



Procedure for audit postponement and for remote audits ⁽¹⁾

Introduction

In response to the COVID-19 pandemic and following our position paper of 24 March 2020, this document sets out a new procedure for audit postponement and the use of remote audits for those pharmaceutical excipients suppliers who are already EXCiPACT certified.

Re-certification or surveillance audits may be impossible due to the strict travel ban and safety rules in place affecting both Certification Body auditors and staff from EXCiPACT-Certified Pharmaceutical Excipient manufacturers and distributors. The procedure describes alternative options to help these suppliers to maintain or renew their EXCiPACT certification. It indicates the conditions and time-periods which are acceptable either to postpone a re-certification or surveillance audit or to replace it by a remote audit. EXCiPACT Registered Certification Bodies should prepare for its implementation in their internal procedures.

These requirements shall remain valid while the COVID-19 pandemic containment measures are in place in the affected world regions and until local regulation travel restrictions are suspended, and that physical (on-site) audits return to normal.

The procedure is published as a Supplementary Annex to the “Additional Requirements for Certification Bodies and Auditors” in the 2017 version of the “EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers”.

¹ Document reference: SOP-QM-001 v. 01, 06 April 2020



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1. Scope

This document should be followed by the EXCiPACT Registered Certification Bodies, when a scheduled audit is affected by an extraordinary circumstance such as a government-imposed travel ban, an unavoidable inability of the Excipient Supplier to be audited and other restrictions applied externally to the Excipient supplier.

This concerns the EXCiPACT GMP and GDP re-certification or surveillance audit; this procedure cannot be implemented for an initial EXCiPACT GMP and GDP Certification. In exceptional cases, Stage-1 certification audit may be performed remotely as per section 4.1.

These requirements are valid while the COVID-19 pandemic containment measures are in place in the affected world regions. It should remain valid until local regulation travel restrictions are suspended, and that physical (on-site) audits return to normal.

2. Definitions

Extraordinary event or circumstance: A circumstance beyond the control of the organisation, commonly referred to as “Force Majeure” or “act of God”. Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.

3. Responsibilities

It is the responsibility of the Certification Body to implement these requirements in its own system of procedures for communication to its team of auditors. The Certification Body shall also communicate these



requirements to their impacted Excipient Suppliers in case a certification audit cannot be performed for the above reason.

It is the responsibility of the Certification Body to inform EXCiPACT asbl at info@excipact.org the decision to either postpone or to perform a remote certification audit, before the decision is implemented.

4. Procedure: conditions for audit postponement or remote audit

4.1. Initial Certification Audit

When a new supplier of a Pharmaceutical Excipient is willing to be certified with reference to the EXCiPACT GMP and GDP Standards, the Stage 1 audit may be performed remotely. However a remote Stage 2 audit cannot be accepted to grant the certification. The Stage 2 certification audit shall be made no later than 6 months after the Stage 1 audit. If such conditions cannot be fulfilled, the best solution would be to wait until an on-site Stage 1 and Stage 2 certification audit can be made.

It is the decision of the Lead Auditor and of the Certification Body to accept a Stage 1 remote audit instead of on-site audit. Such a decision should consider the previous knowledge of the client, the scope of the certification, the size of the site, the number of products to be included in the assessment and the complexity of the production processes. The Lead Auditor should also take into consideration the probability for performing a Stage 2 on-site audit within a 6 months' time period, before performing a remote Stage 1 audit.

4.2. Surveillance Audit

- a) When a Surveillance Audit 1 (SA-1) cannot be performed within one year after the Initial Certification Audit, or when a Surveillance Audit 2 (SA-2) cannot be performed within two years after the Initial Certification Audit, the audit can be delayed for a maximum of 6 months after the initial scheduled date. The initial scheduled date must be considered as the last day of the initial certification audit plus 12 or 24 months.

Therefore, SA-1 should be conducted maximum 18 months after the initial certification audit and SA-2 should be conducted maximum 30 months after the initial certification audit date.

The normal window to perform the audit should be respected based on the revised date.

- b) If such an on-site audit is not possible for the exceptional reasons mentioned above, it may be acceptable to perform a remote audit in place of physical audit. This should be completed within the 6 month period after the initially scheduled audit date.

