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Purpose and Objectives

An on-site EXCiPACT re-certification audit (RCA) or surveillance audit (SA) may be impossible considering some very exceptional situations such as the case that countries face with regards to the COVID-19 pandemic crisis. The safety of people that conduct audits is top priority as determined by governmental regulations, industry, and Certification Body's own policies. The strict travel restrictions and the unavailability of excipient manufacturers and distributors to operate with full manpower on-site have consequences regarding the EXCiPACT Certification Scheme.

Therefore, in April 2020, EXCiPACT asbl issued a Procedure defining conditions for when an on-site audit may be replaced by a remote audit. With experience and review of the effectiveness of remote audits, it is considered possible to extend the case when a remote audit is acceptable.

The goal of this Procedure is to describe alternative options to maintain or to renew the Certification of Pharmaceutical Excipient manufacturers and distributors. It indicates the conditions and time-periods which are acceptable to postpone an RCA or SA or to replace it with a remote audit. The decision to postpone an audit, or to replace an on-site audit by a remote audit, must be consistent with the ISO 9001 certification audit practices.

It is to be communicated to each EXCiPACT Registered Certification Body for implementation in their internal procedures.

Initial (Stage 2) EXCiPACT Certification audits (i.e., those required for a first certificate) and recertification audits (i.e. those required for a renewal of the certificate) are out of scope of this document.

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Supporting documents

- EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers 2021
- EXCiPACT Position Paper: Excipient manufacturer and distributor certification with regards to the COVID-19 outbreak (24 March 2020)
- IAF ID3 2011 Guidance: International Accreditation Forum (IAF) Informative Document for Management of Extraordinary Events or Circumstances Affecting Accreditation Bodies, Certifying [Assessment] Bodies and Certified Organisations

Summary of Changes

a) Version 1 issued on 03 April 2020:
  - Initial procedure
b) Version 2 issued on 04 December 2020:
  - Introduce the possibility of hybrid-remote audit
  - Allowance of remote RCA based on risk assessment
  - Allowance of successive SA-1 and SA-2 remote audits
  - Addition of a summary table in section 4
c) Version 3 issued on 24 Jan. 2022:
  - Extension of version 2 for one additional year, without change in the requirements.
d) Version 4 issued on 31 Jan. 2023
  - Extension of version 3 with a three-years revision period
  - Clarification concerning performing Stage-1 Certification audits

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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 RCA or SA; this procedure cannot be implemented for an initial EXCiPACT Certification. However, Stage 1 certification audit may not always be possible for logistical, auditor availability and other reasons and may be performed based on a documented justification, as per section 4.1.

These requirements are valid for Stage 1 audits and where the COVID-19 pandemic containment measures or any travel forbiddances are in place in the affected world regions.

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.

On-site certification audit: audit performed according to the complete definition of the EXCiPACT Annex to ISO-17021, including an assessment of the quality system by a team of auditors visiting the Excipient supplier.

Remote certification audit: audit performed in compliance with the EXCiPACT Certification scheme when audit team presence on-site is replaced by exchange of information through videoconference and teleconference interview of the Supplier's Subject Matter Experts. It should be noted that a remote audit must include direct exchanges between auditors and auditee and is significantly different from a review of questionnaire and documentation provided by the auditee.

Hybrid Certification audit: an audit performed in compliance with the EXCiPACT Certification scheme when the on-site audit is limited to one part of the audit programme only and is completed by an assessment of the quality system and quality documentation through a remote session.

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 or a hybrid certification audit before the decision is implemented.

Note: EXCPACT does not need to be notified if the Certification Body decides to conduct a remote Stage 1 audit.

4. Procedure: Conditions for Postponement or Remote Audit

4.1 Initial Certification Audit

Certification audit is performed in two stages: Stage 1 (S1) aims to verify the scope of Certification and to determine the audit duration necessary for Stage-2 (S2) Certification. The purpose of the S2 audit is to evaluate the implementation and effectiveness of the management system.

Stage 1 audit:

When a new supplier of a Pharmaceutical Excipient is willing to be certified with reference to the EXCiPACT Standards, the Stage-1 audit may be performed on-site or remotely based on a documented justification, as indicated below.

