



## EXCiPACT™ asbl QUALITY POLICY

EXCiPACT™ asbl is a non-profit Association that owns and manages oversight of a voluntary, independent, high quality, third-party Certification Scheme available to pharmaceutical excipient manufacturers and distributors worldwide. This is a means of enhancing patient safety and improving assurance of supplier quality.

EXCiPACT™ promotes the Quality Certification of Pharmaceutical Excipient manufacturers and distributors through a network of credible certification bodies and qualified auditors. 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.

EXCiPACT™ is committed to ensuring that GMP, GDP and GWP

certifications 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 suppliers and customers. Our vision is to ensure that EXCiPACT™ Certification represents an independent and trustworthy quality assessment of suppliers.

### THE KEY CRITERIA FOR ENSURING THE QUALITY MANAGEMENT SYSTEM ARE:

- The management of EXCiPACT™ is ensured by representatives from the association, who are committed to ensure 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.
- An EXCiPACT™ management body continuously acting in the interest and the ethical rules of the association. This is ensured by a continuous communication to the EXCiPACT™ scheme stakeholders.
- Quality Auditors are duly trained and evaluated by the association, with the goal of delivering consistent audits. This is achieved by ensuring their competences are appropriate with regards to their responsibilities, their GxP expertise and their independence.
- 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. The Quality Standard developed by the EXCiPACT™ association is periodically updated considering the changes of Quality Requirements.

### OUR QUALITY COMMITMENT:

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

- Upgrading our internal processes by the continuous improvement of our quality system which is continuously aligned with the ISO Quality standards.
- A well-defined, independent supervision of Certification Body accreditation and registration, as well as assessing and accepting registered Auditors according to our quality standards.
- The verification of our Registered Certification Bodies, Registered Auditors and Certified Excipient suppliers on our web site, [www.excipact.org](http://www.excipact.org).
- Continuous support to our supply chain community, with the permanent objective of the patient protection and medicinal product safety and efficacy.
- This is achieved via training sessions, direct communication and via our web site ([www.excipact.org](http://www.excipact.org)).

15 November 2023

**Morad Amadji**

**Président**

**Alain Bécart**

**Quality Manager**

EXCiPACT asbl, Rue Marie de Bourgogne 52, 3rd Floor, B-1000 Brussels, Belgium

E: [info@excipact.org](mailto:info@excipact.org) W: [www.excipact.org](http://www.excipact.org) T: +32 2 213 74 49 VAT: BE0545 771 884 IBAN: BE50 3631 3158 8018

RPM Brussels Capital Region - EXCiPACT is a registered trademark