ASPHALION
Knowledge from experience

CMC solutions for biosimilars

We simplify complexity. We anticipate challenges. **We accelerate your path to market.**

ASPHALION
Knowledge from experience

Strategy from the start

A **successful biosimilar** development begins with a **well-defined CMC strategy** that aligns with global regulatory requirements.

- CMC Regulatory Strategy: US, EU, Canada, and Australia
- QTPP Definition
- QbD Implementation
- Risk Management
- Scientific Advice and Pre-Submission Meetings

ASPHALION
Knowledge from experience

Robust and scalable development

We support you in developing solid, reproducible, and **market-ready processes**.

- Formulation Development
- Process Characterization, Optimization, and Validation
- Scale-Up and Technology Transfer
- Analytical Method Development and Validation
- Similarity and Comparability Studies
- Stability Study Design and Shelf-Life Determination
- GMP Compliance

Efficient regulatory execution

We transform technical complexity into clear, well-supported, and **defensible dossiers.**

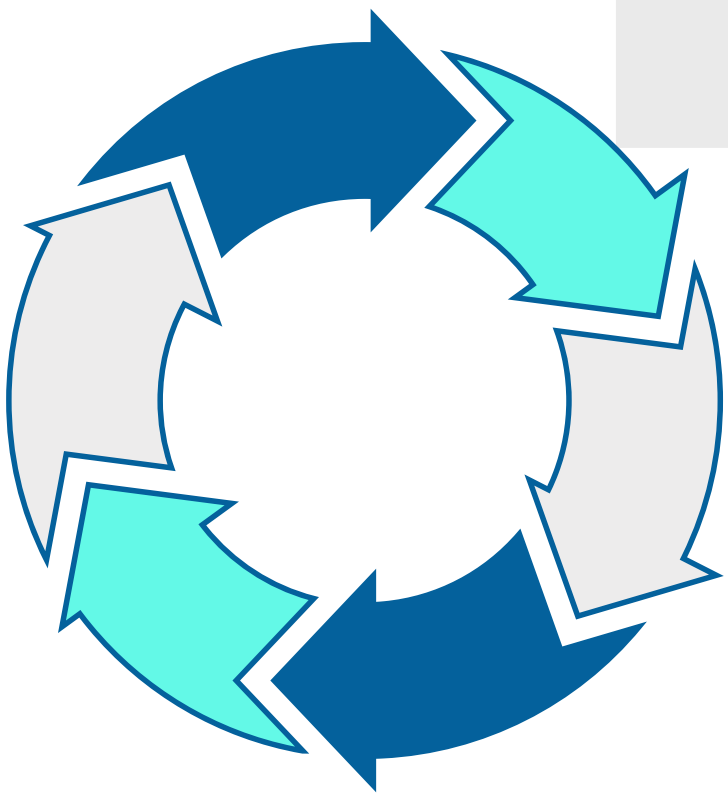
- Preparation of Module 2.3 and Module 3 (eCTD) for IMPDs, INDs, MAAs and BLAs.
- Amendment Management
- Response to Regulatory Authority Questions
- Interaction with Regulatory Agencies

ASPHALION
Knowledge from experience

Life-Cycle control

Approval is just the beginning.
We provide continuous support throughout your product's lifecycle.

- CMC Change Control
- Post-Approval Change Strategy and Management
- Analytical Comparability Exercises
- Gap Analysis and Due Diligence
- Project Management
- Specialized CMC Training for Biosimilars



Your Trusted Partner

Why Asphalion?

- Strategic vision
- Regulatory expertise
- Scientific precision
- Partnership mindset

Let’s build your regulatory strategy together!

Contact us:

info@asphalion.com
www.asphalion.com