The Certification Body shall as a first step perform a quality risk assessment considering the conditions mentioned in section 5.2 "Preliminary Risk Assessment for allowing a remote audit". If the conclusion is that risk is low or moderate, the Certification Body can propose to the Supplier a remote audit according to the procedure described in Section 5. The remote audit will then replace the on-site audit. If the SA-1 was already performed using remote means, then the SA-2 shall be an on-site physical audit (no repetition of two successive remote surveillance audits)

- c) If the preliminary risk assessment concludes a remote audit is not acceptable, or if for any other reason a remote audit cannot be performed, then the EXCiPACT Certification shall be suspended for a maximum 6 months period and be withdrawn immediately after 6 months.
- d) In any case, the Certification Body should inform EXCiPACT asbl at info@excipact.org about the audit's postponement, remote realisation or certification suspension, before the decision is implemented.



4.3. Re-certification Audit

- a) If a re-certification audit (RCA) cannot be performed within the three year period after the Initial Certification Audit, the audit can be delayed for a maximum of 6 months after the initial scheduled date. Therefore, an RCA should be conducted no later than 42 months after the initial certification audit date. In this case, there should be an extension of the expiry date of the certificate. The information is to be communicated by the Certification Body to EXCiPACT asbl at info@excipact.org in order to be reported on the EXCiPACT website.
- b) If such on-site audit is not possible for the reasons mentioned above, it may be acceptable to perform a remote audit, in accordance with Section 5, in order to partially replace an on-site physical audit and to avoid certification suspension. It should be considered that a remote RCA does not replace an on-site audit, but it allows the Certification Body to postpone the RCA for not more than 6 additional months when there is an acceptable risk assessment concerning the Supplier Quality Management System. This remote audit should be completed within 6 months after the initially scheduled audit date.

The Certification Body shall as a first step perform a quality risk assessment considering the conditions mentioned in Section 4.2 "Preliminary Risk Assessment for allowing a remote audit". If the conclusion is that risk is low or moderate, the Certification Body can propose to the Supplier a remote audit according to the procedure described in Section 4.

The remote audit will then allow the on-site RCA to be postponed for not more than 6 months, i.e. not more than 42 months after the initial certification audit. In such an option, the remote audit must be confirmed by an on-site audit within the 6-month period after remote audit. This on-site audit duration will be shorter as documentation was already assessed during the remote audit.

- c) If the preliminary risk assessment concludes a remote audit is not acceptable, or if for any other reason a remote audit cannot be performed, then the EXCiPACT Certification shall be suspended for a maximum 6 months period and withdrawn immediately after.
- d) In any case, the Certification Body should inform EXCiPACT at info@excipact.org about the audit postponement, remote realisation or certification suspension, before the decision is implemented.

5. Procedure: Organisation of a Remote audit

A remote audit is an audit which is performed under a confidential disclosure agreement by remote tools (e.g.: phone, e-mails, Skype, WhatsApp, Zoom), with exchange of electronic documents using internet-cloud system when the size of document cannot be transferred by direct mails (e.g.: WeTransfer, Dropbox). The auditor may also be granted temporary access to the client's IT systems to observe information directly.

A remote audit is different from a questionnaire assessment as there should be a direct discussion between the auditor and the auditee, and the use of a video-conferencing system is essential.

A remote audit is also different from a simple teleconference as the auditor shall have the opportunity to read and assess written audit evidence; therefore, the use of shared screen is encouraged as well.

At the end of the remote audit, it should be considered that, as far as audited topics are concerned, the Lead Auditor shall be able to provide a recommendation about certification extension with the same degree of confidence as after a physical audit. It is agreed that remote audit does not have to include on-site visit and audit of workshops, laboratories and warehouses. A photograph and/or video of these facilities may be requested to support explanation, but it cannot replace an on-site auditor's scrutiny.



5.1. Confidentiality agreement

The realisation of a remote audit does need to exchange documents and photographs through internet-based virtual supports. Therefore, both the auditor and the auditee shall accept to share information for the purpose of the audit only.

There should be a prior commitment to keep confidential any information shared before and during the audit, and to not store and archive any photograph or document unless formally agreed by the auditee.

