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

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

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

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

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

“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”

“Overall patient safety should be enhanced”
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 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 process
- **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?

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 €

POTENTIAL COST SAVINGS FOR STAKEHOLDERS

EXCiPACT Audit
- Audit fee: 10,000 €
- Certificate fee: 5,500 €
- Surveillance: 10,000 €
- Internal cost: 2.5-5,000 €
- TOTAL 3 yrs.: 28-30,000 €

Reduction by:
- one 2-day audit/month
- one day for preparation, at internal cost incl. of 2,000 € each
- 5000 € travel expenses/year

TOTAL COST in 3 years
30,000 €

TOTAL SAVINGS in 3 years
90,000 €

Excipient Supplier
- Reduction by:
  - one 2-day audit/month
  - three days for travel & preparation of the report plus travel expenses

TOTAL SAVINGS in 3 years
180,000 €

Pharmaceutical Company
- Reduction by:
  - one 2-day audit/month
  - three days for travel & preparation of the report plus travel expenses

TOTAL SAVINGS in 3 years
180,000 €

Registered Certification Bodies

- AENOR
- AJA
- blue
- CERTIFIQUA
- DQP
- SGS
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

FOR MORE INFORMATION, PLEASE VISIT
WWW.EXCIPACT.ORG

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