This document has been prepared in response to the "IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients, Version 1, 2020".

Section 1 - Organisational Overview of the Certification Scheme Owner

Company Name

EXCiPACT asbl

A not-for-profit organisation registered in Belgium

Address

Rue Marie de Bourgogne 52, B-1000 Brussels

Belgium

Key Contact(s)

Joanne Blondiau

Administrative Coordinator

info@excipact.org

Please contact Joanne in all cases as she will then be able to direct your communication to the correct person.

Corporate ownership

EXCiPACT is a not-for-profit organisation and the Full Members nominate Board members who are responsible for setting the strategy and employing the personnel who run the day-to-day operations.

The Full members are themselves associations, and individual companies, organisation and individuals are not allowed to be Full Members under the Articles of Association of EXCiPACT. Only Full Members can vote at the General Assembly and nominate Board Members.

The current Full Members are:

- FECC
- IPEC-Americas
- IPEC China
- IPEC Europe
- Pharmaceutical Quality Group (UK)
- SPPEA (China)

Company Details

Not for profit (association sans but lucrative). This means any surplus of income over expenditure cannot be distributed to the Full Members but must be used to further the objectives of the organisation. In Belgian law an asbl should have financial reserves sufficient to operate for two years without income.

General Information

The organisation was established as a legal entity in Belgium in 2014.
As Scheme Owner it defines the standards to be used by the Certification Bodies and sets the requirements for auditor competency. It ensures these standards and requirements are implemented by the Certification Bodies.
The website can be found at www.excipact.org

Certification program scope

Pharmaceutical excipient manufacture, storage, and distribution (which includes repacking and relabelling and warehousing in original containers).
Other materials used in the manufacture of pharmaceuticals, or their starting materials that require the same standards of GMP and GDP.

The Scheme is available globally (subject to any travel restrictions for auditors).

List of relevant procedures

The EXCiPACT Quality Manual highlights the Associations quality procedures.

Section 2 - Scheme Overview and Oversight

Third-party Certification Bodies have a legal agreement with EXCiPACT asbl which requires them to apply the GMP, GDP and Good Warehousing Practices (GWP) standards to the manufacture, storage, distribution, and warehousing of excipients using auditors which are registered with EXCiPACT asbl. Auditor registration requires they are lead auditors for ISO 9001, to have attended a two-day EXCiPACT auditor training course, passed the end of course exam and be witnessed in performing an audit to the EXCiPACT GMP or GDP standards.

Once qualified the Certification Body provides certification services to excipient suppliers. Once a contract is signed between the two parties, an initial (Stage 1) audit will occur to verify the audit duration required and then a full certification audit (Stage 2) will be conducted

against the full GMP, GDP or GWP standard. The auditor will make a recommendation to the Certification Board where an independent review of the certification audit and the findings will take place. Only if this approves Certification will a GMP, GDP or GWP Certificate be issued.

Subsequently there are two annual surveillance audits and then the cycle starts again with a full recertification audit.

The excipient supplier can issue the GMP/GDP/GWP Certification, audit reports and CAPA plans to their customers as evidence of conformance to the standards.

Accreditation

EXCiPACT asbl fulfills many of the responsibilities of an Accreditation Body in its oversight of the Certification Bodies and auditors.

As this is a sector-specific scheme it is not possible for a national Accreditation Body to exercise full oversight of the Scheme, therefore EXCiPACT asbl performs many of the duties associated with an Accreditation Body.

EXCiPACT asbl is not accredited itself.

Oversight approach by internal and external audit bodies

External

EXCiPACT asbl is seeking ISO 9001 certification. The Certification Body that will be selected is not one which performs EXCiPACT GMP or GDP audits so as to avoid conflicts of interest.

Internal

EXCIPACT asbl performs internal audits in accordance with ISO 9001.

Section 3 – Certification Scheme Program Details:

1. Legal responsibility

EXCiPACT asbl is the legal entity that owns the Certification Scheme

2. Certification or service agreement

There is a legal agreement between EXCiPACT asbl and the Certification Bodies which requires them to adopt and implement the scheme rules.

As this is also a commercial agreement, it remains confidential between EXCiPACT asbl and the Certification Body.

The Agreement requires EXCiPACT asbl to communicate significant changes to the CB and to obtain agreement on their implementation.

3. Licenses, certificates, and marks of conformity

There is a legal agreement between EXCiPACT asbl and the Certification Bodies which allows them to use the EXCiPACT logo on certificates and in publicity materials in accordance with specific image requirements.

4. Management of impartiality

The EXCiPACT asbl Board is responsible for the oversight of impartiality. All material decisions concerning the Association must be approved by the Board. Material decisions are those that not defined in the Quality Manual, and thus are outside the normal activities associated with the running of the Certification Scheme. At all times, the Board is mindful of that ensuring patient safety is the overriding intent of EXCiPACT asbl and this must come before any financial or other pressures.

The Certification Scheme ISO 17021-1 annex also prohibits auditors from conducting any audit of an excipient supplier in the two years after performing any consultancy with that supplier (5.2.10).

