IMPLEMENTATION DATE	*15 Jan. 2025*
PERIODIC REVIEW DATE	14 Jan. 2028
DOCUMENT OWNER	EXCiPACT Quality Manager

	NAME / POSITION	SIGNATURE / DATE
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PURPOSE AND OBJECTIVES

This procedure describes the requirements for registration, extension of registration period or suspension and withdrawn status of the auditors involved in the excipient certification process

SUPPORTING DOCUMENTS

EXCiPACT QUALITY MANUAL (current version)

EXCiPACT CERTIFICATION STANDARD FOR PHARMACEUTICAL EXCIPIENT SUPPLIERS: Requirement for auditor competency and third-Party organisation providing certification of management system (Final Draft version 2025)

SUMMARY OF CHANGES

- Version v.01 implemented on 01 October 2021: Initial version of the procedure
- Version v.02 implemented on January 15, 2025:
  Revision of the procedure after a three years period.
  Only minor changes have been included to reflect the update of the new EXCiPACT Standard available as final draft since December 18, 2024, intended to be issued during the first quarter of 2025

Contents

1. INTRODUCTION

This document provides new applicants and existing EXCiPACT Registered Auditors (ERA) with information and instructions to enable them to achieve and to maintain their registration within the EXCiPACT Certification Scheme (hereafter the Scheme).

The Scheme was designed to offer Suppliers of Pharmaceutical grade excipients the opportunity to be certified to either the EXCiPACT Good Manufacturing Practice (GMP) Standard, EXCiPACT Good Warehousing Practices (GWP) Standard and/or the EXCiPACT Good Distribution Practice (GDP) Standard. Extensions to these basic standards have been prepared but with the same ERA requirements (e.g., Good Warehousing Practices).

Suppliers of excipients are defined as "Organisation's manufacturing, processing, storage, supplying or distributing excipients for use in the manufacture of pharmaceutical drug products".

The Scheme ensures:

- the Supplier is ISO 9001 Certified,
- the Supplier contracts with an EXCiPACT Registered Certification Body (ERCB) who employs an ERA to undertake the EXCiPACT GMP and or GDP certification audit,
- ERA competency in applying the requirements of the EXCiPACT GMP and GDP standards and the Scheme itself.

Suppliers and their customers should then be confident that the certification audit is conducted by a competent individual within an accredited Certification Scheme.

Auditor registration within the Scheme is available, without restriction, to all individuals worldwide who satisfy the ERA competency requirements. They may be directly employed or contracted on a case-by-case basis, by an ERCB. The list of ERCBs and ERAs is available on the EXCiPACT website at https://www.excipact.org.

The Scheme has one type of ERA (i.e.: there is no registration process difference between auditors participating to manufacturing or to distribution certification process).

2. REQUIREMENTS FOR REGISTRATION

To become an ERA, auditors should complete the application process step-by-step as follows:

1. Auditor should read this entire document and the EXCiPACT Auditor Competency requirements stated in the "Annex to ISO/IEC 17021-1:2015 for Certification Bodies to ensure they can meet the compulsory requirements. More specifically, applicant shall read and understand the include Annex A "Required knowledge and skills".
2. Auditor selects an ERCB that accepts them as a prospective ERA.
3. Auditor attends an EXCiPACT two-day Auditor Training Course and achieves an end-of-course examination 70% pass mark.
4. Auditor completes the Application Form for Auditor Registration for submission to EXCiPACT via their ERCB.
5. Provisional Auditor status: EXCiPACT Quality Manager confirms the Auditor has met their provisional requirements but to qualify as an ERA he/she must successfully complete a witnessed audit. At this point the applicant for ERA has "provisional" status which allows them to conduct an audit whilst being witnessed.

