

# REMOTE VENDOR AUDIT (REVA)



## CONFIDENTIAL

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Definition of communication methods:

- **Audio:** communication between participants via audio only (telephone line, computer audio). Via this method documents would be sent via email, placed in shared area only etc.)
- **Audio-visual:** communication using Webcon/Video Includes ability to see participants being interviewed allowing the visual sharing of documents, to have direct “viewing” access via the interviewee to computerized systems in use by the auditee (i.e. via screen sharing), or to see computer screens where screen sharing is not possible (e.g. X-Ray, Ultrasonic systems etc.) or via video transmission using a camera at auditee’s site giving the auditor direct sight via live camera link, of auditees, equipment, materials, rooms etc.
- **Direct Access to systems:** auditor’s direct access to auditee’s validated system (where permissible by local regulations) using their own unique access and password (i.e. SOP system, training system, etc)

### Objective:

REmote Vendor Audits (REVAs) can be conducted as part of a sponsor’s risk-based approach to auditing providing a level of confidence in the compliance status of the vendor.

An assessment phase will be introduced to devise an approach to the audit conduct phase. The results of this assessment phase will be agreed with Sponsor, and Vendor (as applicable) before moving to the next phase of the audit.

Should the outcome of the REVA fall below the level expected, or not all required information can be obtained during the REVA, an on-site audit should be considered at a later date and may include a reduced scope.

If an audio-visual section of the REVA **IS** possible and the confidence level is as expected, an on-site audit may not be required.

If an audio-visual section of the REVA is **NOT** possible a reduced scope on-site audit should be considered at a later date.

### Confidentiality for REVA audits:

Recording of audio or video (including any kind of recording outside the software being used i.e. voice recording, screen shots, screen printing, photo taking of the screen, etc.) of all or part of the REVA by all parties is prohibited by national data privacy and protection regulations (for example, GDPR).

Should one or more of the parties require a separate confidentiality agreement that captures the prohibition of recording, GXP-Engaged has a template available for use between the Vendor and the Auditor.

## REVA Assessment Phase:

For those REVAs where an assessment has been fully or partially performed by the sponsor/client, the assessment phase performed by the auditor may be reduced but the auditor should make sure they have all necessary information before beginning the conduct phase of the audit.

The assessment phase should include:

- Introduction of auditor to auditees and arrange date/time for assessment call
- Telecon with auditees as necessary to investigate the most appropriate approach to the REVA and understand:
  - technical capabilities of vendor to assess whether audio-visual link possible, agreement on tools to be used, possible access to vendor eSystems such a document repository etc. and timing for a test run.
  - how each area of the audit scope can be accomplished and who will be involved in covering the area of the audit scope,
  - the staffing of the vendor, who performs which task and their availability for an interview during audit conduct,
  - how access to documents required for the audit preparation and conduct maybe provided,
  - whether a virtual facility tour, partial tour to key areas may be possible and if so how and to what extent,
  - who should be involved in opening and closing meetings,
  - If the use of video is agreed, remind all parties of the need to adhere to legal requirements to refrain from recording of all or part of the audit. A template for a separate confidentiality agreement is available if required
- Feedback to Sponsor on suggested approach and draft scope
- Agreement with sponsor on documents required to be reviewed prior or during the audit
- Agreement with sponsor on content and distribution of deliverables
- Agreement with sponsor to progress to REVA preparation

## REVA Preparation

- Preparation of a detailed draft agenda/plan describing the scope of the REVA and how this will be achieved, reference standards, date and time of the REVA conduct, and the deliverables
- Request for comments/approval by the sponsor to the agenda/plan
- Finalisation of agenda/plan and issue to agreed distribution as appropriate and agreed with sponsor
- Gain access to all required electronic systems for document review (where required) with sufficient lead time to perform steps below
- Review of all (electronic) documents related to vendor that are available up front, examples may include:
  - Standard Operating Procedures of sponsor and auditee
  - Organizational Charts
  - Floor Plans
  - Contracts
  - Documents relevant for the task(s) considered for outsourcing
  - etc (modify to the documents expected for the audit discipline (i.e. GMP/GDP/VP/GCP/GLP .....

