

Bridging continents: EU → US & Canada



- **CMC Feasibility Assessment & Regulatory Roadmaps**
- **CMC Regulatory Strategy** for all FDA/CA procedures
- **Parallel development EU/US/CA**
- **CMC & Technical Scientific Documentation Writing**
- **Including Gap Analysis** of EU pre-existing dossiers **and refurbishment** towards U.S/CA registration
- **e-Submission CMC Expert Services**

US and Canada Market Entry and Strategic Alliances in figures:

In the past five years, ASPHALION has managed over 100 projects involving the preparation, submission, and/or maintenance of various types of applications for the US and Canadian markets.

These activities have included Medical-Scientific Writing (CMC, Clinical, Non-Clinical), Publishing, meetings arrangement, and meeting packages elaboration.