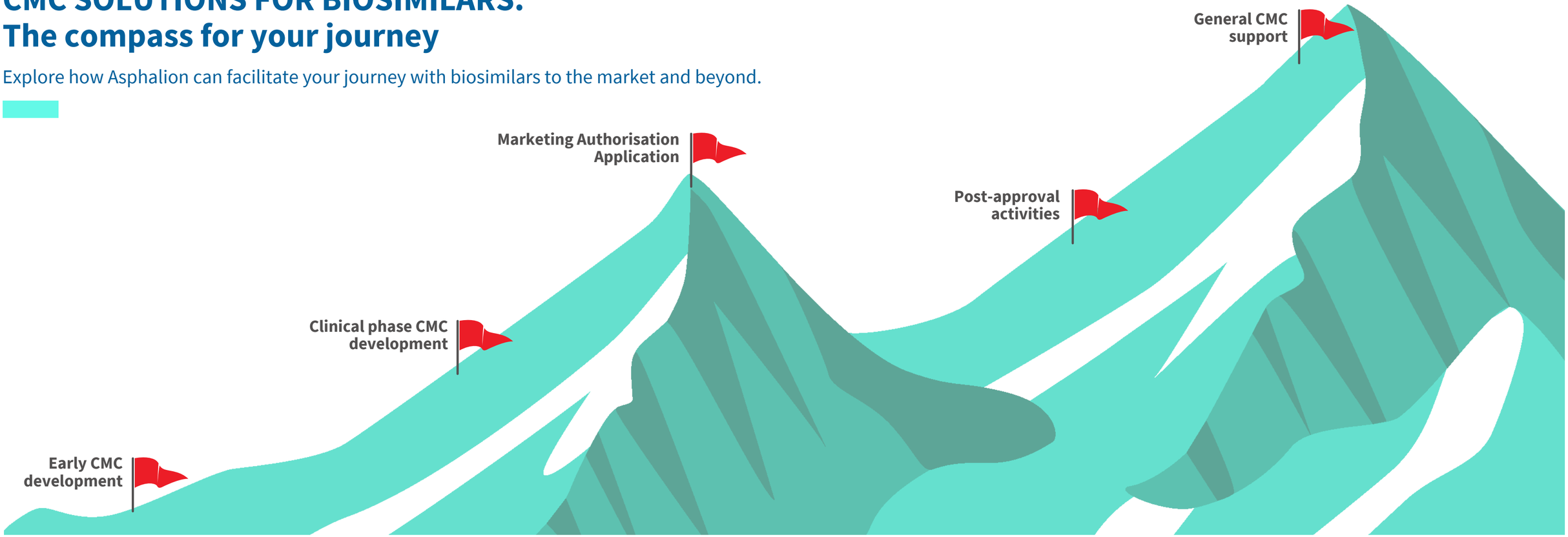
CMC SOLUTIONS FOR BIOSIMILARS: The compass for your journey

Explore how Asphalion can facilitate your journey with biosimilars to the market and beyond.



Early CMC development

- Development of **CMC regulatory strategy** for new products.
- Reference medicinal product selection.
- Formulation development.
- Implementation of **QbD principles**.
- Definition of **QTPP** for biosimilars.
- Manufacturing process characterisation, validation and transfer.
- **Risk management** strategies.
- Development, validation and transfer of **analytical methods**.
- Design and review of **stability testing** protocols.
- Stability data analysis and shelf-life determination.
- **Similarity studies** between biosimilar and reference medicinal product.

Clinical phase CMC development

- CMC requirements for **highly regulated markets** and regulatory pathways.
- **Scaling up** to commercial scale and technology transfer.
- Good Manufacturing Practice (**GMP**) compliance.
- Preparation of CMC sections for regulatory submissions (**IMPDs, pre-INDs/INDs**).
- Analytical **comparability** exercises.
- Substantial and non-substantial amendments for INDs and IMPDs.

Marketing Authorisation Application

- Writing of CMC sections of regulatory submissions (**MAAs, BLAs**).
- Writing of **module 2.3 and module 3** for Electronic Common Technical Document (eCTD).
- **Response to** Regulatory Authorities' questions on CMC **issues**.
- Analytical comparability exercises.

Post-approval activities

- CMC **change control**.
- Strategy, writing and submission of **post-approval changes** (EU and US).
- Analytical comparability exercises.

General CMC support

- **Gap analysis.**
- **Due diligence.**
- **Scientific advice** and pre-submission meetings.
- **Response to** Regulatory Authorities' questions on CMC **issues**.
- **Project management.**
- **Training sessions** and workshops on biosimilar CMC regulatory topics.

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ASPHALION
Knowledge from experience

CMC SOLUTIONS FOR BIOSIMILARS: The compass for your journey

Explore how Asphalion can facilitate your journey with biosimilars to the market and beyond.

Early CMC development

- Development of **CMC regulatory strategy** for new products considering regional requirements (US, EU, Canada, Japan, Australia).
- Assistance on selection or validation of the reference medicinal product/comparator.
- Formulation development support.
- Implementation of **Quality by Design (QbD)** principles in product development.
- Assistance in defining the **Quality Target Product Profile (QTPP)** for the biosimilar, which outlines the desired quality characteristics that the drug product should possess to ensure it meets the intended use, safety, and efficacy.
- Manufacturing process characterisation, including support in development, optimisation, scale-up and validation of manufacturing processes assuring that are reproducible and scalable.
- Implementing **risk management** strategies to identify, analyse, and mitigate risks associated with the biosimilar development and manufacturing.
- Support in development and validation of **analytical methods** that are robust, reliable, and suitable for the analysis of the biosimilar product.
- Analytical and manufacturing site transfer support.
- Design and review of stability testing protocols.
- **Stability data analysis** and shelf-life determination, including extension plans.
- Guidance on designing and conducting **similarity studies** between the biosimilar and the reference medicinal product, including analytical characterisation, biological activity, immunochemical properties, and purity.

Clinical development

- CMC requirements for **high regulated markets** and regulatory pathways (sections preparation, submission and interaction with Regulatory Agencies).
- Guidance on **scaling up** the manufacturing process from laboratory to commercial scale and transferring technology between facilities or to contract manufacturing organisations (CMOs).
- **Good Manufacturing Practice (GMP)** and other relevant regulatory guidelines compliance support.
- Preparation of CMC sections of regulatory submissions (**IMPDs, pre-INDs/INDs**).
- Guidance on designing and conducting analytical **comparability** exercises pre- and post-manufacturing changes.
- Handling of amendments for INDs and IMPDs, including analysis of impact of changes on product safety and quality, update of IMPD sections and support for responses to Regulatory Authorities' questions.

Marketing Authorisation

- Preparation of CMC sections of regulatory submissions (**MAAs, BLAs**).
- **Module 2.3 and module 3** preparation for Electronic Common Technical Document (eCTD).
- **Response to** Regulatory Authorities' questions on CMC **issues**.
- Guidance on designing and conducting analytical comparability exercises pre- and post-manufacturing changes.

Post-approval activities

- CMC **change control** preparation, assessment and management.
- Strategy, writing and submission of **post-approval changes** in European variations and US supplements.
- Guidance on designing and conducting analytical comparability exercises related to the proposed post-approval changes.

General CMC support

- **Gap analysis.**
- **Due diligence.**
- **Scientific advice** and pre-submission meetings.
- **Response to** Regulatory Authorities' questions on CMC **issues**.
- **Project management.**
- Tailored **training sessions** and workshops on biosimilar CMC regulatory topics.