EXCiPACT asbl

Auditor Registration Scheme

EXCiPACT Auditor Registration Scheme

INTRODUCTION

Background

Suppliers of Pharmaceutical grade excipients may choose to be certified to the EXCiPACT Good Manufacturing Practice (GMP) and or Good Distribution Practice (GDP) standards concurrently with an ISO 9001 assessment. Certification follows a successful audit by an auditor meeting the EXCiPACT Auditor Competency requirements and who is employed by a Registered EXCiPACT Certification Body.

Suppliers of excipients are defined as.

- Organisations manufacturing, processing, supplying or distributing excipients for use in the manufacture of pharmaceutical drug products.

Auditors assessing suppliers to the EXCiPACT GMP and GDP standards with the intent of their Certification Body of issuing a Certification to the supplier must be registered by EXCiPACT asbl (hereinafter referred to as EXCiPACT). This registration assures that auditors are competent in applying the requirements of the EXCiPACT GMP and GDP standards and the Certification Scheme itself. Suppliers and their customers may then be confident that they are being audited by a competent individual.

Registration within the EXCiPACT Certification Scheme is available, without restriction, to all individuals worldwide who satisfy the EXCiPACT Auditor Competency requirements. They may be directly employed, or contracted on a case by case basis, by a Registered EXCiPACT Certification Body. The list of EXCiPACT Registered auditors is available on the EXCiPACT website at http://www.excipact.org/auditors.html

Note: training organisations are approved by EXCiPACT to carry out training of EXCiPACT Auditors.

Who is it for?

The EXCiPACT Auditor Registration Scheme is intended for:

- ISO 9001 certified lead auditors who audit suppliers of pharmaceutical excipients.

The Purpose of this document

This document provides new applicants and existing EXCiPACT registered auditors with information and instructions to enable them to become and maintain EXCiPACT Registration.

1. REGISTRATION GRADES

The EXCiPACT Certification Scheme has one grade of auditor registration -

EXCiPACT Auditor

2. REQUIREMENTS FOR PROVISIONAL REGISTRATION

To be eligible for EXCiPACT Scheme registration, applicants should meet the requirements stated in the EXCiPACT Auditor Competency annex to ISO 17021-1:2015. Certification as an ISO 9001 Auditor meets the basic auditing requirements but additional knowledge of excipient GMP and or GDP are also required.

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

Note: 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 a given 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 EXCiPACT Registered Auditor, 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 and or GDP standards.
- 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 and 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 (more than 10 years) experience in relevant fields can be considered.

Auditor Training

- Attendance at an EXCiPACT approved two-day training course and attainment of a pass in the end of course exam (For details please contact info@excipact.org)
- This training should be completed within the 3-year period immediately prior to application to undertake EXCiPACT Certification audits. 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

- Audits must be in accordance with EXCiPACT Conformity Assessment requirements. Any deviation should be justified in the application. EXCiPACT has to 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.

Witnessed Audit

Each auditor shall be required to undergo at least one EXCiPACT Audit whilst being witnessed by either an EXCiPACT designated person or by the EXCiPACT registered Certification Body's designated representative who meets EXCiPACT's 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 Certification Body has to arrange (and pay for) another Registered EXCiPACT auditor to perform the audit again
- No certificate can be issued as a result of the audit from the failed audit

The reasons for the failure by the auditor to conduct the audit to EXCiPACT's standards will be reported to the Certification Body 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.

3. How to Apply

What you do

Complete and submit the EXCiPACT Auditor Registration application form and provide all supporting documents. The application form can be downloaded from the EXCiPACT website at www.excipact.org.

Send the application to EXCiPACT as directed on the form, including evidence of the previous audits.

Upon completion of witnessed audits, evidence of such must be provided to EXCiPACT before full status is conferred.

What we do

Acknowledge the receipt of the application. It then usually takes at least four weeks to process each application. But that time may vary depending on the time required to verify the information submitted with the application.

Upon initial approval, Auditor details are added to the EXCiPACT register of Provisional Auditors pending Registered status following the witnessed audit. Once Registered status is attained, EXCiPACT will issue a Certificate of Registration and will update the website accordingly.

4. 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 Registration.

The following link shows details of all Registered EXCiPACT Auditors - http://www.excipact.org/auditors.html

The 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.

Appeals and Complaints

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

Registration

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 taken action 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.

5. FEES

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

6. REQUIREMENTS FOR RENEWAL OF REGISTRATION

The process for renewal of registration is every 3 years in accordance with this document. The requirements for the EXCiPACT Certification Scheme are:

Continuing Professional Development (CPD) (See Appendix 1)

- At least 25 hours of appropriate CPD audit experience relating to GMP or GDP requirements for the excipient supplier industry. The 25 hours CPD may be structured, semi-structured or unstructured.

Audit Experience

Copies of the audit log sheets or equivalent evidence must be supplied to EXCiPACT.

- These audits must be of the pharmaceutical excipient 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.

The 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 EXCiPACT registered auditor is conditional on the Code of Conduct (see Appendix lll) 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.

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 three yearly 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 a registered auditor.

Any update to the EXCiPACT standards will initiate the formal publication of those changes. They will be used as the basis for Webinar based training for all registered auditors. 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. 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 Continuing Professional Development (CPD)

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

For renewal of a Certificate of Registration, the auditor must demonstrate a minimum of 25 hours CPD over a three-year 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 CDP in order to

become re-certified for a further 3 years. Evidence must be presented in a format that is clear, unambiguous and in date order showing the type of CDP, 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 organization 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's 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 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 as a result of an alleged breach of this code.