seen a remote audit done with just Skype and Facetime and it worked out well. All audits have limitations, so:
      o Work with what you have;
      o Keep it simple; and
      o Don't be afraid to descope if you can't effectively evaluate an area.

Poll Results

Poll #1: Do you currently think of virtual audits as: ☰▾

| View Votes | Edit | Reopen |

This Poll is closed for voting. To allow participants to vote, click Reopen.

Poll #1: Do you currently think of virtual audits as:

- ○ A temporary measure during the pandemic and potentially used in the future only when necessary. — 15.6... (24)
- ○ An approach that will be integrated into your audit program and how audits will be performed in the future. — 77.1... (118)
- ○ Don't know. — 7.19% (11)
- ⦿ No Vote

☑ Broadcast Results

Note: The wording of the second polling question below should have been: "In comparison to a traditional onsite audit, does your organization currently allocate: …" It appears the respondents understood the question correctly.

Poll #2: In comparison to a traditional onsite audit, does your currently alloca ☰▾

| View Votes | Edit | End Poll |

Poll #2: In comparison to a traditional onsite audit, does your currently allocate:

- ○ More time for the virtual audit process — 33.8... (46)
- ○ Less time for the virtual audit process — 13.9... (19)
- ○ Same amount of time for the virtual audit process — 22.7... (31)
- ○ Company does not conduct virtual audits — 29.4... (40)
- ⦿ No Vote

☐ Broadcast Results