



The International Pharmaceutical Excipients Council

GMP Certification Scheme and Certification Body Qualification Guide

For Pharmaceutical Excipients

First Version
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This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this Guide may be used to achieve an equivalent level of assurance for excipient quality.

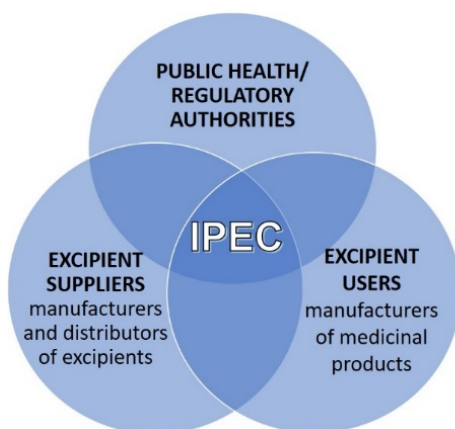
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FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major stakeholder groups:

1. excipient manufacturers and distributors, defined as suppliers in this document,
2. pharmaceutical manufacturers, defined as users in this document, and
3. public health and regulatory authorities.



This Guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the rules and regulations applying to excipients will vary from region to region and country to country. In addition, the rules and regulations are continually evolving. It is the responsibility of users of the Guide to determine whether there are any additional legal or regulatory requirements, in addition to the recommendation given in this Guide, applicable to a particular region or country in which they are doing business.

This guide offers best practice and guidance for excipient users qualifying Certification Schemes and Certification Bodies (CBs) involved in third-party excipient GMP certification. Excipient suppliers may find the information in this guide useful in their selection of a certification body.

Throughout the guide GMP will be used to represent both GMP and GDP and excipient supplier will be used to include an excipient manufacturer or a distributor (or both).

NOTE: Refer to the “International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms¹” for definitions. The first use of a term found in the glossary will be in **BOLD**.

¹ *IPEC Federation General Glossary of Terms and Acronyms*; The International Pharmaceutical Excipients Council, 2014.

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ACKNOWLEDGEMENTS

This Guide was developed by representatives from International Pharmaceutical Excipients Council (IPEC) member companies. IPEC is an industry association whose members consist of excipient manufacturers, distributors, and users. The company representatives who worked on this Guide are listed below:

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1 INTRODUCTION

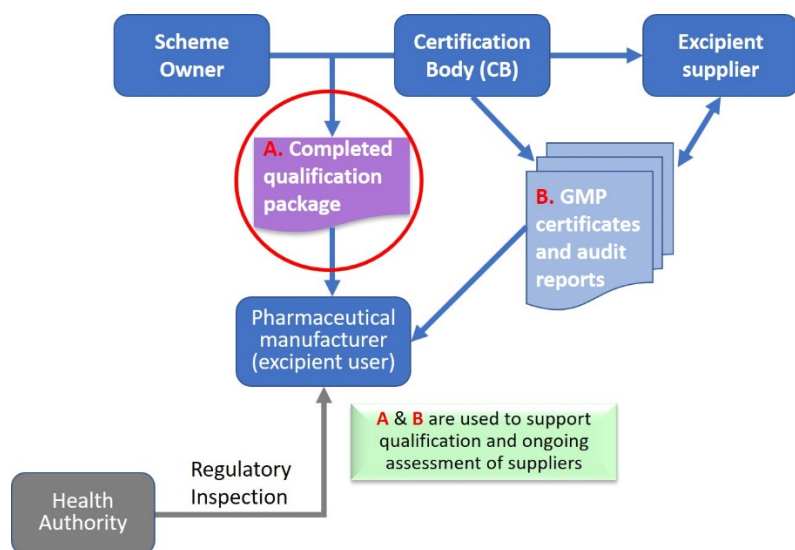
1.1 Background

Excipient **users** need to obtain information about the excipient **manufacturer**, the **distributor** (where applicable) and the **excipient** itself as part of their **supplier** and excipient qualification process.

Excipient users who rely on third-party **good manufacturing practices (GMP)/good distribution practices (GDP)** audit reports and certificates should also gather information about the organizations and the auditors involved in performing the audits.

To avoid excipient users issuing non-standardized requests for information for their qualification of the Certification Scheme and Certification Body, this **Guide** and associated “sample” template have been designed to facilitate the provision of information to the user. The use of a standardized package of information will help provide consistency in the level and type of information/documentation necessary.