6. ERCB and EXCiPACT Senior Advisor Operations decide whether an EXCiPACT assessor or an ERA employed by their ERCB shall witness the audit.
7. Auditor undertakes an EXCiPACT witnessed audit via their ERCB.
8. The witnessing party submits to EXCiPACT a report of the Auditor's audit performance versus requirements.
9. EXCiPACT Registered Auditor status: EXCiPACT Quality Manager approves the report and confirms to the Auditor via the ERCB achievement of ERA status for a 3-year period.
10. EXCiPACT adds their name to the ERA list at https://www.excipact.org/auditors.html.
11. Three months before the expiry of their existing ERA registration period, the auditor applies to renew their registration by submission of a completed Application Form for Auditor Registration via the ERCB to EXCiPACT for approval.
12. EXCiPACT Pending Renewal status: the 3-year registration period is expired and the auditor did not renew the registration, for different reasons such as long absence, no audit performed during previous years, etc. Therefore, the previous certification audits performed when the auditor was duly registered are valid, but the auditor cannot lead new audit without following the re-registration process. The remediation of this situation is to be approved by the Quality Manager.

More detail on each of these registration and registration-renewal steps is given below along with other relevant information.

At Step 4 above, EXCiPACT will evaluate applications based on the demonstration of the additional GMP and/or GDP competencies required for effective audits of quality management systems in the pharmaceutical excipient supplier industry. These competencies can be demonstrated through a combination of education, work experience, auditor training, audit experience evidenced by submitting a CV, course certificates and audit logs.

Certification as an ISO 9001 Auditor meets the basic auditing requirements but importantly additional knowledge of pharmaceutical excipient GMP and/or GDP are also required.

The term GMP (Good Manufacturing Practice) is used in this document. Auditors need to be aware that the term cGMP (current Good Manufacturing Practice) may also be used by regulators and industry. The auditor must make sure that, in each context, they know exactly what is meant by the term being used and the GMPs to be applied.

EXCiPACT Certification Scheme Auditing Competencies

To become an ERA, the following requirements are compulsory, and evidence of attainment must be provided with the application:

General

- The application of the fundamental competencies during pharmaceutical excipient supplier audits in relation to the EXCiPACT GMP, GDP and GWP standards, and any supplements that may be issued by EXCiPACT from time to time,
- The understanding and application of GMP and or GDP principles applicable to the excipient supplier,
- The understanding of the importance of managing hazards and risks associated with supplying the pharmaceutical industry.

Education & Work Experience

- Auditors should have a tertiary education in a scientific discipline,
- Auditors should have at least 5 years of general auditing and work experience in the pharmaceutical or excipient supplier industry for GMP auditors or 3 years for GDP auditors. If auditors wish to perform both GMP and GDP audits, then the requirement is 5 years. Where a tertiary education has not been attained then a substantial (>10 years) experience in relevant fields can be considered.

Auditor Training

- Attendance at an EXCiPACT two-day auditor training course and attainment of a 70% pass mark in the end of course exam,
- This training should be completed within the 3-year period immediately prior to application to become an ERA. Training completed prior to this period may be accepted if evidence is provided of recent, relevant work experience, and currency of auditing skills.

General Guidance on Acceptance of Audits

- An Applicant's audits must be in accordance with EXCiPACT conformity assessment requirements. Any deviation should be justified in the application. EXCiPACT must be able to verify all audit experience submitted in audit logs and to ensure that detailed information of the audits performed is included in applications and provides sufficient contact details for verification purposes,
- EXCiPACT is only able to accept audits that have been performed on excipient suppliers to the pharmaceutical industry and which must be verifiable as to the nature of business of the audited organisations.

Provisional audit and Witnessed Audit

An auditor shall be required to undergo at least one full certification (Stage 1 and Stage 2) EXCiPACT Audit whilst being witnessed by either an EXCiPACT designated person (assessor) or by the ERCB's designated representative (assessor) who meets EXCiPACT requirements for Registered auditors. Successful registration requires the witness to indicate that the audit was conducted in accordance with EXCiPACT Standards and Scheme requirements. Only following a successful witnessed audit will the auditor be registered and then added to the register on the EXCiPACT Website. It is in the interest of the Auditor, Certification Body and Auditee to ensure that witnessed audits are conducted soon after successful application as an EXCiPACT Provisional Auditor.