For REVAs including an audio-visual section:

- Prepare and issue confidentiality agreement if required
- Perform test of technical equipment to be used during conduct phase (i.e. video, where required)

REVA Conduct:

- Opening meeting with agreed parties, confirmation of approach to the REVA, the scope and agenda
- Review of (electronic) documents related to vendor that are only available during the REVA conduct
- Interviews with key vendor staff identified on the agenda to cover audit scope and answer questions noted during preparation and conduct phase e.g.
  - gaps in documentation
  - gaps in training
  - clarification of questions process and documentation details not clear from document review
- Debriefing including communication of findings and comments to agreed site staff.

For REVAs including an audio-visual section also include:

- During opening meeting include confirmation of confidentiality expectations
- Virtual facility tour (where feasible) to the areas agreed during the assessment phase

Post REVA Activities:

- Providing a short summary of the audit results via email to sponsor QA prior to the audit report
- Writing of draft audit report
- Distribution of draft audit report to nominated person(s)
- Finalisation of audit report based upon feedback received from sponsor/client and preparation of audit follow-up template
- Review of CAPAs suggested by auditee, and confirmation of acceptability of suggested actions (where appropriate)
- Issue of audit certificate to the auditee(s) upon request of sponsor

## **Points for consideration:**

### **Prior to the audit**

1. Determine the time difference between you and the auditees accurately and consider it while drafting the audit agenda. If you and the auditees are in different time zones, indicate both times for each session in the audit agenda. It is possible that different members of the auditee team may be in different time zones.
2. Test the line of audio / video communication including screen-sharing with the site / vendor (mention this in the audit notification letter). Allow sufficient lead time for the test to ensure the audit can go ahead as planned. Ensure you have a redundant telephone / internet line available at the time of audit, just in case, the main line fails during the audit.
3. Consider parallel use of different systems (video conferencing and remote document access), and ensure you have two screens available to allow verification of different documents without taking notes and avoiding errors.
4. Keep available the IT support contact details handy during the audit. Suggest the Vendor informs their IT department (where applicable) of the audit dates and duration.
5. If video communication line is being used, dress up as if you are attending the audit in person.

### **Audit Conduct**

6. Open the line of audio / video communication 10 minutes prior to the scheduled audit start time. This will give time to resolve issues with the communication line, if any, and start the audit on the scheduled time.
7. Ensure that you (and the auditees!) are in a silent and noise-free surrounding during the audit. If required, request the auditees, in advance, to ensure the availability of a dedicated room for the audit duration.
8. Remind each person involved in the audit that recording of audio or video communication is prohibited by law.
9. Take attendance of each member on the call. If any key contributor (auditee) - who is required on the call and has confirmed attendance - is not present, check if he/she is going to join. If not, confirm the time when the member will be available.
10. Explain the reasoning for the REVA approach at the beginning, and repeat the rules related to data protection (no recording, photos, etc.) according to the CDA.
11. Discuss slowly but clearly.
12. Try to build rapport with the auditees by introducing yourself and holding a brief conversation. This will also help to get adjusted to the language / accent of the auditees. Remember, it's difficult to build rapport remotely.
13. While discussing the agenda, explain the duration of each session and the arrangement for breaks – to keep the line on mute or to disconnect and re-connect after the break.
14. Describe the process for interrupting the communication line and leaving or joining the call. Request each member to inform you when they leave or re-join the call.
15. Confirm the process for receiving additional documents from the auditees during and post-audit. Convey and confirm your contact details while requesting additional documents, if any. Suggest providing requested documents within an agreed timeline and make a note of when to expect the document

16. Address each question to a particular attendee if more than one auditee is on the call. Ensure that the questions are succinct and understood by the auditee (questions on a call are sometimes easily misunderstood!).
17. Responses to questions, indicating noncompliance and potential audit finding, should be re-confirmed with the auditees during the discussion.
18. Check with each interviewee after the discussion if they have any question for the auditor.
19. In case of live video tour of facilities, determine the important facility area and request the auditees to take you through those area only. Discuss and agree on the sequence in which the facility tour should be conducted. If areas, devices and/or (emergency) equipment are critical for trial (safety, endpoints, etc.), and the scope of audit, request a floor plan with manual entry of location of areas/devices/equipment, together with brand names, serial numbers, etc. to allow full traceability of relevant equipment.
20. Follow the audit agenda as far as possible. Remember, this is a REVA limiting the flexibility to re-arrange sessions, if required.
21. Remember not to take remote access control of any auditee computer system (even if offered by the auditee) unless you can log into it using your access details.
22. During document review, ask for time out and let the auditees continue their routine work with an agreed time to reconvene.