It is the decision of the Lead Auditor, the Certification Body and the Client to accept a S1 remote audit instead of an 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.

EXCiPACT asbl preference is to have an on-site audit at clients seeking EXCiPACT Certification for the first time but it is recognised that this may not always be possible for logistical, auditor availability and other reasons. In many cases a remote Stage 1 audit some time before the actual Stage 2 audit will be preferable than performing the Stage 1 on one day and commencing the Stage 2 on the following day, which can happen in cases where extensive auditor travel is required to get to the client site.

Certification Bodies may perform remote Stage 1 audits at new clients seeking EXCiPACT Certification where:

a) both the Certification Body and the client agree to the arrangement, and there is a sufficient capability to conduct the audit remotely

b) a video tour or slide show of the manufacturing facility is available to judge the visual aspects of GMP implementation

    c) the content and duration of the Stage 1 audit is the same as or longer than an on-site audit (including for example an evaluation of competencies, quality performance as well as quality system preparedness), such that the Stage 2 audit preparations are not compromised

    d) the Certification Body documents a risk assessment which concludes the identified risks to the reputation of the EXCiPACT Certification scheme can be managed such that the Stage 2 audit quality is the same as that which would be done with an on-site Stage 1 audit. The risk assessment shall be approved, and any identified actions shall be implemented before implementation of the remote audit.

All four conditions need to be met before the remote Stage 1 audit can proceed remotely.

Stage 2 audit:

The Stage 2 audit shall take place at the site(s) of the client. A remote Stage 2 (S2) initial certification audit cannot be accepted. It may be acceptable to perform a hybrid audit to limit as far as possible on-site contact and duration of auditor's presence in the facilities, if:

- The full scope of the audit is covered
- All concerned workshops, storage and laboratories can be audited
- Supplier's Subject Matter Experts and operational employees are present during the audit and available for answering the auditor's questions
- The on-site part of the audit is made no later than three months before or after the remote assessment of the quality system
- The on-site part of the audit represents approximately the same duration as the remote part, unless justified and documented in the audit report

The Stage-2 certification audit shall be completed 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 S1 and S2 certification audit can be made. The Lead Auditor should also take into consideration the probability for performing a S2 on-site audit within a 6 months' period, before performing a remote S1 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.

    The replacement of an on-site SA by a hybrid on-site/remote audit is considered as equivalent to a full on-site audit, based on auditor justification and responsibility, and a risk assessment to support such decision is optional. The on-site part of the audit represents approximately the same duration as the remote part, unless justified and documented in the audit report.

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 the 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.

c) If the preliminary risk assessment concludes that high risk is associated with a remote audit, and then a remote audit is not acceptable, or if for any other reason a hybrid or a remote audit cannot be performed, then the EXCiPACT Certification shall be suspended for a maximum 6-month 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   Recertification Audit (RCA)

a) If an RCA cannot be performed within the three-years 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.

Therefore, it is recommended to organise a hybrid RCA allowing to restrict as much as possible the presence of auditors on site and physical meetings as well. The replacement of an on-site RCA by a hybrid on-site/remote audit is considered as equivalent to a full on-site audit only when there is no change of the scope and list of products to be audited, no significant change of the facilities and processes compared to the initial certification audit and based on auditor justification and responsibility.

The on-site part of the audit should represent approximately the same duration as the remote part, unless justified and documented in the audit report.

A remote RCA may replace an on-site RCA if it is supported by a documented risk assessment prepared based on information provided by the Supplier and approved by the Certification Body. The Certification Body shall approve the 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 agree with the Supplier to perform a remote RCA according to the procedure described in Section 4.

c) If the RCA is conducted remotely, the following Surveillance audit 1 (SA-1) will need to be an on-site or a hybrid audit.

d) 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-month period and withdrawn immediately thereafter.

4.4   Information to be supplied to EXCiPACT asbl

The Certification Body should inform EXCiPACT at info@excipact.org about the audit postponement, remote realisation, or certification suspension, before the decision is implemented, other than for remote S1 audits.

