

Is your CMC dossier ready to support expansion and licensing?

CMC life-cycle maintenance is not only about compliance. It also affects how quickly and confidently a portfolio can move.



The broader role of the dossier

A well-maintained dossier supports more than regulatory continuity.

For mature products and broad portfolios, the quality of **CMC documentation** can also **influence how efficiently** a company approaches **new registrations, partnerships, transfers or due diligence processes.**



Why expansion creates pressure

Entering new markets requires documentation that is clear, consistent and current.

When **CMC information is fragmented**, outdated or difficult to trace, preparing dossiers for new geographies becomes **slower and more resource-intensive**.



Why licensing raises the bar

Licensing discussions often test the dossier before the authority does.

Potential partners need confidence that the **CMC package is organized, reliable and fit for evaluation**. Gaps or inconsistencies can create unnecessary friction during assessment.



Common friction points

Readiness issues are often not visible until the dossier is needed.

Typical challenges include:

- Inconsistencies across versions or markets
- Limited traceability of historical changes
- Outdated supporting documentation
- Lack of a consolidated CMC view across the portfolio



What readiness looks like

A dossier ready for expansion or licensing is more than technically complete.

It should also be:

- Structured
- Up to date
- Internally consistent
- Easy to navigate
- Able to support efficient review by regulators, partners or third parties



Supporting Long-Term Portfolio Success

In many cases, dossier maintenance is not just a regulatory activity. It is part of portfolio readiness.

A stronger CMC maintenance model can help companies support international growth, reduce friction in licensing discussions and improve the overall usability of their dossiers.

At Asphalion, we support pharmaceutical companies in maintaining CMC dossiers that are not only compliant, but also fit for business opportunities.



Your Trusted Partner

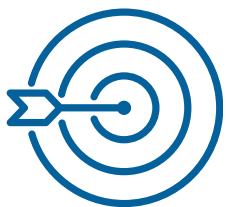
Why Asphalion?



**Strategic
vision**



**Regulatory
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**Scientific
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**Partnership
mindset**

Let's build your regulatory strategy together!

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