PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 056-1
Appendix
1 January 2025

PIC/S GUIDANCE ON REMOTE ASSESSMENTS

Editor: PIC/S Secretariat

e-mail: info@picscheme.org
web site: https://www.picscheme.org

TABLE OF CONTENTS

Page

1. DOCUMENT HISTORY

Adoption by Committee of PI 056-1	15 November 2024
Entry into force of PI 056-1	1 January 2025

2. INTRODUCTION

2.1 Remote assessment including hybrid inspection are inspection processes developed during the pandemic to enable GMP inspections to continue where it has been difficult to conduct these on-site.

2.2 It has been recognised that the remote assessment and hybrid inspection will have a place in an inspector toolkit beyond the pandemic.

3. PURPOSE AND SCOPE

3.1 This guidance is intended to provide guidance on the approach and use of remote assessments including a hybrid inspection as inspection tools to establish consistency amongst Inspectorates.

3.2 This guidance will enable a common approach (including shared definitions) on remote and hybrid assessment.

3.3 Consistency in the approach and shared definitions will assist in the following:

a) Improve inter-agency communication;

b) Facilitate GMP Inspection reliance;

c) More efficient use of global inspection resources.

3.4 Areas of application:

a) Travel restrictions, e.g., pandemic situations, safety concerns

b) Re-Inspections if a manufacturer demonstrates good levels of compliance in previous inspections and when the activities of the inspected site are limited (eg agency policy)

c) Verification of certain aspects of Corrective and/or Preventative Actions

d) Rapid Assessment of GMP aspects in specific circumstances where there is an immediate need.

e) To gather information for an inspection

4. DEFINITIONS/TERMINOLOGY

There are three types of remote assessments which vary depending on the level of interaction, and one combination type, to define different levels of

interaction made during different assessments by National Competent Authorities.

In the context of this document following terms can be used interchangeably:

- firm, plant, company, manufacturer, inspected site, …
- national competent authority, regulatory authority, regulatory agency

The level of interaction distinguishes the several types of remote assessments.

4.1 Fully Interactive Remote Assessment

An evaluation or assessment of a site performed remotely or distant from the site location by National Competent Authorities, which rely on technology to facilitate live interactions during the entire assessment period. This will include video meetings, document sharing, video streaming (from the plant), and/or other live streaming interactive technology to determine compliance with GMP/GDP principles.

Other terms, which have been used or are in use by some regulatory agencies to define remote assessment, are remote inspection, virtual inspection, desktop inspection, or distant assessment.

The benchmark for activities for a fully interactive distant or remote assessment includes: *(Note: This is not an exhaustive list. See also appendix 1)*

- Fully interactive video meetings to resemble live interaction during a face-to-face inspection, including document sharing and video discussions with the inspected firm.
- Opening, daily wrap-up, and closing meetings held with the firm personnel via video meetings to discuss observations found during the interactive assessment, if necessary.
- QA documentation review to start during preparation phase.
- Location verification: SMF, layout versus online satellite maps, usage of GPS coordinates (during inspection if necessary).
- Video interviews of subject matter experts located at the firm.
- Documents may be shared via electronic means such as e-mail or another platform agreed upon. Documents and computer screens may also be screen shared during video meetings to allow first-hand observation.
- Live video streaming from the site of all manufacturing or other areas concerned by the scope of the inspection.
- If live video is not possible, video files of all manufacturing or other areas concerned by the scope of the inspection shared and discussed with regulators.

- QA documentation, manufacturing records, QC documentation review as comprehensive as during on-site inspections, ideally via document sharing tool and screen sharing; walk through (explanations) by SME, data integrity ideally via screen sharing.
- Assessment of corrective and preventative action plan.
- Issuance of a report.

4.2 Partially Interactive Remote Assessment

An evaluation or assessment of a site performed remotely from the site location with some interactive component, such as video or phone meetings and document sharing, to determine compliance with GMP/GDP principles.

Other terms, which have been used or are in use by some regulatory agencies to define this mode, include distant assessment, virtual assessment, or remote GMP evaluation.

The benchmark for activities for a partially interactive remote assessment includes: *(Note: This is not an exhaustive list. See also appendix 1)*

- Meetings are scheduled with the firm whenever needed, e.g., to facilitate the assessment and request documents such as an opening meeting, a meeting halfway through the assessment and a closing meeting.
- This assessment does not include / require a fully interactive interaction during the entire assessment period.
- Documents may be shared via e-mail, screen share, or another platform agreed upon.
- wrap-up, and closing meetings are held with firm personnel to discuss observations found during the assessment, if necessary. These are scheduled as necessary during the assessment period.
- Video or phone interviews with subject matter experts located at the plant, if necessary.
- Meetings may be held to allow interactive discussion on documents received & reviewed by regulators to allow ability to ask follow-up questions and potentially request additional documentation.
- QA documentation, manufacturing records, QC documentation review as deemed necessary.
- Issue a report.