5.2. Preliminary Risk Assessment for allowing a remote audit

A remote audit may be used to replace a surveillance audit or to postpone an RCA when there is sufficient confidence that the EXCiPACT Certified Supplier's Quality System is in place and sufficient knowledge about past quality experience exists. Therefore, a quality risk assessment should be performed by the Certification Body, with input from EXCiPACT, before proposing a remote audit to the Excipient Supplier. EXCiPACT should be questioned concerning quality complaints received, as part of this risk assessment. The conclusion of the risk assessment should be based on Supplier's knowledge, press-release, and preliminary information provided based on a questionnaire completed by the supplier.

The risk assessment for determining whether to permit a remote audit, must be documented and referenced in the audit report.

Such risk assessment should at a minimum consider the following items:

- No change concerning the certification scope
- No change concerning the production site address and production facilities
- Significant change concerning manufacturing equipment should be specifically considered
- No significant change concerning other category of products manufactured in the same plant or using the same production equipment
- No Quality Complaint communicated to either EXCiPACT asbl or the Certification Body, concerning Supplier Quality System deficiency.
- Evaluation of all observations during the previous audit and the already provided action implementation evidence: the observation of more than two (2) major non-conformities during the previous Certification or Surveillance audit should be considered as a high-risk situation.
- Other items may be included in the risk assessment if they are material to situation

5.3. Preparation and duration of a remote audit

The success of a remote audit will depend on the possibility for both the auditor and the auditee to have direct exchange concerning the quality matters that are not limited to a review of documentation only. The use of videoconference instead of a voice-only teleconference may facilitate such exchanges. It is also very important that auditor has a direct view of a requested document and the opportunity to ask questions and to receive immediate answers during the review.

The time for connection of the attendees should be carefully managed, as well as the availability of documents in electronic format.

It shall be agreed during the audit preparation phase the communication tools to be used, their connection. The ability to exchange documents should be tested a few days before the audit.

A list of documents to be prepared should be communicated in advance, with the audit program. Additional documented evidence will be requested during the audit.



In case translation is needed between the auditor and the auditee, it is recommended that one translator is available on both sides. If this is not possible, the translator should be in the same place as the auditor rather than with the auditee.

The audit duration should be not less than the one defined for on-site physical audit, even if there is no visit of the facilities. For instance, if a surveillance audit is defined to last one day, the remote surveillance audit should last not less than 8 hours. It is recommended to organise the remote audit agenda into several sections. This will allow named auditee' employees to be present to discuss relevant concerns, and the auditor to have time to assess document on his own. The remote audit may be organised over several days, with only a few hours per day for the interview.

For example, an agenda corresponding to remote audit organisation is proposed in the Appendix.

5.4. Realisation of a remote audit

The remote audit realisation shall follow the same basic steps as a physical audit:

- Audit program (*the audit program should mention that it is a remote audit*)
- Opening meeting
- Interview of Excipient supplier teams, Question and Answer
- Review of documentation
- Daily conclusion meeting
- Audit conclusion meeting
- Audit Report issuance (*The audit report should mention it is a remote audit which was justified based on a documented risk assessment.*)
- Supplier's commitment for improvement – CAPA plan assessment
- Final auditor recommendation regarding EXCiPACT GMP and GDP Certification
- Certification Body Certification decision
- Communication of the certification conclusion to EXCiPACT

However, as there is no visit to the plant, the auditor may request specific photographs of e.g., the production area and utilities. He/She also should request to review raw data using shared screen in case of electronic data or using webcam pictures of paper documentation.

The organisation of such a remote audit should ensure when auditee representatives for each topic and each function is available, and when other members do not need to be present. Therefore, the continuous communication between the auditor and the auditee's Team Leader is crucial for adapting the agenda continuously.

5.5. Content of the remote audit: Items to be audited

The remote audit shall follow a risk-based approach, and it shall consider the key items listed in the EXCiPACT asbl GMP and GDP Standard for Pharmaceutical Excipients.

The following sections of the EXCiPACT Standard should be reviewed during the remote audit (non- exhaustive list):

a) CAPA from the previous audit

- Even if the preventive and corrective action plan was accepted as part of the initial certification, a review of action implementation and corresponding time schedule should be assessed. Evidence for implementation such as pictures and/or documents shall be requested during the audit preparation phase.