If an auditor fails to be approved at the witnessed audit, then:

- The ERCB must arrange (and pay for) another ERA to perform the audit again,
- No certificate can be issued following a failed audit.

The reasons for the failure by the auditor to conduct the audit to EXCiPACT standards will be reported by the Assessor to the ERCB and EXCiPACT and from these a program of additional and/or remediation actions would be developed to allow the auditor to correct their performance.

Evidence that these actions had been successfully completed would need to be provided to EXCiPACT before the auditor could be scheduled for another audit, at which they would have to be witnessed again by an EXCiPACT-approved witness assessor.

3. REQUIREMENTS FOR RENEWAL OF REGISTRATION

The process for renewal of registration is every 3 years in accordance with this document.

Each ERA shall be reminded minimum 3 months before their expiry date by the Secretariat to submit objective evidence as required in the "Auditor Registration Scheme" document. The Secretariat will check that the information submitted is complete against the document's requirements and remedy any deficiencies with the applicant. Once the information is completed, the application will be sent to the Quality Manager for review and decision of the applicant's continued registration.

Upon successful reregistration, the Auditor shall be sent an updated Certificate of Registration by the Secretariat.

If the reregistration is refused, the applicant will be sent a letter of explanation which will also detail how the situation may be remedied.

In all cases the Secretariat will update the applicants' status on the Register and on the website.

Before the end of the three-years validity period, the auditor shall submit to EXCiPACT a renewal application with corresponding requirement evidence.

The requirements for the Scheme are:

- **Continuing Professional Development (CPD) (See Appendix I):**
  - At least 10 hours of appropriate CPD audit experience relating to GMP or GDP requirements for the excipient supplier industry. The 10 hours CPD may be structured, semi-structured or unstructured,
  - EXCiPACT does provide free-of-charge ERA training sessions to introduce contemporary topics and developments to the Scheme from time to time. Where indicated by EXCiPACT attendance at these sessions will be mandatory and will count towards the CDP. EXCiPACT will issue certificates to indicate the CPD credits earned by the session.
- **Audit Experience**

  Copies of the audit log sheets over the last three years, or equivalent evidence must be supplied to EXCiPACT. These audits should be of the pharmaceutical starting material supplier industry.
- **Declaration of Complaints**

  It is an EXCiPACT requirement that any complaint made against an auditor's professional conduct and standards must be notified by email to info@excipact.org. This will initiate a formal review and investigation of the nature of the complaint.

  EXCiPACT findings of the investigation will be final with no option to appeal.

  Failure to disclose any complaint made against the auditor will result in the withdrawal of the Certificate of Registration for a period of 12 months after which the auditor will have to re-apply as a new EXCiPACT auditor.
- **Compliance with the Code of Conduct**

  Acceptance as an ERA is conditional on the Code of Conduct (see Appendix III) being respected and followed.
- **Demonstration of Current Knowledge**

  Evidence of appropriate knowledge that auditors are up-to-date with new and revised standards as they arise.

4. SUSPENSION OR WITHDRAW OF THE AUDITOR REGISTRATION

During the validity period of the EXCiPACT auditor registration, the EXCiPACT Association or the ERCB may decide to suspend the registration for a defined period of time or to withdraw the auditor registration.

Suspension or withdrawal of the registration must be the conclusion of an assessment involving both the ERCB management and EXCiPACT Management Body, represented by the Quality Manager. It must be justified and documented. This assessment should consider the root cause of the suspension or withdrawal, and the potential impact on already delivered audit report by the Auditor.

The auditor is informed of such decision by the ERCB

- In case of registration suspension, the duration should be agreed and should not exceed 6 months. The registration is granted back by the EXCiPACT Quality Manager based on appropriate documentation provided by the ERCB. During the suspension period, auditor is not allowed to perform any audit activity on behalf of EXCiPACT. The name of the auditor is maintained on the auditor list on EXCiPACT web page.
- In case of registration withdrawal, the auditor is no longer allowed to perform any EXCiPACT audit activity. The name of the auditor is removed from the EXCiPACT website as soon as the decision is effective. A new registration will require the auditor to satisfy the full new auditor registration scheme as described in section 2.

