IPEC Position Paper

Pharmaceutical Excipients GMP Reference Documents supported by the IPEC Federation

July 2025

Purpose of Position Paper

Several different excipient Good Manufacturing Practice (GMP) guides and standards are available. This position paper explains the purpose of these documents and how they may be used. With this information, the excipient manufacturer can have a better understanding of and ultimately make appropriately informed decisions regarding which they would like to adopt.

Background Information

The following documents apply to the manufacture of excipients intended for use in medicinal products. They provide quality management system (QMS) criteria and the extent of GMP necessary to be implemented in the manufacture of excipients considered appropriate by the IPEC Federation. The components of the quality management system were designed to protect the patients from harm and the excipient customer from product failure. Excipient manufacturers are advised to align their QMS with the document that best aligns with their internal quality system.

Although other versions of the guides or standards are available, it is the IPEC Federation's position that only the most current version should be referenced since older versions do not reflect current practices or requirements. The use of outdated versions can create confusion for example, during audits and may be viewed as not conforming to current excipient GMP expectations by customers.

1. The International Pharmaceutical Excipients Council & The Pharmaceutical Quality Group: The Joint Good Manufacturing Practices Guide for Pharmaceutical Excipients [1]
2. EXCiPACT® Certification Standards for Pharmaceutical Excipient Suppliers, GMP [2], "EXCiPACT® GMP Annex"
3. NSF/IPEC/ANSI 363, Good Manufacturing Practices (GMP) for Pharmaceutical Excipients, American National Standard (ANSI 363) [3]

Below is a brief discussion regarding the content and development of these three documents.

1. The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients

This guide, initially developed in 1991 has gone through several iterations, the most recent revision being published by the IPEC Federation in 2022. This is a guide and not a certifiable standard. It is aligned with ISO 9001:2015 and can be used by companies that do not intend to have their GMP quality system certified by a third-party certifying body, as an effective auditing tool. Equally, it can assist manufacturers in implementing the requirements of certifiable GMP standards.

As there is no official guideline on GMP for pharmaceutical excipients published by regulatory authorities in most regions, this document has been developed to identify GMP principles considered to be appropriate for the excipient manufacturer. To make this guide relevant to excipient manufacturers, a risk-based approach features as one of the guide's core principles. Highlighting the

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium
www.ipec-federation.org -- +32 (0)2 213 74 40 -- info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region

differences between excipients and active pharmaceutical ingredients was a key consideration by the IPEC Federation and PQG when writing the document.

Excipient manufacturers and suppliers using older versions should have a plan to transition to the latest version.

2. EXCiPACT® GMP Annex

This is an excipient GMP standard based on ISO 9001:2015 and is intended to be used if the manufacturer is ISO 9001:2015 certified or is in the process of becoming certified. EXCiPACT GMP is presented as an annex to the ISO 9001:2015 standard completing it with GMP requirements. EXCiPACT asbl, as owners of the scheme, authorizes certifying bodies and qualifies auditors to conduct audits and issue certificates to this standard.

This standard is fully aligned and based on the IPEC-PQG GMP Guide and the requirements in NSF/IPEC/ANSI 363.

3. NSF/IPEC/ANSI 363

This is an excipient GMP standard based on ISO 9001 and aligned with ISO 9001:2015 and is intended to be used whether the manufacturer is not ISO 9001certified. This is an American National Standards Institute (ANSI) standard and was developed with input from IPEC and the U.S. Food & Drug Administration. Certification is available against this standard.

***Note**:* Companies may decide to comply to either of the latter two standards without going through the process of achieving certification.

The excipient manufacturer should consider the following when selecting a document to align with:

1. Is there an intent to achieve excipient GMP certification?
    - If so, then NSF/IPEC/ANSI 363 or the EXCiPACT GMP Annex should be considered.
2. Is the manufacturer ISO 9001:2015 certified or is ISO 9001 certification an objective for the site of manufacture?
    - If so, then the EXCiPACT GMP Annex may be more advantageous than NSF/IPEC/ANSI 363.
3. Is the intent solely to implement an excipient GMP QMS?
    - In this case, The Joint IPEC-PQG GMP Guide for Pharmaceutical Excipients may be the best to implement as it is written as a guide similar to other GMP guides to be used to implement applicable GMP principles into a QMS of a manufacturer of related products.
4. The Joint IPEC-PQG GMP Guide for Pharmaceutical Excipients is also recommended as a tool providing support in the preparation of an EXCiPACT and/or NSF/IPEC/ANSI 363 certification.
5. The IPEC Federation Risk Assessment Guide for pharmaceutical excipients [4]; risk assessment for excipient manufacturers provides additional guidance on conducting the risk assessments required in the Joint IPEC-PQG GMP Guide and the two standards. It is recommended to study

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium
www.ipec-federation.org -- +32 (0)2 213 74 40 -- info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region

this document when designing a quality management system that will be compliant with these GMP principles.

IPEC Federation Position

All three documents play an important role in the implementation of excipient GMPs in the QMS of an excipient manufacturer. The manufacturer can choose to implement a QMS aligned with any of the three. An excipient manufacturer should decide whether to pursue excipient GMP certification or not, which would be a consideration when deciding with which document to align initially.

These documents, especially The Joint IPEC-PQG GMP Guide for Pharmaceutical Excipients may also be used by auditors and customers to evaluate the extent of implementation of GMP principles of at an excipient manufacturing site. It should be clear which document has been implemented to ensure auditing is conducted to the correct GMP.

References:

1. The International Pharmaceutical Excipients Council & The Pharmaceutical Quality Group: The Joint Good Manufacturing Practices Guide for Pharmaceutical Excipients https://ipec-federation.org/resources/
2. EXCiPACT™ Certification Standards for Pharmaceutical Excipient Suppliers, GMP https://www.excipact.org/files/EXCiPACT/Downloads/20180123%20EXC%20Standard_Final-webversion.pdf
3. NSF/IPEC/ANSI 363, Good Manufacturing Practices (GMP) for Pharmaceutical Excipients, American National Standard (ANSI 363) https://webstore.ansi.org/standards/nsf/nsfipecansi3632016
4. The International Pharmaceutical Excipients Council Risk Assessment Guide for Pharmaceutical Excipients - Risk Assessment for Excipient Manufacturers https://ipec-federation.org/resources/

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl
Rue Marie de Bourgogne 52 – 1000, Brussels, Belgium
www.ipec-federation.org -- +32 (0)2 213 74 40 -- info@ipec-federation.org
VAT: BE 0823931361 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region