



**INTERNATIONAL
PHARMACEUTICAL
EXCIPIENTS CERTIFICATION**



**SAVE MONEY AND TIME
USING EXCI PACT**



**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”

“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”



Suppliers

“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!”



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”

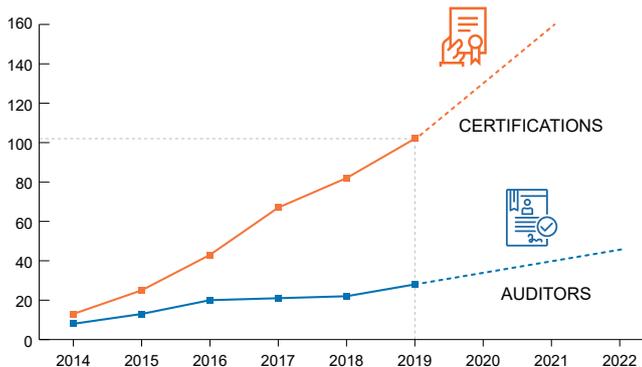
EXCiPACT

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.

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

EXCiPACT PROGRESS



FOR MORE INFORMATION, PLEASE VISIT

WWW.EXCiPACT.ORG

WHAT IS EXCIPACT CERTIFICATION SCHEME AND HOW DOES IT WORK?

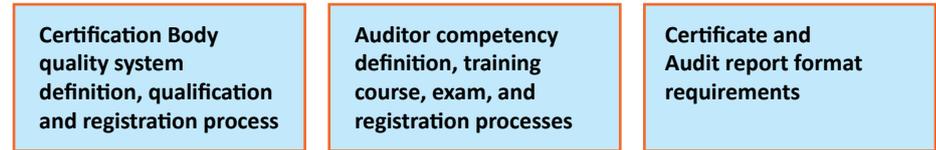
EXCIPACT is an **independent, voluntary, GMP/GDP Certification Scheme** for pharma excipient suppliers. The scheme was developed by suppliers and users of excipients. The scheme comprises the following:

- **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

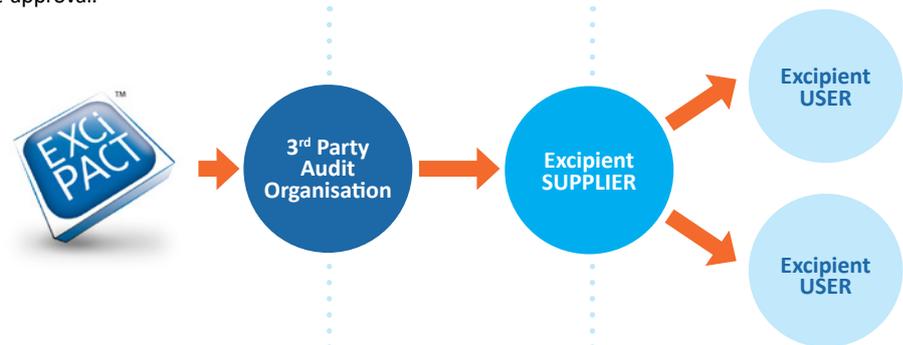


EXCIPACT FULFILS THE ROLE OF AN ACCREDITATION BODY

It carries out Certification Body approval via a structured process to ensure they comply with all requirements:



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



Legal Agreement with 3rd Party Audit Organisations

Publish list of Certificates and Registered Auditors for validity on website

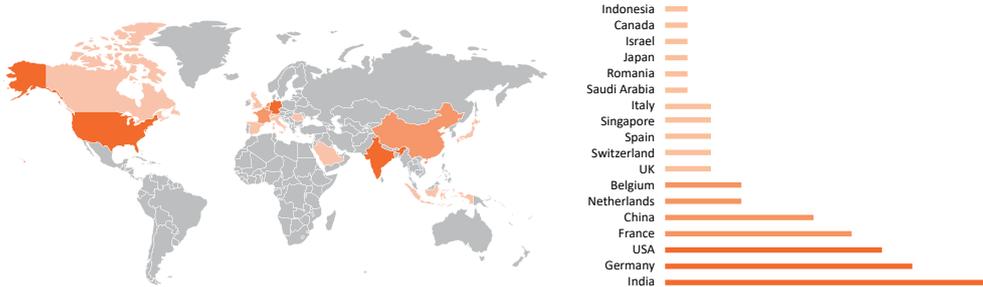
Agreement with supplier

Provides audit report and Certificate

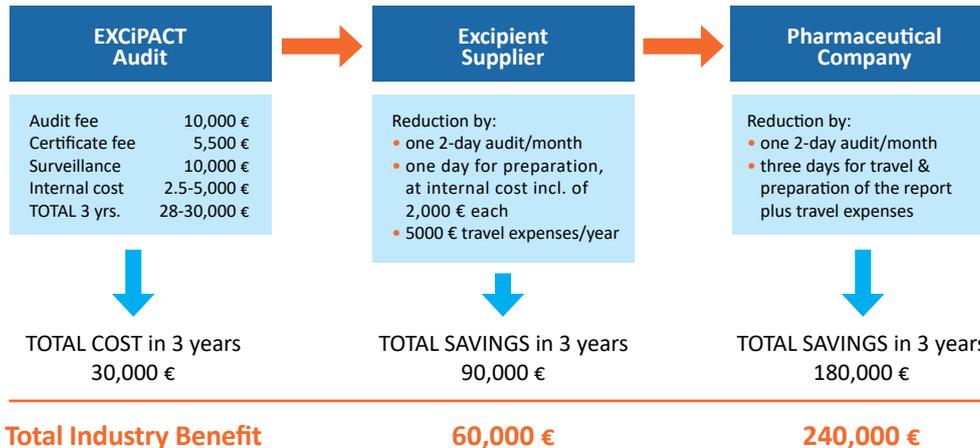
Supplier passes on audit report

User can verify report and Certificate with EXCIPACT

WHERE HAVE EXCiPACT CERTIFICATES BEEN ISSUED?



POTENTIAL COST SAVINGS FOR STAKEHOLDERS



REGISTERED CERTIFICATION BODIES



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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