Figure 1 Overview of Certification Scheme and Certification Body (CB) Qualification Process



Roles and Responsibilities

Scheme owner responsibilities include:

- defining GMP standards,
- defining auditor competency standards,
- establishing legal agreements with certifying bodies, and
- verifying the implementation of these details.

CB responsibilities include:

- employing auditors meeting defined “auditor competency standards”,
- contracting with excipient suppliers to perform GMP audits,
- authenticating GMP certificates and audit reports.

Excipient supplier responsibilities include:

- making GMP certificates available to the customer,

Note: best practice would also be to make the GMP audit reports and corrective and preventative action (CAPA) plans (if any) available to their customer, with protection of confidential information.

1.2 Purpose and Scope

Excipient users can utilize this guide to justify acceptance of the third-party Certification Bodies (CBs) through qualification of the Schemes involved in third-party excipient GMP certification. CB qualification will further accelerate acceptance for excipient GMP certification audit reports and certificates.

The primary goal of this Guide is to facilitate sharing of information from the CB and Scheme Owner to the excipient user in a standardized way. By replying to requests for information with a standardized template, the Scheme Owner and CB can respond in a timely and efficient manner while ensuring that consistent and accurate information is provided. Excipient users experience a faster turnaround time to their requests. This process assists all parties in the management of such information. In addition, the excipient user can assure that the information provided is kept current.

The content of the accompanying template is based on information needed by excipient users. It is not intended to cover all questions that may be asked by excipient users, and supplemental information may need to be provided in some cases.

The template provides information about:

1. The certification Scheme Owner
2. The CBs who conduct excipient GMP audits and issue excipient GMP certificates and audit reports, as well as the pertinent details of the auditors they employ.

1.3 Principles Adopted

For purposes of this guide, certification bodies (CBs) are defined as non-governmental organizations that assess conformance of an excipient supplier to the requirements of a recognized standard [1]. Certification Scheme Owner and the CBs are referred to as “CB/Scheme Owner” herein. In addition, the term “suppliers” is used to designate both excipient manufacturers and excipient distributors.

1.4 Format of Certification Scheme and Certification Body Qualification Guide

The format of the Certification Scheme and Certification Body Qualification Guide and template is set up with designated sections to include specific content. The topics covered in each section are defined; however, additional related information can also be provided in the completed template at the discretion of the CB/Scheme Owner. It is recommended that the typical needs of the excipient users are considered when determining how much detail to provide in the completed template for a specific topic. If some topics are not applicable these should be explicitly indicated as such in the completed template.

The content and format of the information provided in the completed template is at the discretion of the Data Owner (CB or scheme owner). Short, bulleted formats are encouraged. When referring to people, job titles, functions or roles should be used rather than names to minimize the need for updates. The completed template should be a controlled document that is shared with the user.

Data Owners should review the completed qualification documents periodically and consider adding a review date even if no changes have been made to maintain a more current effective date. It is not expected that updating the qualification documents would require the Data Owner to proactively send them to every excipient user that has ever received a copy, as in most cases this is not manageable.

1.5 Application and Usage by Excipient Users

The completed qualification documents are intended to be used by individuals responsible for supplier qualification. The information provided should be evaluated by pharmaceutical companies as part of their qualification of the Data Owner.

1.6 ISO Audit Process

The audit process and audit types are explained in ISO 17021-1. This involves an initial Certification Audit, completed in two stages, followed by two surveillance audits in the following two years. At the third anniversary of the initial certification audit, a recertification audit occurs. Stage 1 of the Certification Audit is to determine the readiness of the excipient supplier to be audited fully in the Stage 2 audit. It is also used to determine the number of auditors and the time required on site to conduct a full audit. The recertification audit is the same as the Stage 2 Certification Audit. The Surveillance audits are not as comprehensive in scope as the Certification/Recertification audits. The whole three-year cycle is as follows:

Year 0	Certification Audit
Year 1	Surveillance Audit
Year 2	Surveillance Audit
Year 3	Recertification Audit

This cycle continues as long as the excipient supplier remains certified.

