



PRESS RELEASE

SIMPLIFIED, STANDARDISED QUALIFICATION OF EXCIPIENT SUPPLIERS CERTIFIED USING THIRD-PARTY GMP/GDP SCHEMES

Brussels, 16 March 2021

New guidance⁽¹⁾ has recently been published to help pharma companies to simplify their qualification of the Certification Scheme Owners (CSO) and Certification Bodies (CBs) who provide third-party GMP and GDP audit reports and certificates for pharma excipient suppliers.

EXCiPACT asbl is one such CSO who has legal Agreements with seven Registered CBs to offer their GMP/GDP Certification Scheme worldwide.

In response to this guidance, EXCiPACT has volunteered to support its recommendations by publishing⁽²⁾ their first CSO qualification template and encouraging its CBs to volunteer to complete their templates. To date, two have done so and completion of the rest is expected in the coming weeks.

When complete, both EXCiPACT and their CBs will refer pharma companies to their qualification templates rather than completing the myriad of non-standard requests for essentially the same information in a simple, standardised way which can be easily updated as needed.

Full details of the availability of the qualification templates will be available on our website at www.excipact.org where up-to-date Information on our 130+ certificate holders, certificates, and their registered auditors, is also available. The certificate holders own the intellectual property of their audit reports and are legally required by the CSO to provide a system for their release to customers and other interested parties.

References

- (1) *IPEC GMP Certification Scheme and Certification Body Qualification Guide for Pharmaceutical Excipients.* <https://ipec-federation.org/resources/>
- (2) [*EXCiPACT Certification Scheme - Qualification Form for Pharma Companies*](#)

Notes for the Editor

EXCiPACT asbl owns and provides management oversight for the voluntary, independent, high quality international EXCiPACT Certification Scheme that provides for independent 3rd party GMP and/or GDP certification of manufacturers, suppliers, and distributors of pharmaceutical excipients worldwide. The Scheme ensures patient safety through supplier quality while minimising the overall costs for assessing the excipient supply chain. Operational from 2013 since when considerable interest has been generated among pharmaceutical excipient suppliers, their customers, and regulators. For further information see www.excipact.org or contact info@excipact.org.