

International Pharmaceutical Excipients Certification

Pharmaceutical excipients are essential components of medicinal products, and their quality directly impacts the safety, efficacy, and quality control of the final drug product. Therefore, the implementation of Good Manufacturing Practices (GMP) for excipients is of critical importance. **The EXCiPACT international certification scheme for pharmaceutical excipients** adopts GMP, GDP, and GWP standards based on the widely recognized IPEC-PQG GMP and IPEC GDP Guidelines for Pharmaceutical Excipients, providing an independent third-party certification audit for excipient manufacturers and suppliers.

The EXCiPACT certification standards establish additional requirements to the ISO 9001. Excipient suppliers may opt to undergo integrated certification audits for both ISO 9001 and EXCiPACT standards simultaneously. The voluntary third-party certification approach not only enhances patient safety and strengthens supplier's quality assurance systems, but also reduces the number of audits excipient companies are required to host, thereby lowering time and cost burdens.

The European Union Falsified Medicines Directive (FMD) explicitly requires Marketing Authorization Holders (MAHs) to evaluate whether excipient manufacturers and suppliers comply with applicable GMP and GDP standards.

- **Stage 1 Audit:** The auditor reviews the client's documentation against the audit criteria, identifies any non-conformities, and agrees with the client on the time required to resolve these issues before the detailed on-site Stage 2 audit begins.
- **Stage 2 Audit:** The auditor conducts a comprehensive on-site evaluation in accordance with the audit criteria. Upon completion, an audit report is submitted, including any major non-conformities, for review and certification decision.

③ Issue Certificate:

Kaixin will review the audit documentation and findings to make a certification decision. The certificate will only be issued after all non-conformities have been closed.

EXCiPACT will directly issue an invoice for the certification application fee to the client. Once the fee is received, the client's information will be listed on the EXCiPACT website's list of certified companies.

Scope of Certified Products:

EXCiPACT® is a voluntary international program that provides independent third-party certification for pharmaceutical excipient manufacturers, suppliers, and distributors worldwide.

Certification Process:

① Submit Application & Sign Agreement:

Client shall submit application to Kaixin, along with relevant qualifications and documents as required in the attachment to the application form.

② Audit Services:

Stage 1 Audit + Stage 2 Audit

④ Surveillance Audit:

Surveillance audits are conducted at least once a year to verify compliance with all program requirements, including internal audits, actions on previous non-conformities, complaints, and the effectiveness of the quality management system. A written report is issued to the client following each audit.

⑤ Re-Certification Audit:

A re-certification audit shall be conducted before the initial three-year certification period expires, to confirm continued compliance with the current EXCiPACT standards.

Why Kaixin Certification?

Pharmaceuticals are one of the essentials in people's daily lives, and their quality and safety are critical to public health. Pharmaceutical excipients impart key characteristics to drug formulations, including desirable appearance, stability, and effective release of the active pharmaceutical ingredients. Therefore, the application of Good Manufacturing Practice (GMP) in the production of excipients is of vital importance. Regulatory authorities increasingly require pharmaceutical manufacturers to conduct risk assessments and apply appropriate GMP for excipients to ensure patient safety.

One of Kaixin's key objectives is to reduce uncertainty across the pharmaceutical and agri-food supply chains through comprehensive audits. To this end, we offer a wide range of business solutions and services. Since its establishment, Kaixin has successively obtained international certification accreditations including EXCiPACT, FSSC 22000, FAMI-QS, Organic Certification, and GAP. We continue to expand our service scope and enhance our network, contributing to economic prosperity, environmental sustainability, and social responsibility.



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