EXCiPACT asbl does not provide any consultancy services.

5. Non-discriminatory conditions

EXCiPACT asbl places no restriction on any Certification Body which meets the criteria stated in the standards and which is prepared to sign the legal agreement. Certification Bodies that meet these criteria will be listed on the EXCiPACT asbl website. They will be able to conduct audits once they have access to an EXCiPACT registered auditor. There is no requirement for the Certification Bodies to have any affiliation to any industry, trade, or other group.

6. Confidentiality

EXCiPACT asbl is not party to information that Certification Bodies or certified excipient suppliers would consider as confidential. Whereas EXCiPACT asbl can request access to an audit report under exceptional circumstances it would not make public any details therein or the audit report itself.

Legal agreements (e.g., Certification Bodies) and contracts (employment or service) are considered confidential and are not shared by EXCiPACT asbl.

7. Publicly available information

- The following information is publicly available on the EXCiPACT asbl website at www.excipact.org :
- GMP, GDP and GWP Standards
- ISO 17021-1 Annex and auditor competency requirements
- List of Certification Bodies who have signed up to the Scheme
- List of auditors who have met the auditor requirements, including those whose credentials may have expired (e.g., due to retirement).
- List of excipient suppliers who have received EXCIPACT GxP Certificates from EXCiPACT registered Certification Bodies who have used EXCiPACT registered auditors.

8. Organisational structure

EXCiPACT asbl comprises:

- A Board of directors, up to one per Full Member (at present a maximum of 6). The Board members are not renumerated, although they may claim expenses to attend any physical meeting.
- A number of contractors (currently the Senior Advisor, Quality Manager, Audit Consultant and 2 Marketing Consultants).
- The services of an individual contracted to IPEC Europe who provides secretarial and administrative services (part-time).

Currently there are no direct employees.

9. Resource requirements and personnel competence

The Board Members and the consultants all have much more than 10 years' experience in the Pharmaceutical industry. The Senior Advisor and the current President were part of the project inception that led to the formation of the EXCiPACT Certification Scheme.

The oversight of the Certification Scheme does not require a great many resources at this point. Further consultants could be readily contracted should the need arise. Any new consultants would undergo a period of orientation undertaken by the Quality Manager.

10. Certification decision

EXCiPACT asbl is not involved in any certification decision by any Certification Body.

The EXCiPACT ISO 17021-1 annex 9.4.5.3 classifies audit findings as:

- Life threatening
- Critical
- Major
- Minor

Life Threatening Non-conformity is one where there is a situation which has produced product that is harmful to the human or veterinary patient or a product which if released would be harmful to the human or veterinary patient. Where identified the excipient supplier is required to notify the relevant regulatory authorities, and if they fail to do so, then EXCiPACT would have to undertake the communication.

A Critical excipient is one that poses a significant risk to patient safety. Remediation before further excipient is produced would be indicated and/or a recall should be considered.

The definitions of Major or Minor non-conformity are those in ISO 17021-1

- Major nonconformity is one that affects the capability of the management system to achieve the intended results, either in isolation or as the result of multiple minor nonconformities
- A minor nonconformity is one that does not affect the capability of the management system to achieve the intended results but otherwise compromises the quality management system

No Certification can be issued of an excipient supplier if any Life-threatening, Critical or Major nonconformities are identified. Certificates would be suspended if any Life-Threatening or Critical, non-conformities were identified at subsequent audits. Major non-conformities would not usually result in suspension of the certificate unless they were not addressed within the agreed timescales.

11. Changes affecting certification scheme

All changes to the EXCiPACT asbl Certification Scheme are progressed by ad-hoc teams of experts, assembled from industry stakeholders including:

- Full Member nominees (usually personnel from within their membership)
- Certification Bodies nominees
- Consultants with relevant experience

A mix of skills and experience is usually sought including those from excipient suppliers and excipient users.

Drafted changes are then consulted widely and publicly in the industry, before being finalised and implemented by EXCiPACT asbl.

12. Complaints and appeals

If any party has a complaint about the EXCiPACT Certification Scheme, then they should contact EXCiPACT asbl at info@excipact.org.

Any such complaint will be examined by the Quality Manager who will then ensure the matter is dealt with confidentially and in accordance with the internal EXCiPACT procedure.

EXCiPACT asbl may be involved in an appeal by an excipient supplier to a Certification Body where the ISO 17021-1 appear process has been exhausted, and they remain dissatisfied. EXCiPACT asbl will review the decision.

Section 4 - Roles and Responsibilities of the Scheme Owner

The details have been elaborated in previous sections.

Section 5 - Revision history

This is Version 2 of this document. Prepared 01 July 2021.

Alain Bécart,
EXCiPACT Quality Manager

Appendix - References

1 IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients, Version 1, 2020

2 ISO 17021-01 - Conformity assessment-requirements for bodies providing certification of excipient management systems, 2015

3 EXCiPACT Certification Standards for Pharmaceutical Excipient Suppliers 2017