Case Study

Due diligence of the dossier documentation for a medicinal product

Challenge

Evaluation of drug product documentation under time pressure

Solution

Ad-hoc support by a dedicated Regulatory Expert

Outcome

Confirmation obtained for acquisition and marketing of the medicinal products

- Medium-sized EU-based pharmaceutical company.
- The client intended to acquire the marketing authorizations for three strengths of an oral anti-diabetic medicinal product intended for use in patients with type II diabetes.
- Client was in the need of due diligence to review the dossier and assess the quality of a planned acquisition by the company before imminent expiry (Sunset Clause).

- Dedicated Regulatory Expert lead this ad-hoc due diligence project; no extended governance framework was required.
- Focus of review and assessment was a gap analysis of the quality documentation and the pharmacokinetic / bioequivalence study.
- Regulatory advice to avoid imminent expiry of the marketing authorizations (Sunset Clause) provided.

- Client obtained confirmation that the quality of the dossier documentation is completely applicable.
- No hidden gaps or issues were identified which may have a critical impact critical on a successful product acquisition and launch before expiry as well as long-term marketing of the medicinal products.