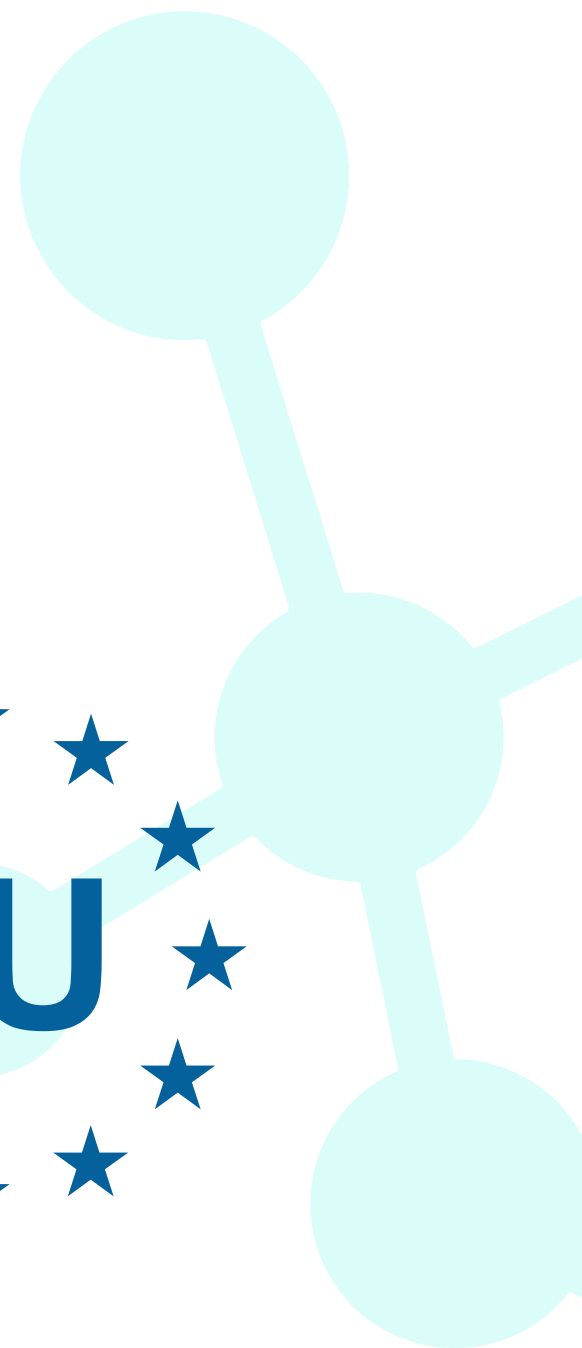


ASMF vs CEP

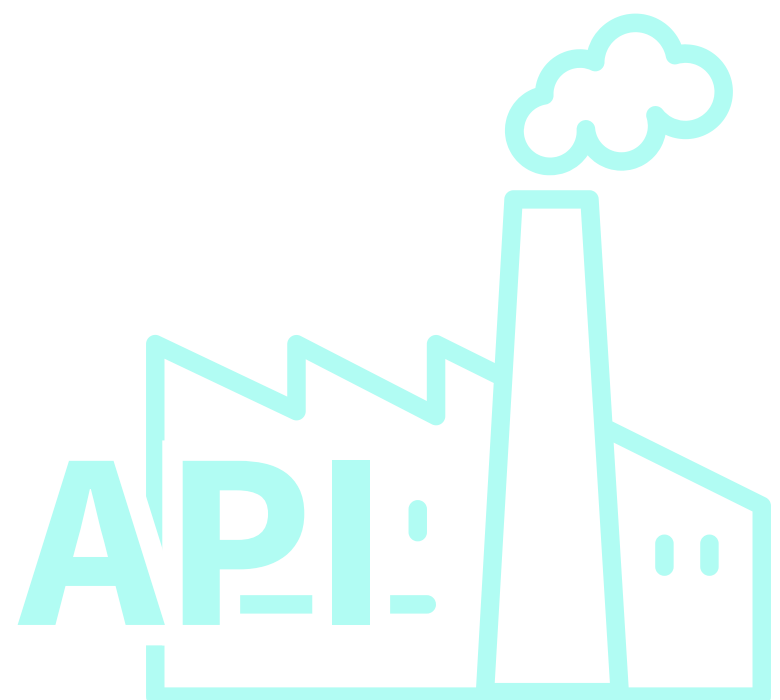
**What API manufacturers need
to know for the EU market**



Why this matters

Why does this matter for **API manufacturers?**

For companies supplying APIs to Europe, **understanding ASMF and CEP is key to supporting customers**, enabling submissions, and building the right regulatory strategy.



