



Press Release

Brussels (Belgium), 31 March 2026

IPEC Federation announces the availability of an updated version of its IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients.

The guide, initially published in November 2020, was developed for excipient users (e.g. pharmaceutical manufacturers) to qualify both certification bodies (CB) that issue excipient GMP and GDP certificates and audit reports as well as Certification Scheme Owners. The use of the guide is intended to facilitate sharing pertinent information from the CBs and Scheme Owners to excipient users in a standardized way.

Key changes include the clarification of supplier responsibilities, with a new subsection covering responsibilities for excipient users; clarification of 'How to Use the Guide'; clarification of the ISO audit process; and an update of references and alignment with EMA requirements for third-party audits of API suppliers.

The guide and its associated sample template are designed to standardise information exchange between the certification body or scheme owner and excipient users, accelerating communication and reducing the need for multiple diverse questionnaires.

Qualifying the CB and/or scheme owner should facilitate acceptance of excipient GMP and GDP certification schemes, audit reports, and certificates as substitutes for audits performed by excipient users.

The guide and the template will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](https://www.ipecfederation.org) and national/regional members' websites.

For further information contact the IPEC Federation Secretariat at:

+32 2 213 74 40 / info@ipec-federation.org

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl

Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium

W: [ipec-federation.org](https://www.ipec-federation.org) T: +32 2 213 74 40 E: info@ipec-federation.org.

VAT: BE 08239313 61 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region