2 QUALIFICATION OF CERTIFICATION SCHEME OWNER AND CB

2.1 Background and Core Principles of the ISO Standards for Certification Bodies

This Guide was developed in alignment with basic concepts and responsibilities defined in ISO 17021-1 [4] and ISO 17065 [5] Standards. Core principles from these Standards most relevant to the assessment of third-party audit organizations (Certification Bodies) include:

- Impartiality
- Competence
- Responsibility
- Openness
- Confidentiality



Impartiality

Impartiality is vital for confidence in the CB's decisions and audit reports. ISO recognizes that impartiality can be compromised because the CB depends on its income from the audit services it provides. Therefore, the decisions made by the CB must be based on objective evidence and not opinions. Its decisions must be free from influence of other parties. For instance, it is from this principle that auditors are not allowed to provide consultancy services or to make certification decisions for the excipient supplier being assessed for certification.

Central to effective impartiality is having freedom from conflicts of interest. Thus, there should be no other business relationship between the parties than those involved and managed by the scheme. There should be no consulting, such as providing advice on achieving compliance or making recommendations in audit reports.

Competence

The competence of the auditor and those determining audit durations, resources, and ultimately making the certification decision are key. Both require knowledge and understanding of pharmaceutical excipient manufacture and **distribution** to assess the supplier's operations and capability to apply **risk management** principles, and continuous improvement to quality management principles. The competencies of the auditors and those making certification decisions must be clearly defined, be verifiable, and ideally made publicly available.²

² ISO 19011 and ISO 17021-1 provides guidance on the expectations for auditor qualification.

Responsibility

Responsibilities should be clearly defined and agreed upon in a contractual agreement between the CB and excipient supplier, as well as between the CB and the Scheme Owner, where applicable. They should be established by the CB/Scheme Owner and be known by the excipient supplier and auditor.

NOTE: these agreements may be treated as confidential.

Openness

Openness of the process and standards in the scheme are essential to the assurance of quality, confidence and credibility of the results. This applies to the CB/Scheme Owners. In some cases, the CB is the Scheme Owner and the same expectations of openness apply.

Confidentiality

Information related to certification of the pharmaceutical excipient supplier must remain confidential. CB auditors and their employers must not disclose confidential information. At a minimum, there should be a confidentiality agreement between the CB and the excipient supplier. All parties must have assurance of the integrity of the auditors and the CB. This principle also applies where the Scheme Owner is directly involved with the certification process.

2.2 Detailed Information to Share with Excipient User

The information in this section is intended to be utilized by excipient users when qualifying a CB and Scheme Owner involved in third-party excipient GMP certification. The final document showing alignment of the CB and their operations with basic concepts and responsibilities, as taken from ISO 17021-01 and ISO 17065 Standards, should be used by the excipient user to support and qualify the CB and their excipient GMP audit reports and certificates.

2.2.1 Organizational Overview of the CB

Provide an overview of the CB organization which includes the following information:

CB Company Details

- CB Company Name(s)
- CB Address(es)
- CB Key Contact(s)
 - Name(s) and Title(s)
 - Contact Information: phone, email
- General Company Information
 - History, years in business as a CB
 - Business volume
 - Number of employees

- List of recognized accreditations, e.g. ISO 17021-1
- Other certification programs e.g. EXCiPACT®, FSSC 22000, EFfCI
 - evidence of participation
- Corporate ownership (if applicable) (Legal entity that is the owner of the above)

2.2.2 Scheme Overview and Oversight

Provide an overview of the Scheme Owner's program including:

- Accreditation to ISO 17021/17065, if applicable
 - Accrediting Organization, Certificate Number, and Expiration Date
- Additional oversight of the CBs:
 - Scheme Owner audit scope and frequency
 - CB Internal audit scope, frequency
- A description as to how the CB ensures the validity of the excipient GMP certification, including auditor training in the excipient GMP standard, assessment of the auditor certification report, ongoing qualification of auditors, etc.

2.2.3 Certification Scheme Program Details

Suggestions for excipient users on the information from the CB/Scheme Owner

NOTE: Information expected is highlighted gray, *key elements of CB response are blue.*

2.2.3.1 Legal responsibility

As found in:

ISO 17021-1	ISO 17065
5.1 Legal and contractual matters 5.1.1 Legal responsibility 5.1.2 Certification agreement 5.1.3 Responsibility for certification decisions	4.1 Legal and contractual matters

Confirm the legal entity that is responsible for conducting audit / certification activity.

The CB should provide the legal name. This could be used to independently verify the financial viability of the company (e.g. Dunn & Bradstreet®).

