



EXCiPACT asbl QUALITY POLICY

EXCiPACT asbl is a non-profit Association that owns and manages the oversight of a voluntary, independent, high quality, third-party Certification Scheme which is available to pharmaceutical excipient manufacturers and distributors worldwide. This enhances patient safety and improves assurance of supplier quality, through a global network of Registered Certification Bodies and their Registered auditors.

EXCiPACT is committed to ensuring that GMP and GDP certification of pharmaceutical excipient suppliers is granted according to a well-defined and rigorous process. This Certification Scheme allows final excipient users to integrate EXCiPACT certification conclusions into their own supplier quality management system, with cost savings for both excipient suppliers and excipient users. Our vision is to ensure that EXCiPACT Certification represents an independent and trustworthy quality assessment of Suppliers.

OUR PEOPLE

EXCiPACT asbl is managed by representatives from the members of the Association, who are responsible for ensuring the sustainability of the Certification Scheme. As an association of associations, impartiality is assured as there are no direct relations between the certified excipient suppliers and the EXCiPACT association.

The EXCiPACT management body is responsible for ensuring that all functions and contractors are continuously acting in the interest and the ethical rules of the Association. EXCiPACT registered auditors are trained, witnessed, and qualified by the Association itself to ensure their competence meets the Quality standard.

OUR COMMUNITY

EXCiPACT asbl is committed for supporting the whole excipient community of stakeholders by enhancing a high level of quality along the Pharmaceutical Excipients Supply Chain. The Quality Standard developed by the EXCiPACT association is periodically updated considering the changes of Quality Requirements. The selection and the accreditation of the EXCiPACT Registered Certification Bodies is made according to the ISO-17021 Quality Standard and its Appendix defined in the EXCiPACT Quality Standard.

OUR QUALITY COMMITMENTS

The EXCiPACT Association is committed to achieving excellence and providing our entire community supply chain with a set of high-quality services designed, produced, and maintained to meet or exceed their expectations as follows:

- Upgrading our internal processes by the continuous improvement of our quality system which is aligned with the ISO 9001 Quality standard
- Applying a well-defined, independent supervision of Certification Body accreditation and registration, as well as assessing and accepting the registered Auditors according to our quality standards
- Verification of our Registered Certification Bodies, Registered Auditors and Certified Excipient suppliers on our web site, www.excipact.org



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- Continuous support to our supply chain community to help them to comply with the current EXCiPACT standards and with the permanent objective of assuring patient protection and medicinal product safety. This is achieved via training sessions, conferences, direct communication and via our web site (www.excipact.org)

July 2020

A handwritten signature in black ink, appearing to be 'Iain Moore'.

Iain Moore
President

A handwritten signature in black ink, appearing to be 'A. BÉCART'.

Alain Bécart
Quality Manager