5. OTHER INFORMATION

The Registration Period

An auditor's Certificate of Registration as an EXCiPACT Auditor will be issued initially for a period of 3 years as evidence of EXCiPACT auditor Registration.

The following link shows details of all Registered EXCiPACT Auditors:

https://www.excipact.org/auditors.html

The name of registered auditors, provisional auditors and pending renewal auditors are listed in the EXCiPACT Auditors web page.

The 3-year Registration Period commences the month in which the Certificate of Registration was awarded after which EXCiPACT requires that the auditor applies for re-registration in good time. The Secretariat will issue a reminder to all ERAs 3-months prior to the expiration of their registration.

Appeals and Complaints

An auditor has the right of appeal relating to any registration decision made by EXCiPACT by contacting info@excipact.org.

Registration suspension or withdrawal: EXCiPACT has the right to suspend or withdraw registration if the auditor:

- Fails to maintain the registration criteria of the scheme,
- Breaches the Code of Conduct.

Confidentiality

Although all information submitted to EXCiPACT as part of the registration process is considered as strictly confidential, EXCiPACT reserves the right to publish with discretion certain auditor details on its website for mutually beneficial purposes.

If requested, EXCiPACT also reserves the right to disclose details of your certification record to other auditor Certification Bodies and/or Accreditation Bodies. EXCiPACT will do so with discretion and only in instances where we consider withholding this information will compromise the integrity of certification, e.g., where EXCiPACT has acted against (i.e., suspended or withdrawn) an auditor's registration.

Legal Status

All EXCiPACT activities are governed by Belgium Law and thus subject to the exclusive jurisdiction of the Belgium Courts.

6. FEES

Under current rules there are no fees associated with the registration of auditors.

7. REFRESHER TRAINING

If a provisional EXCiPACT auditor has not performed his/her witnessed audit (first EXCiPACT audit) within a period of three years, then that individual should re-apply for registration. The new application will be considered based on the information provided but the recommendation would be to conduct a telephone interview by an EXCiPACT designated person to establish current knowledge and ongoing understanding i.e., that the knowledge has been retained.

For auditors undertaking a minimum of two audits a year, the triennial re-registration application would require the submission of evidence of three years CPD (to maintain and develop).

Refresher training may be required as part of a remediation plan resulting from a justified complaint received about an ERA.

Any update to the EXCiPACT standards will initiate the formal publication of those changes. They will be used as the basis for a webinar-based training for all ERAs. If an individual auditor does not attend one of the published webinars, then (s)he should not perform another audit until their knowledge has been updated, unless otherwise approved by the EXCiPACT Quality Manager. Such exception must be documented. Other Certification Body staff involved with the management of the scheme (e.g., certification managers) should also attend such webinars.

8. APPENDIX I: GUIDANCE ON CONTINUOUS PROFESSIONAL DEVELOPMENT (CPD)

EXCiPACT supports CPD as a means of adding to an auditor's knowledge and experience by keeping up-to-date with the latest developments.

For renewal of a Certificate of Registration, the auditor must demonstrate a minimum of 10 hours CPD over their three-year EXCiPACT Auditor Registration period that are related to pharmaceutical excipient auditing (GMP and or GDP) and Quality Management Systems.

EXCiPACT does not provide a template for recording CPD and it will be the auditor's responsibility to provide evidence of acceptable CPD to become registered for an additional 3 years. Evidence must be presented in a format that is clear, unambiguous and in date order showing the type of CPD, course and training title and date undertaken.

