PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

AIDE-MEMOIRE

REMOTE ASSESSMENTS

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1. Document history

Adoption by Committee of PI 057-1	15 November 2024
Entry into force of PI 057-1	1 January 2025

2. Introduction

2.1   The remote assessment process was introduced during the pandemic to provide a tool for continuing to perform remote assessments where it has been difficult to travel to perform on-site inspections and/or to prioritise inspections.

2.2   The remote assessment is a tool in the inspector's tool kit to be used, as required.

2.3   The Aide-Memoire provides a harmonised approach to achieving consistency when conducting remote assessments with an interactive part.

3. Purpose

3.1   The purpose of this document is to assist GMP inspectors in the life cycle process of remote assessments. Parts of this Aide-Memoire may also be useful (with suitable modification) during other GXP remote assessments, where similar principles apply.

3.2   This Aide-Memoire should also contribute to a harmonised approach for remote assessments between the different PIC/S Members and foster reliance.

4. Scope

4.1   The Aide-Memoire utilises best practices for performing an interactive remote assessment, including hybrid inspection.

5. Aide-Memoire

5.1   The Aide-Memoire should be used with the following general comments:

- It should be considered with the PIC/S guidance on remote assessments
- It should consider that the Inspector is already trained in performing the core technical function of an inspection
- It can also be useful for the training of new inspectors

6. Revision history

Date	Version Number	Reasons for revision

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1. Preparation for a remote assessment

The purpose of this portion of the Aide-Memoire is to outline some prompts to consider when preparing for remote assessments

Nr.	Prompt	Reference
1.1	Have you determined the feasibility of performing a remote assessment?	PIC/S Guidance on remote assessments section 6
1.2	Consider a teleconference with the site to discuss the planned remote assessment: minimum technical requirements, scope, duration - Establish whether the site can meet requirements for the remote assessment - Identify the point of contact for the site for all requests and communications - Establish timeframes for the technical and organisational preparation of the remote assessment. - Identify which live videoconference platform you will use with the site (e.g. MS Teams, Webex, Zoom, Google Meet)	PIC/S Guidance on remote assessments
1.3	Consider break-out rooms/conferences to facilitate parallel channels of discussion between different inspectors and the site.	
1.4	Consider which secure platform can be used to allow for the timely sharing of electronic documents e.g. Eudralink, Sharepoint, cloud server, encrypted email?	

1.5	Consider performing a connectivity test before the start of the remote assessment
	
	- Information gathering on Network availability, performance, and hardware,
	
	   o Request of information related to any area of subject to the remote assessment: Type of Network (e.g. LAN, Wifi, cellular data, mobile hotspot), Expected bandwidth (upload and download speeds), Hardware to be used (head mounted device, cell phone, other devices, headsets power backups and battery life/ time
	
	- Test items for all videoconference applications:
	
	   o Virtual Meeting
	     ▪ Connection (video, sound quality)
	     ▪ Screen sharing (both parties)
	     ▪ Host to give control to other party - remote (read-only) access to inspectors to computerised systems)	

	- Capability for the live sharing of screens displaying computerised systems used by the manufacturer - Ability to share documents/messages. - Clearly state expectations with regards to recording of the remote assessment. o <u>Paper Documentation review</u> - <u>Camera/Device recognised by application</u> - <u>Test of device (resolution, zoom, sound)</u> - <u>Document sharing platform</u> o <u>Connectivity tests including sound at inspected/assessed areas (e.g. Production, Laboratory, Utilities, Warehouse)</u>	
1.6	Consider the need for an independent translator E.g. via Embassy, Manufacturer, Consultants	
1.7	Consider the time zone of the site and the location of the inspector(s) - Determine an agreeable time to connect. Is there a sufficient over-lap time each day to hold live discussions? Can the inspector's working hours be adjusted to maximise benefit of the remote assessment? - Can there be sufficient documentation available for review when site personnel are not online?	PIC/S Guidance on remote assessments
1.8	Request for documents prior to remote assessment - Are documents required to be submitted in a specific format? - Consider numbering your document requests. Can the received file name include the original request number, to facilitate finding a document and confirming that all requests have been received? If multiple inspectors are involved in the remote assessment, considerations may be made for multiple numbering or filling folder systems to distinguish different assessment topics / focus. - Is there a preferred language for all submitted documents? - Can encrypted and password-protected files be accessed by the regulatory agency? - Consider machine translation in case of a large number of requested documents (indicated as such) - Consider Scanner / Document viewer capabilities. - Should documents maintained in paper format be scanned as a searchable Portable Document Format (PDF) file?	Refer to PIC/S Guidance on remote assessments.