4.3 Desktop Assessment

An evaluation or assessment of a site performed remotely from the site location by National Competent Authorities that relies upon document review only and no live interaction with the firm. This review may lead to issuance of a site compliance rating and/or determine if an on-site inspection is required.

Other terms, which have been used or are in use by some regulatory agencies to define desk top assessment, include desktop paper assessment, remote GMP evaluation, or document assessment)

The benchmark for activities for a desk top assessment includes: *(Note: This is not an exhaustive list. See also appendix 1)*

- Review is performed remotely.
- Additional information should be requested from the manufacturing site, as required (for example, information relating to inspections by other regulatory authorities in a defined period, information to assess risk factors such as recalls, rapid alerts, changes in processes/products/personnel, …).
- No meetings between firm personnel and regulators necessary.
- Issuance of an assessment report if applicable.
- The outcome of the assessment is communicated to the manufacturing site if applicable.

4.4 Hybrid Inspection

An evaluation or assessment of a site performed by Competent Authorities using a combination of on-site inspection and remote assessment.

- Combination could be one inspector who conducts both on-site and remote assessment of the site.
- Combination of inspectors on-site and inspectors (may be the same or different authorities) connecting remotely at the same time to the ongoing activities at the facility using a virtual technology.

5. Logistics for Remote Assessments (including Hybrid Inspections)

5.1 Technical requirements to consider depending on level of remote interaction.

a) Conferencing software

b) Secure shared data storage place

c) Data connections at GMP relevant facilities

d) Web cameras, such as mobile phone, head mounted devices, tablets

e) High efficiency scanner

f) Possibility of sharing the screen of computerised systems (data integrity verification)

g) Document camera

h) Audio equipment, such as speakers (where necessary)

5.2 Preparations for the remote assessment

a) Preparatory teleconference to inform the company about details of the relevant inspection approach and the necessary technical requirements and logistical arrangements.

b) Connectivity test: aimed to check whether all GMP relevant areas are well connected with the internet and can therefore be virtually inspected.

c) Upload to shared space information, such as SOPs, production data, layouts etc. Note: in case the assessment or hybrid inspection takes place in a non-English speaking country and bearing in mind that a larger number of documents needs to be translated, machine translation can be utilised, but should be indicated as such.

5.3 Conduct: depending on the level of the remote interaction

a) When deploying a full interactive or partially interactive approach during the entire time of the agreed time slot, the conduct can follow the principles deployed during on-site inspections. Potential obstacles such as different time zones or insufficient coverage in some areas should be considered.

b) Without real-time interaction, the extent of documents to be reviewed shall be thoroughly defined ahead of the remote assessment and may comprise:

- Previous inspection reports, trusted authorities included.
- Compliance information from data bases
- Core SOPs requested from the firm.
- Product related documentation
- Statistical data, e.g., number of batches etc
- Manufacturing area/equipment related information, e.g., dedicated vs multi-purpose.
- Outsourced activities

6. Feasibility Approach to Remote Assessment (including Hybrid Inspection)

6.1 Risk assessment.

a) A remote assessment may not be the first choice. Before deciding whether to carry out the remote assessment, it may be appropriate

to carry out a risk assessment to determine whether the desired scope may be achieved in the given circumstances. This would also apply to hybrid inspections.

b) Where high and/or multiple medium risk factors are identified, an assessment on whether these risks are deemed acceptable, or whether they require mitigation, could be considered.

c) Where risks are identified that are not considered acceptable (even after any potential mitigation factors have been applied), an alternative inspection approach may be considered.

An overview of some areas that could be considered are provided below:
(Note: This is a guide, in some instances, case-by-case assessment is required.)

Description	Low	Medium	High	Potential / Mitigation
Previous Inspection History (including information from any other regulators)	No significant indicators of non-compliance	Moderate indicators of non-compliance Satisfactory PQS – further assessed case-by-case	Significant indicators of non-compliance The scope was not previously inspected during routine inspection, pre-approval / focused inspection	Familiarity with the site, e.g., same inspector, contact with previous inspector
Activities carried out at site	Non-Sterile Operations Dedicated facility or specific product	Terminally sterilised Low sensitising /potent in shared facility	Aseptic operations Highly sensitising / potent in shared facility	Familiarity with the site, e.g., same inspector. Contact with previous inspector.
Length of time since last on-site inspection (years)	1-2	3-4	>4	Team inspection for longer duration inspection Onsite /hybrid inspection
Information relating to the site from any regulatory authority / source. (e.g. recalls / complaints / intelligence / whistle blower)	No / Minor issues	Moderate issues	Significant issues	