9. APPENDIX II: DEFINITIONS

- Audit
  A systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively against agreed standards to determine the extent to which audit criteria are fulfilled.
- Auditee
  The organisation being audited.
- Audit Client
  The person or organisation requesting an audit.
- First Party Audit
  An audit performed within an organisation by that organisation's own auditing resource. Also referred to as an internal audit.
- Second Party Audit
  An audit of contractors/suppliers undertaken by, or on behalf of, a purchasing organisation. This may include the audit of companies or divisions supplying goods or services to others within the same group. Also referred to as a supplier audit.
- Third Party Audit
  An audit of an organisation performed by a body that is independent of the organisation being audited, e.g., Certification Body or Registrar.

10. APPENDIX III: CODE OF CONDUCT

It is a condition of registration that an auditor agrees to act in accordance with EXCiPACT Code of Conduct, as shown below.

1. To always act in a professional and unbiased way when planning and conducting audits either alone or part of an audit team.
2. To declare any conflict of interest such as a relationship with the auditee or their company to either yourself (the auditor) or your Certification Body.
3. Not to accept any inducement, gifts or favour from the company being audited or anybody with an interest in the company apart from in-house meals and refreshment.
4. Do not disclose any audit findings to a third-party or any confidential company information disclosed as part of the audit process.
5. Not to act in a prejudicial way to the detriment, interest or credibility of your employer, the company being audited or EXCiPACT.
6. To cooperate fully in any formal investigation because of an alleged breach of this code.
7. Where an EXCiPACT auditor has concerns that the company being audited is not compliant with the Code of Ethics, then they should notify EXCiPACT without delay.

11. APPENDIX IV: EXCiPACT AUDITOR STATUS

Auditor Status	Description	Role
Applicant	Provides the EXCiPACT asbl with CV, qualification and education evidence, list of audits performed in the Chemistry and/or Health domains. ISO-9001 qualified auditor Attend the EXCiPACT – 2 days auditor training	
Provisional Auditor	Above condition + successfully passed the 2 days auditor training course exam	Able to perform EXCiPACT Certification audit under the witness and supervision of an EXCiPACT Registered Auditor
EXCiPACT Registered Auditor (ERA) *3 years validity of the ERA status*	Above conditions + was assessed successfully as Pharmaceutical Excipient auditor during witness audit. Complete qualification package assessed and approved by the EXCiPACT Quality Manager	Authorised for performing certification audit of Pharmaceutical Excipients Listed in the ERA list on EXCiPACT web pages.
Pending Renewal	Auditor previously registered as EXCiPACT ERA, when her/his registered status is expired, waiting to pass the re-registration status	Previous audit performed are still valid but no new audit can be made without the witness of an ERA and with the assessment of application file and approval by the EXCiPACT Quality Manager
Re-Registration of ERA	Provide EXCiPACT asbl with updated list of audits performed, list of trainings, updated CV Has been assessed through a witness audit by an ERA	Registration date extended for a three-years period on EXCiPACT webpages.

20241227_Excipact SOP-QM-004 v02_Auditor Registration Scheme

Final Audit Report 2025-04-24

Created:	2025-04-24
By:	Chimene Bosele (chimene.bosele@ipec-europe.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAqOkDikRmXpwUdxlwFyfdvxidpTJMKl9-

"20241227_Excipact SOP-QM-004 v02_Auditor Registration Scheme" History

Document created by Chimene Bosele (chimene.bosele@ipec-europe.org)
2025-04-24 - 1:24:53 PM GMT

Document emailed to Alain Bécart (qm@excipact.org) for signature
2025-04-24 - 1:24:57 PM GMT

Document emailed to Iain moore (operations@excipact.org) for signature
2025-04-24 - 1:24:57 PM GMT

Email viewed by Alain Bécart (qm@excipact.org)
2025-04-24 - 4:25:52 PM GMT

Document e-signed by Alain Bécart (qm@excipact.org)
Signature Date: 2025-04-24 - 4:27:35 PM GMT - Time Source: server

Email viewed by Iain moore (operations@excipact.org)
2025-04-24 - 5:07:52 PM GMT

Document e-signed by Iain moore (operations@excipact.org)
Signature Date: 2025-04-24 - 5:08:10 PM GMT - Time Source: server

Agreement completed.
2025-04-24 - 5:08:10 PM GMT