- b) List of Changes implemented since the previous audit
 - New equipment, new products, change of process, new activity within the site, change of organisation
 - For each change, an impact assessment should be available. Such change should be considered as of minor importance with regards to quality of manufactured excipient, otherwise a remote audit cannot replace on-site audit.
 - List of Change Information to customers
- c) Annual Quality Review
 - Number of batches manufactured, number of batches rejected, recalls
 - Number and list of customer complaints received since previous audit
 - Customer satisfaction assessment
 - Number and list of Deviations identified during the period, corresponding quality ranking, impact on supplied product(s)
 - Retest-date justification, stability program and change, as appropriate.
- d) Batch Record
 - At least one production and quality control batch record should have been prepared for remote assessment by the auditor. The auditor should be able to select the batch record to be audited.
 - A specific focus should be made on the testing, release and shipment process, as well as reference to the Master Batch document.
- e) Quality Control
 - Organisation of the QC, role and responsibilities
 - Audit of an analytical batch record with specific focus on raw data traceability and data integrity management
 - Number of out-of-specification results recorded since previous audit.
- f) Certification and Inspections
 - Inspections and Conclusions from Health Authorities since the last EXCiPACT audit
 - Certification (e.g.: ISO-9001, FSSC-22000, EFfCI)
- g) Documentation
 - List of SOP's, Number of SOP issued since previous audit
 - Management of analytical testing methods and product specifications
 - Issuance of Certificate of Analysis and Certificate of Compliance
- h) Self Inspection program
 - Annual program, list and duration of the audits performed, process review
 - Processes covered by the internal audit program since previous audit
- i) Suppliers' and Contractors' Management
 - New suppliers, monitoring of approved suppliers, audit of contractors, qualification evidence
 - List of approved suppliers
- j) Organisation roles and Responsibilities
 - Number of employees (changes since previous audit), percentage of temporary employees
 - Organisation chart and corresponding job descriptions
- k) Personnel Qualification
 - GMP / GDP training program and realisation
 - Reference to EXCiPACT standards



- Example of training program traceability
- Management of consultants and temporary employees, if any

l) Utilities (*Risk assessments may be asked in advance as part of the audit program*)

- Environmental monitoring program and results of the controlled-environment production areas
- Purified water sampling plan and results, trending studies
- Cleaning and sanitation procedures and corresponding evidence
- Compressed gas control, if any
- Pest control program and report, if identified as at risk considering the processes

6. APPENDIX: Example of Remote Audit Agenda

Day	Time	Participant	Topic to be audited	Technical tool
D-1	08:30	All	Opening Meeting – roundtable, test of connection, scope – objectives	Videoconference
	09:15	concerned managers	Discussion of CAPA from previous audit (based on document provided prior the audit)	Videoconference
	10:00	Break		Tool change
	10:15	Team 1 (e.g.: HR + QA)	Topic 1 (e.g.: Training & personal qualification)	webcam & shared screen
	10:45	Team 2	Topic 2	webcam & shared screen
	11:10	Team 3	Topic 3	webcam & shared screen
	11:30	Auditee Team Leader	Request for additional documentation	e-Mail, Cloud transfer
	11:45	Break		Tool change
	12:00 12:30	Auditee's team	Preliminary feedback after Day 1, documents to be prepared for Day 2	Videoconference
	D-1 Afternoon	Auditor only	Review documentation, request for additional evidence, communication to the auditee's team leader	Mail, phone, office work

D-2	08:30	Auditee's team	Day-2 introduction meeting Feedback of the 1 st day, Program of the 2 nd day Availability of Company representatives	webcam & shared screen
	09:00	Team 4	Topic 4	webcam & shared screen
	09:20	Team 5	Topic 5	webcam & shared screen
	09:40	Team 6	Topic 6	webcam & shared screen
	10:00	Auditee's team	Auditor ask for documents, photographs, other evidence	webcam & shared screen
	10:05	Break		



	10:20	Ad-hoc team	Last item(s) to be audited, last questions about provided documentation	webcam & shared screen
	11:15	Auditor time		Room / Tool change
	11:45	All	Audit Conclusion meeting List of non-conformities and observations	Videoconference
	12:30	End of the audit		