Changes since last inspection	Minor (e.g., Updated production lines small number of personnel, no adverse metrics)	Moderate (e.g., new production lines, changes in key personnel, some adverse metrics)	Significant (e.g., new building, frequent changes in key personnel, key changes to processes and release testing, numerous adverse metrics)	Onsite /hybrid inspection
Extent of scope	Single building / Small number of production lines	Several buildings / Moderate number of production lines	Multiple buildings / Considerable number of production lines	Consider team inspection for large facility On-site / hybrid inspection
Organisational culture (If known) (Note: Consider including communication and culture together)	Empowering / Learning / Knowledge Driven		Hierarchical / Authoritative / Blame culture	Consider team inspection On-site / hybrid inspection
Site communication style (if known) (Note: Consider including communication and culture together)	Open	Closed	Obstructive	Consider team inspection On-site / hybrid inspection
Internet connectivity of site	High Speed and in all areas	Moderate speed / in most areas	Poor connectivity in all areas.	Perform a dry run prior to the assessment
Internet connectivity of inspectors	High Speed	Moderate speed	Slow speed	Prior sharing of documents Communication medium consideration (E.g.: Choice of VC platform)
Time Difference (hours) (Risk for data integrity issues; inspector fatigue)	1-4	5-7	8-12	Agreed timeframe that is suitable for both inspector and manufacturer
Language barriers and difficulty in sourcing appropriate/independent translator	None	Some	Significant	Establish an inventory of reliable translators through experiences
Number of inspectors required	1	2-3	>3	On-site / hybrid inspection

7. Remote Assessments Documentation

7.1 When a report be issued, it should clearly document the inspected areas as well as the mode of the assessment or inspection i.e., on-site, remote or hybrid (including detailed information on type of remote assessment employed). If areas are not covered during the assessment or inspection, then they should also be clearly documented.

7.2 Regulatory databases (where applicable) should describe the type of remote assessment employed including hybrid inspections (if applicable).

7.3 Internal documents (where applicable) should be prepared accordingly for the assessment performed.

7.4 Should a GMP certificate (or similar documentation) be generated as an outcome of the assessment, it should clearly document whether the assessment or inspection was performed remotely, on-site or hybrid. See Appendix for examples of some standard phrases for the GMP certificate.

8. Follow-up on Remote Assessment Effectiveness

8.1 The effectiveness of Remote Assessments may be assessed (if required) during future on-site inspections.

9. Glossary

Acronym	Meaning
BMR	Batch Manufacturing Record
GPS	Global Positioning System
QA	Quality Assurance
SME	Subject Matter Expert
QC	Quality Control
SOPs	Standard Operating Procedures
GMP	Good Manufacturing Practice
GDP	Good Distribution Practice

10. REVISION HISTORY

Date	Version Number	Reasons for revision

Appendix:

1. Summary Chart to show differences between types of remote assessments
(Disclaimer: This summary chart is provided as a guidance and may not necessarily address all scenarios and may overlap.)

Benchmark	Fully Interactive Assessment	Partially Interactive Assessment	Desktop Assessment
Live video meetings throughout entire assessment	X		
Live stream plant tour	X		
Live video interviews with firm personnel	X		
Live document and/or computer screen sharing during video meetings	X		
Document sharing via email or file sharing platforms	X	X	X
Plant tour shared via video recording	(X)	X	(X)
Opening, check-in, and closing meetings held via scheduled meetings	X	X	
Interviews with personnel done via scheduled meetings		X	
Official feedback of assessment provided via live video	X		
Assessment of Corrective and Preventative Actions	X	(X)	(X)

Report Issuance/ GMP Certification / Official Closure Letter	X	(X)	(X)

(X): May apply (depending on the Agency)

2. Examples of standard phrases for the GMP certificate:

Example 1 – Eudra GMDP Database

If the outcome of the distant assessment is positive, GMP/GDP certificates should be issued. For GMP distant assessments, the Type of Inspection on the certificate should indicate Distant Assessment. If a limited on-site inspection as per paragraph 2.5. was conducted, the Type of Inspection on the certificate should reflect the on-site inspection and a clarifying remark may be included to indicate that part of the inspection was performed as a distant assessment. Existing regulatory risk management principles should be used to determine the duration of the validity of GMP/GDP certificates issued following distant assessments.

Example 2

This inspection was performed using hybrid mode and the following areas were covered remotely:

XXXXXX
XXXXXX

Example 3

This certificate relates to COVID-19 vaccine. Due to the restrictions caused by COVID-19, this certificate is based on a distant assessment of inspection data from XXX Competent Authority related to the site, and additional information provided by the manufacturer. An on-site inspection will be conducted as soon as COVID-19 restrictions will be lifted