2.2.3.2 Certification or Service Agreement

As found in:

ISO 17021-1	ISO 17065
5.1 Legal and contractual matters 5.1.1 Legal responsibility 5.1.2 Certification agreement 5.1.3 Responsibility for certification decisions	4.1 Legal and contractual matters

Confirm how the CB communicates the auditing scheme and the rights and duties of the auditee to the auditee.

The CB should provide auditee with a policy document/certification agreement that includes an overview of the auditing scheme and the roles and responsibilities of each party.

Confirm there is an agreement between the CB and Scheme Owner or accreditation body. Agreement should include:

- obligation to communicate substantive changes to the CB
- maintain confidentiality
- authorized use of the certification mark (e.g. agreement)
- other

The CB should have a signed legal agreement between the auditee and CB. The legal agreement should include,

- *obligation of the auditee to communicate substantive changes to the CB*
- *maintenance of confidentiality by the CB*
- *authorized use of the certification mark (e.g. agreement) by the auditee*
- *etc.*

2.2.3.3 License, certificates and marks of conformity

As found in:

ISO 17021-1	ISO 17065
8.3 Reference to certification and use of marks	

Confirm that the auditing / certification agreement includes provisions which describe the appropriate and / or inappropriate use of certificates, marks, and statements of GMP conformance.

The CB should confirm that use of certificates, marks and statements of GMP conformance are not batch specific, but rather, cover certification of the quality management system.

Establish how the CB defines the scope and how is it communicated to the Auditees. Confirm that the certification clearly identifies what is in-scope and/or out-of-scope.

The CB should clearly define the certification scope in the agreement with the auditee, i.e., bulk package of finished excipient. Scope statements should be visible on the certificate.

2.2.3.4 Management of Impartiality

As found in:

ISO 17021-1	ISO 17065
5.2 Management of impartiality 5.2.2, 5.2.3, 5.2.5	4.2 Management of impartiality

Confirm how the CB manages impartiality to ensure no commercial, financial or other pressures compromise audit / certification decisions and how is this assured.

Confirm that there is an acknowledgement from the auditor that they comply with the impartiality procedure.

The CB should have a written policy and/or procedure which describes the steps they take to assure impartiality. All auditors used by the CB should be bound by the requirements for impartiality, be they employees or contractors, and acknowledged in writing.

Auditors should not be permitted to participate in audits of, e.g.:

- a former employer for a period of time since last employment (e.g. a stipulated number of years),*
- where they have known significant financial interest in the company being audited,*
- where they have provided consultancy to the auditee for a stipulated period of time (refer to Section 2.1, Impartiality).*

Confirm that consulting service is not part of the services rendered by the auditing / certification legal entity, including during the Stage 1 audit (refer to Section 1.6 above)

The CB should confirm that their legal entity, if applicable, does not or has not recently (as defined by a stipulated period of time) provided consulting to the auditee. If consulting was provided, state the nature and timeframe.

2.2.3.5 Non-discriminatory conditions

As found in:

ISO 17021-1	ISO 17065
	4.4 Non-discriminatory conditions

Confirm how the CB ensures its services are offered in a non-discriminatory manner and without affiliation to any industry, trade or other group.

The CB should provide evidence that they are working independently and that there is freedom from conflict of interest when performing/conducting certification.

The CB should not have pre-conditions for certification other than those required under ISO 17021-1 or defined by the CB scheme (e.g. CBs cannot require their clients to be members of a specific industry, trade association or other group).

2.2.3.6 Confidentiality

As found in:

ISO 17021-1	ISO 17065
8.4 Confidentiality 8.4.1, 8.4.3, 8.4.4, 8.4.5	4.5 Confidentiality

Confirm how the CB ensures confidentiality

The CB should provide an explanation for how they ensure confidentiality of information obtained from the audit. Best practice is to allow the auditee to review the draft audit report for confidential information.

What to look for

- Does CB have CDAs in-place with the excipient manufacturer or distributor?*
- Does CB have CDAs in place with their employees, auditors and contractors?*

2.2.3.7 Publicly available information

As found in:

ISO 17021-1	ISO 17065
8.1 Public information 8.1.1, 8.1.2, 8.1.3	4.6 Public information

Provide details from the CB for publicly available information.

