

ASPHALION'S EXPERIENCE WITH API REGISTRATION

Business Case: long-term regulatory support for API registration and life-cycle management in Europe

An **international pharmaceutical manufacturer** required regulatory support to **establish and maintain the European pathway for one of its active pharmaceutical ingredients (APIs)**. The project initially focused on registration activities and subsequently expanded to include the preparation of the Active Substance Master File (ASMF), its lifecycle management in eCTD format, and ongoing dossier maintenance. In parallel, Asphalion supported the client in the development and maintenance of API monographs across two major pharmacopoeial frameworks, ensuring alignment with applicable quality and regulatory requirements.



CHALLENGE

An **international manufacturer needed support** not only for the initial **registration of an API in Europe**, but also for ensuring **long-term regulatory compliance** and **continuity** in line with evolving regulatory requirements.

The project involved several interconnected needs:

- Support for the initial EU registration strategy.
- Preparation of the Active Substance Master File (ASMF).
- Adaptation of the dossier to eCTD requirements.
- Ongoing maintenance throughout the product life-cycle.
- Collaboration in API monograph preparation activities.



SOLUTION

Asphalion provided **end-to-end regulatory support** across the full life-cycle of the API dossier, including:

- Support for the initial European registration of the API.
- Preparation and structuring of the ASMF.
- Development and transition of the ASMF into eCTD format.
- Long-term maintenance and updates of the dossier.
- Collaboration with the client on API monograph preparation across two pharmacopoeial frameworks.



OUTCOME

This project reflects the value of a long-term regulatory partnership for API manufacturers operating in Europe.

Beyond the initial registration milestone, the support provided helped ensure ongoing dossier maintenance, alignment with evolving submission requirements, and contributed to broader technical and regulatory activities related to the API.

It highlights an important point for API manufacturers:

Regulatory success in Europe depends not only on achieving initial registration, but also on maintaining a sustainable strategy for dossier life-cycle management.