

CMC dossier writing for biosimilars

From IMPDs and INDs to MAAs and BLAs
Clear. Consistent. Submission-ready.



The challenge

Complex CMC data requires a **clear regulatory narrative**

Biosimilar dossiers must include critical information on:

- Manufacturing
- Analytical methods
- Control strategy
- Comparability
- Stability

Structured to ensure **consistency, compliance, and readiness for submission**



How We Support You

We provide preparation and support for:

- IMPDs
- pre-INDs / INDs
- MAAs / BLAs
- Module 2.3
- Module 3
- eCTD-ready CMC documentation

Across **clinical development, registration, and life-cycle management.**

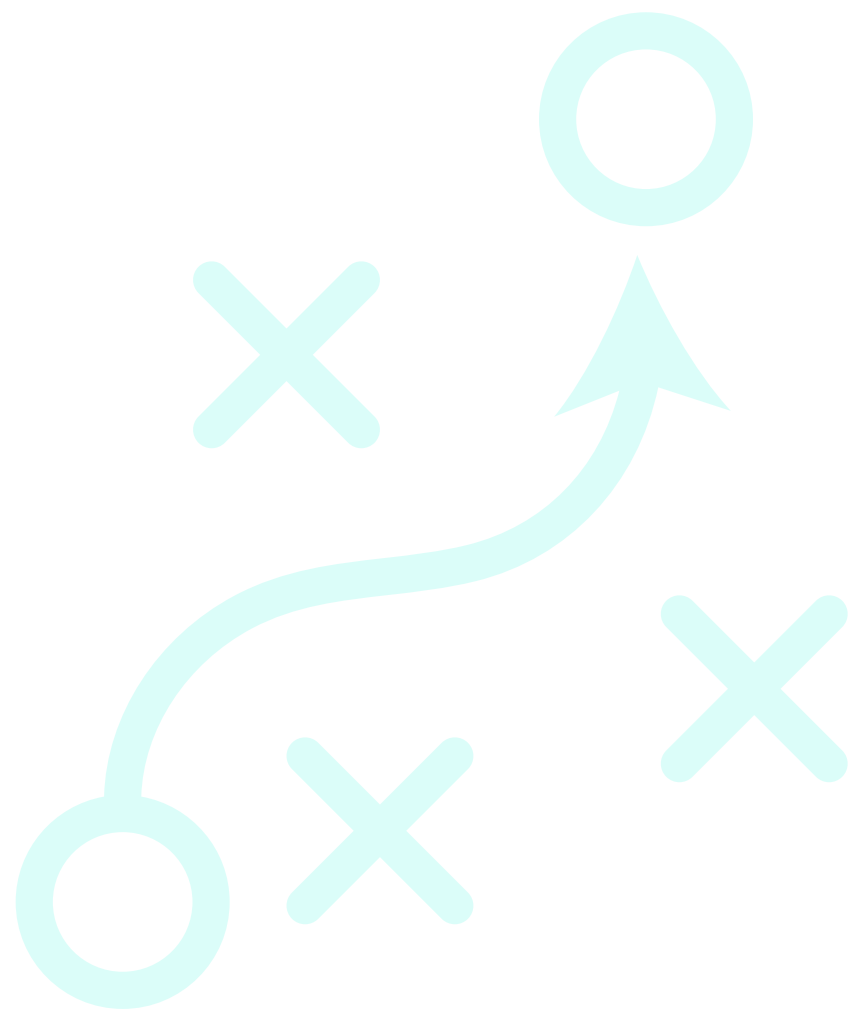


Beyond writing services

Beyond dossier authoring, we support:

- CMC dossier strategy
- Content structuring and consistency
- Data gap identification
- Responses to Health Authority questions
- Amendments and post-approval updates
- Interactions with Health Authorities

Because **strong documentation** begins with **strong regulatory thinking**.



Why Asphalion

We help transform complex CMC information into dossiers that are:

- Scientifically robust
- Regulatory-aligned
- Clearly structured
- Submission-ready

In biosimilars, the quality of documentation matters.



Why Asphalion?

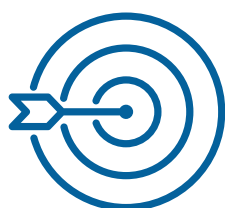
Your Trusted Partner



**Strategic
vision**



**Regulatory
expertise**



**Scientific
precision**



**Partnership
mindset**

Let's build your regulatory strategy together!

Contact us:

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