

API

Optimize your Active Pharmaceutical Ingredient Life-Cycle Management

Structured, scalable, and expert-driven support for marketed pharmaceutical portfolios

Asphalion acts as a strategic CMC life-cycle management partner for your APIs, providing specialized regulatory expertise and flexible operational support to ensure dossier consistency, compliance, and long-term portfolio sustainability across global markets.



Staying Ahead of Regulatory Changes

The expected update to the ICH M4Q guideline will likely introduce substantial changes to the structure and presentation of Modules 2.3 and 3. Preparing early is essential to minimize future operational impact and ensure a smooth regulatory transition.



Strengthening Portfolio Consistency & Compliance

Managing dossier updates, post-approval commitments, document updates, and alignment across multiple markets requires robust oversight to minimize inconsistencies and mitigate regulatory risk.



Enabling International Expansion & Licensing Activities

Well-structured and up-to-date CMC documentation plays a key role in supporting registrations in new territories and facilitating licensing or due diligence processes with third parties.



Optimizing Operational Efficiency

Outsourcing CMC Life-Cycle Management enables companies to access specialized expertise without increasing internal headcount or operational fixed costs.

Strengthen Compliance Through Smarter APIs Life-Cycle Management

WHY ASPHALION

- **Specialized expertise** in CMC life-cycle management
- **Scalable outsourcing support** tailored to portfolio needs
- **Proactive guidance** for regulatory changes and ICH M4Q updates
- **End-to-end management** of dossier updates and post-approval activities
- Strong focus on **compliance, consistency, and traceability**
- **Global alignment** of CMC documentation across markets
- Support for **international registrations and licensing activities**
- **Flexible and cost-efficient** operational support
- **Continuous oversight** to maintain regulatory readiness
- **Long-term partnership** focused on portfolio quality and sustainability