INTERNATIONAL PHARMACEUTICAL EXCIPIENTS CERTIFICATION

SAVE MONEY AND TIME USING EXCIPIACT

A CERTIFICATION SCHEME WIDELY RECOGNISED BY REGULATORS

MINIMISE RISK
MAXIMISE TRUST
MEMBERS

Our members are either national or regional associations involved in the pharmaceutical excipients industry in Europe, the Americas and China. As an association of associations, impartiality is assured.

WHAT THEY SAY ABOUT EXCiPACT CERTIFICATION SCHEME

Regulators

“Third-Party certification schemes can assist medicinal product manufacturers in achieving compliance with GMP at reduced cost and impact on time and resource”

Suppliers

“The audit was very thorough – at least as good as a regulatory inspection and at the same level as the best customer audits”

“Such schemes will also benefit excipient manufacturers by reducing the number of audits they are required to host with a consequential reduction in time and cost”

“Overall patient safety should be enhanced”

The EXCiPACT certificate and the audit reports are well accepted by the customers”

Pharmaceutical companies

“The EXCiPACT Certificate and Audit Report allowed us to decrease audit frequency and spend half a day on site rather than a full audit”

“Helps avoid duplication of effort since each element of the excipient GMP standard is already periodically assessed”

“EXCiPACT audit reports provide an expedient and cost-effective means for excipient users to assess GMP/GDP conformance of suppliers, which is needed to demonstrate ongoing supplier qualification”

“The investment has paid off, customer feedback is very positive!”
EXCiPACT

EXCiPACT asbl is a non-profit organisation established in Belgium in 2014 that owns and manages the oversight of an independent, high quality, third-party GMP and GDP Certification Scheme available to pharmaceutical excipient manufacturers, suppliers and distributors worldwide via Registered Certification Bodies.

EXCiPACT PROGRESS

BENEFITS

01 Credible, independent third-party certification using highly trained auditors certified to GMP/GDP standards

02 Public certification scheme with criteria for approving CBs and their auditors

03 More robust than 1st/2nd party certification

04 Scheme audit covers many days and annual surveillance audits

05 Verification of auditor competency and independence of Certification Bodies is key

06 Audit reports based on unbiased, excipient GMP/GDP practices

07 Allows pharma companies to redirect internal auditors to issues outside the GMP/GDP standard’s scope

08 Regulatory acceptance of accredited, third-party audits for assessing quality and safety

FOR MORE INFORMATION, PLEASE VISIT
WWW.EXCIPACT.ORG
EXCiPACT fulfils the role of an accreditation body. It carries out Certification Body approval via a structured process to ensure they comply with all requirements:

- Certification Body quality system definition, qualification and registration processes
- Auditor competency definition, training course, exam, and registration processes
- Certificate and Audit report format requirements

All Certification Bodies are re-audited every three years and their performance reviewed prior to re-approval.

EXCiPACT is an independent, voluntary, GMP/GDP Certification Scheme for pharma excipient suppliers. The scheme was developed by suppliers and users of excipients. The scheme comprises the following:

- GMP Standard for excipients – annex to ISO 9001
- GDP Standard for excipients – annex to ISO 9001
- Auditor Competency definition, training course, exam, and registration process – annex to ISO 17021
- Certification Body quality system definition and qualification process – annex to 17021

Legal Agreement with 3rd Party Audit Organisations
Publish list of Certificates and Registered Auditors for validity on website

Agreement with supplier
Provides audit report and Certificate

Supplier passes on audit report
User can verify report and Certificate with EXCiPACT
WHERE HAVE EXCiPACT CERTIFICATES BEEN ISSUED?

POTENTIAL COST SAVINGS FOR STAKEHOLDERS

<table>
<thead>
<tr>
<th>EXCiPACT Audit</th>
<th>Excipient Supplier</th>
<th>Pharmaceutical Company</th>
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</thead>
<tbody>
<tr>
<td>Audit fee</td>
<td>Reduction by:</td>
<td>Reduction by:</td>
</tr>
<tr>
<td></td>
<td>• one 2-day audit/month</td>
<td>• one 2-day audit/month</td>
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<tr>
<td>Certificate fee</td>
<td>• one day for preparation, at internal cost incl. of 2,000 € each</td>
<td>• three days for travel &amp; preparation of the report plus travel expenses</td>
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<td>Surveillance</td>
<td>• 5000 € travel expenses/year</td>
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<td>Internal cost</td>
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<td>TOTAL 3 yrs.</td>
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TOTAL COST in 3 years: 30,000 €
TOTAL SAVINGS in 3 years: 90,000 €
TOTAL SAVINGS in 3 years: 180,000 €

Total Industry Benefit: 60,000 €
240,000 €
EXCiPACT CERTIFICATION ADDS VALUE TO THE PHARMACEUTICAL INDUSTRY

IMPROVES the quality and the safety of medicines

ANNUAL AUDITS optimises supply chain security

REDUCES the burden and costs of audits for suppliers and their customers

PROVIDES confidence in certificates issued by Registered Certification Bodies

MEETS the risk assessment needs of Manufacturing Authorisation Holders

ADDRESSES issues specific to excipient distribution process (GDP)

HELPS the pharma producers identify qualified suppliers

SUPPORTED by key regulatory authorities

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