	- Consider requesting scanned documents for the ease of review before the remote assessment, giving sufficient time for the site to prepare such (Note: Request for documents may vary. Similar considerations would apply to document requests during the conduct of the remote assessment.)	
1.9	Consider the communication process between inspectors. - To allow time and a private virtual meeting room for inspectors to communicate with each other. - to ensure that all requests for documents are visible to all inspectors. Consider preparatory meeting (teleconference) to discuss agenda, scope, activities of the site, etc.	
1.10	Consider informing the company whether recording is permitted or not (by video or audio) by the inspected site, of any information exchanged during the assessment, including opening and closing meetings.	

2. Conduct of the remote assessment

The purpose of this portion of the Aide-Memoire is to outline prompts to consider when conducting a remote assessment

Nr.	Prompts	Reference
2.1	Consider how you will present your identification to the company remotely	
2.2	Consider how and when the opening meeting will take place with the site - Present Agenda and update / revise depending on production schedule, plant tour - What documents will you request? - Availability of SMEs?	
2.3	Consider preparing a daily tentative schedule to ensure the availability of SMEs for interviewing and the viewing of operations at the facility, while maintaining the flexibility to deviate from the schedule, where needed, based on findings	
2.4	Consider how and when the daily wrap-up meetings (if required) will occur to ensure that all required personnel are available	
2.5	Consider how and when the closing meeting with site is performed	
2.6	Consider how and when site tours (if applicable) will be conducted remotely (e.g. Production, Laboratory, Utilities, Warehouse). - Have you communicated your intent in advance of each assessment day to see specific areas or processes in	

	order for the manufacturer to have sufficient time to make the necessary IT and logistic arrangements?	
	- If live site walk-throughs are not possible, then consider pre-recorded videos.	
	- Consider requesting the site schematics, drawings and/or process flow diagrams for reference to facilitate orientation.	

2.7	Consider how long it will take for documents to be made available following your request.
	
	    - Are there paper-records, electronic records or a combination?
	
	    - Is there a maximum amount of time for the company to provide the documents?
	
	    - Have you communicated this to the company?	

2.8	Consider the timing of your requests to ensure the documents will be available when you require them (e.g. consider the time required for scanning).	
2.9	Consider communicating to the site the timeframe in which you expect a response or corrective actions submitted to the Agency in response to the observations identified during the closeout of the assessment?	
2.10	Consider having all inspectors co-located (where possible) to reduce the strain on infrastructure and facilitate faster exchange of information	

3. Post assessment activities for a remote assessment

The purpose of this portion of the Aide-Memoire is to outline prompts to consider after conducting a remote assessment.

Nr.	Prompts	Reference
3.1	Consider what type of document will be issued after the remote assessment (e.g. remote assessment report, list of observations, forms, official letters). − Is the remote assessment type mentioned in the document?	Para 7.1 and 7.4 and the Appendix from the Guidance document

3.2	Consider whether a GMP certificate or equivalent will be issued.
	
	    − Is the assessment type mentioned in the GMP certificate or equivalent (if applicable)?
	
	    − Does the duration of the GMP certificate validity reflect the assessment type if needed (e.g. shortened validity)?
	
	    − If no certificate is required, has there been a close out letter to indicate that the assessment is closed out.
		Para 7.4 and the Appendix from the Guidance document

3.3	Consider the actions following an unacceptable compliance outcome during a remote assessment. - Requirement for onsite inspection - Not issuing a GMP certificate - Consider the rejection of product registration application - Issuance of statement of non-compliance	
3.4	Consider the remote assessment type and outcome when planning the next inspection interval.	

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