

5 Signs your Portfolio's CMC Maintenance needs a stronger approach

In large portfolios, **life-cycle maintenance can become increasingly complex** if it is not managed in a structured way.



Life-Cycle management has become largely reactive

Variations, document updates, post-approval commitments, and market alignment activities are **managed based on urgency rather than** through a **clear, structured and sustainable plan.**



Maintaining consistency across CMC documentation requires increasing effort

As the number of products, markets, and accumulated changes grows, so does the **risk of misalignment across dossiers, document versions, and regulatory strategies.**



Document traceability is not always immediate

When historical information, implemented changes, or the regulatory rationale are not well organized, **even routine updates or reviews can require more time and resources than expected.**



The dossier is not always ready for new markets or licensing activities

International expansion, transfers, or third-party **opportunities require CMC documentation that is well organized, up to date, and easy to assess.** Achieving this level of readiness quickly can be challenging.



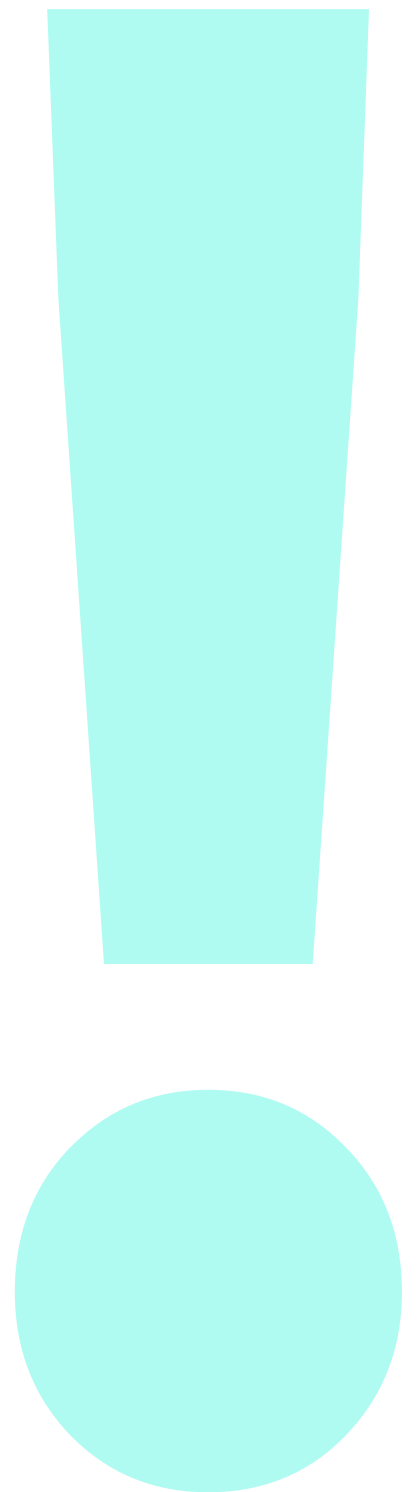
Future regulatory changes are seen as an additional burden

The expected evolution of references such as **ICH M4Q**, with potential impacts on the structure of **Module 2.3 and Module 3**, will make it even more important to maintain well-structured dossiers and have a clear adaptation strategy.



**When these signs
keep recurring,
the issue is usually
not isolated.
It is usually the
underlying model**

A more structured and scalable approach to **CMC maintenance** can help reduce internal workload, improve document consistency, and better **prepare the portfolio for future regulatory and business challenges.**



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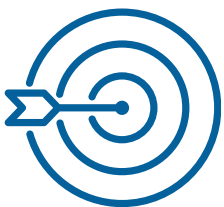
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