4.5   Summary concerning possibility to perform remote or hybrid

Audit Step / Possibility of remote or hybrid audit	Initial Certification Stage 1	Initial Certification Stage 2	Surveillance Audit 1	Surveillance Audit 2	Recertification
On-site audit	Recommended	Mandatory	Recommended	Recommended	Recommended
Hybrid Certification audit	N/A	Acceptable	Acceptable	Acceptable	Acceptable based on a documented risk analysis
Remote Certification audit	Acceptable	Not acceptable	To be accepted based on a documented risk analysis. Not acceptable if the previous RCA was a remote audit	To be accepted based on a documented risk analysis	May be acceptable based on a documented risk analysis. Not accepted if change of the scope and/or the facilities

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-mail, Skype, WhatsApp, Zoom), with exchange of electronic documents using internet-cloud systems 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 significantly different from a questionnaire assessment as there should be a direct discussion between the auditor and the auditee, and the use of a videoconferencing 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 recommended as well.

At the end of the remote audit, it should be considered that, as far as audited topics are concerned, the Lead Auditor is able to provide a recommendation about the certification, its extension or the certification renewal with the same degree of confidence as after a physical, on-site audit.

It is agreed that a remote audit does not have to include an 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 SA 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 the 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, as 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 SA 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 especially important that the 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. 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 programme. 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 SA is defined to last one day, the remote SA 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 her/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 Appendix 1.

5.4   Realisation of a remote audit

The remote audit realisation shall follow the same basic steps as a physical audit:
- Audit programme (*the audit programme 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/or 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 are 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 Standards for Pharmaceutical Excipients.

The following sections of the EXCiPACT Standard should be reviewed during the remote audit (non- exhaustive list), considering these items must be covered as a minimum, in one of the two SAs as well as during the RCA:

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 the 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
- Information of changes to customers.

c) <u>Annual Quality Review (as included in the Site Management Review):</u>
- Number of batches manufactured, corresponding yield, number of batches rejected, recalls
- Assessment of customer complaints received since the previous audit
- Customer satisfaction assessment
- Assessment of the Quality Deviations identified during the period, corresponding quality ranking, impact on supplied product(s)
- Retest-date justification, stability program and change, as appropriate.

d) <u>Batch Record:</u>
- 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) <u>Management of 'non-conform products", batch recalls, batch rejected</u>

f) <u>Customer complaints management</u>

g) <u>Quality Control:</u>
- 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

h) <u>Certification and Inspections</u>
- Inspections and Conclusions from Health Authorities since the last EXCiPACT audit
- Certification (e.g., ISO 9001, FSSC 22000, EFfCI).

i) <u>Documentation:</u>
- 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.

j) <u>Self-Inspection programme:</u>
Annual programme, process review, list of the audits performed, completion and corresponding action assessment, processes covered by the internal audit programme since the previous audit.

k) <u>Suppliers' and Contractors' Management</u>
- New suppliers, monitoring of approved suppliers
- Audit of contractors, qualification evidence
- List of approved suppliers.

l) <u>Organisation roles and Responsibilities</u>
- Number of employees (changes since previous audit), percentage of temporary employees
- Organisation chart and corresponding job descriptions.

m) <u>Personnel Qualification</u>
- GMP / GDP training programme and realisation
- Reference to EXCiPACT standards
- Example of training program traceability
- Management of consultants and temporary employees if any.

n) <u>Utilities</u> (*Risk assessments may be requested in advance as part of the audit programme*)
- 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

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- Compressed gas control if any
- Pest control program and report, if identified as at risk considering the processes.

5.6   Remote and Hybrid Audit Report

- The audit report must mention if this was an on-site, a hybrid or a remote audit
- In case of a hybrid audit, the sections assessed remotely must be identified in the report, as well as the facilities which were audited through auditor on-site visit
- In case of a hybrid audit, if the duration of the on-site part is not equivalent to the remote part, this should be documented and justified in the audit report

6.   APPENDIX 1: 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 to 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 1st day, Programme of 2nd 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	Auditors 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		

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Final Audit Report   2023-01-30

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