The CB should provide:

- Description of the auditing process, audit standard, and certification scheme*
- Information on how complaints from excipient users questioning the audit report or certification decision are handled*
- List of active certificates*
- Means by which excipient users can acquire information on suspended and withdrawn certificates*
- Details on how the excipient user can request an audit report or verify the authenticity and accuracy of an audit report received from an excipient supplier.*
- Where applicable, accreditation status of the CB*

2.2.3.8 Organizational structure

As found in:

ISO 17021-1	ISO 17065
6. Structural requirements 6.1.1 & 6.1.3 6.1 Organizational structure and top management	5. Structural requirements 5.1 Organizational structure and top management

Describe the organizational structure of the CB noting who makes decisions on certification or certificate withdrawal.

CB should provide an organizational description (e.g. high-level diagram providing evidence of a separate legal structure) showing the independence of the body making certification decisions and the auditors.

In addition, refer to response for items 10 (Resource requirements and Personnel Competence) and 11 (Certification Decision) below.

2.2.3.9 Resource requirements and Personnel Competence

As found in:

ISO 17021-1	ISO 17065
7. Resource requirements. 7.1 Competence of personnel 7.1.2 Determination of competence criteria 7.2 Personnel involved in the certification activities 7.2.4 & 7.2.5	6. Resource requirements.

Confirm the resources in place to manage the audit scheme and ensure ongoing compliance with procedures including accreditation requirements, as applicable.

The CB should provide evidence that the organizations (Scheme Owner and CB) have their own quality management system and provide oversight demonstrating compliance.

Confirm that independent contractor agreements (ICAs) are in place with the auditors, as applicable. Confirm whether the ICA include provisions for confidentiality and impartiality.

The CB should confirm that ICAs are in place where contract auditors are used. Such ICAs should cover impartiality and confidentiality.

Confirm how the auditing / CB ensures support and auditors are competent in their respective roles / assignments.

Confirm how auditor competencies are reviewed and maintained.

The CB should describe their qualification program for auditors and those involved in program oversight, including training and continuing education for auditors and reviewers, in addition to, periodic witness audit requirements for ongoing qualification.

2.2.3.10 Certification Decision

As found in:

ISO 17021-1	ISO 17065
9.5 Certification decision 9.5.1 General 9.5.1.1	

Confirm how certification decisions are taken.

The CB should describe who within their organization is making certification decisions. The CB should provide confirmation that certification decisions are not being made by the auditor (s).

The CB should describe the competency requirements for those making the certification decisions.

Confirm how audit findings are classified. Confirm the basis on which a certification decision is made?

The CB should describe how audit findings are classified and how they relate to certification decisions.

2.2.3.11 Changes affecting Certification Scheme

As found in:

ISO 17021-1	ISO 17065
8.5 Information exchange between a certification body and its clients 8.5.3	

Confirm how the CB handles changes to the audit standard and criteria.

The CB should describe how changes to Certification Scheme or to ISO 17021-1/17065 requirements are addressed internally, and communicated and disseminated to all interested parties.

Explain how timelines are communicated when changes are being implemented.

2.2.3.12 Complaints and Appeals

As found in:

ISO 17021-1	ISO 17065
9.7 Appeals 9.7.1, 9.7.2, 9.7.7 9.8 Complaints 9.8.1, 9.8.3, 9.8.5, 9.8.6, 9.8.11	

Confirm how the CB manages complaints and appeals.

The CB should provide an overview of their process for managing and communicating complaints and appeals.

The persons engaged in addressing appeals (when an auditee disagrees with an audit finding or decision on certification) should be different from those carrying out the audits or making certification decisions.

2.3 Roles and Responsibilities of the Scheme Owner or Accrediting Body

Overview of the key requirements established by the Scheme Owner or the accrediting body that shows how they certify that the CB has the systems in-place to provide excipient GMP certificates in accordance with the scheme rules.

- CB accredited by EXCiPACT®,
- CB accredited by accreditation body, e.g. American National Standards Institute (ANSI), UKAS, etc.
- CB self-declaration, if the CB is also the Scheme Owner.

3 REFERENCES

1. NSF/IPEC/ANSI 363 – 2019 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients.
2. EXCiPACT® Certification Scheme; <https://www.excipact.org/the-certification-scheme.html>
3. EXCiPACT® Certification Standards for Pharmaceutical Excipient Suppliers: Good Manufacturing Practices, Good Distribution Practices, 2017.
4. ISO 17021-01 - Conformity assessment-requirements for bodies providing certification of excipient management systems, 2015
5. ISO 17065 - Conformity assessment-requirements for bodies certifying products, processes and services, 2012
6. ISO 19011- Guidelines for Auditing Management Systems, 2018.