What is an ASMF?

ASMF: Active Substance Master File

An **ASMF** is a regulatory submission used in Europe to provide detailed information on the manufacture and control of an API, while allowing confidential information to remain protected from the marketing authorisation holder.

Useful when detailed API information needs to support a medicinal product dossier.



What is a CEP?

CEP: Certificate of Suitability

A **CEP** confirms that the quality of a substance is suitably controlled by the relevant **European Pharmacopoeia monograph**, with additional information assessed by EDQM where needed.

Often used to simplify support for multiple customers and submissions when applicable.



Key differences

ASMF vs CEP: what is the difference?

	ASMF	CEP
Authority involved	National authorities / EMA in the context of a dossier	EDQM
Purpose	Support a specific medicinal product application	Demonstrate suitability to Ph. Eur. monograph
Use of confidential information	Protects restricted part for API manufacturer	Central certification approach
Strategic use	Useful for product- specific dossier support	Useful for broader customer support, if eligible



When is each pathway more relevant?

When might an ASMF or CEP be the preferred route?

The best approach **depends on the API**, the **existence of a Ph. Eur. monograph**, the **business model**, **customer needs**, and long-term **lifecycle strategy**.

- **ASMF** may be preferred when **detailed dossier support is needed**.
- **CEP** may be preferred when the **substance is suitable for certification** and **broader reuse is expected**.

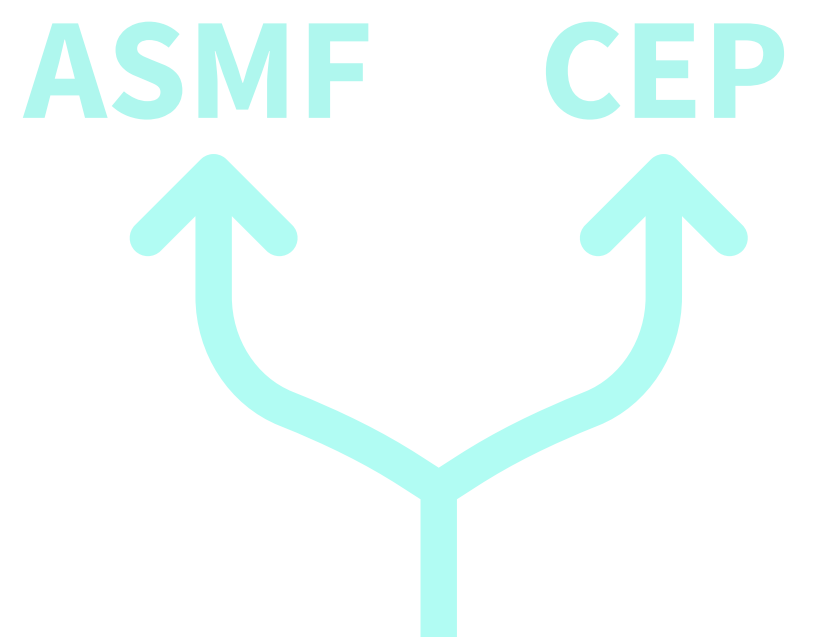


Takeaway

There is no one-size-fits-all approach

Choosing between ASMF and CEP is not only a regulatory decision. It can also impact customer onboarding, submission timelines, confidentiality, and lifecycle management.

A strong EU API strategy starts with understanding which pathway fits your substance and business goals.



Why Asphalion?

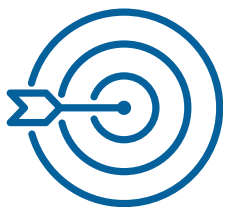
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