We add value and differentiation to your business as your Regulatory Partners

>> From lab to market

Specialized standalone or integrated CMC solutions

Our EU/US CMC experts can actively collaborate with you in:

1. REGISTRATIONS / APPLICATIONS

- CTD Mod. 2 and 3 writing, review and/or updates for EU and US, including:
  - EU ASMF and US/RoW DMF
  - Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP)
  - EU MAA (CP, DCP, MRP, NP)
  - US ANDA and NDA (505b1 and 505b2)
- Dossier gap analysis (Mod. 2.3 and Mod. 3.2.S, 3.2.P and 3.2.R)
- Due diligence of in-licensing dossiers
- Expert support on responses to Deficiency Letters
- Expert reports

2. PHARMACEUTICAL DEVELOPMENT

- Strategy and Roadmaps development– Integrated with Non-clinical & Clinical development
- Gap analysis at every stage of development
- Implementing and managing Quality by Design
- EU IMPD & US IND Application – writing, review and/or updates
- Dossier writing, review and/or update – EU to US or US to EU
- Due diligence of in-licensed dossiers
- Expert Reports
- Ad hoc regulatory strategy

3. MAINTENANCE / LIFECYCLE MANAGEMENT

- CMC regulatory strategy
- Regulatory compliance gap analysis
- Updating dossier sections – strategy, writing and review
- Variations – strategy, writing, review and/or update of dossier
- Expert support on responses to Deficiency Letters
- Expert reports (including updates)
- Dossier consolidation of legacy dossiers (Mod. 2.3 and 3) towards eCTD publishing
- Ad hoc regulatory strategy

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Specialized standalone or integrated CMC solutions

At ASPHALION, we have a sound knowledge and experience in a wide range of pharmaceutical forms and types of products:

- Solid, liquid and semisolid dosage forms
- Injectable (including freeze-dried), inhaled, topic and oral dosage forms, among others.

We can either provide you with a full integrated support (from lab to market) or with a tailored support as per your specific needs, at any stage of development or during post approval lifecycle of Human Medicinal Products:

- Innovative (chemical and biological)
- Generics
- Biosimilars
- EU Hybrids / US 505b2
- Well-established use
- Herbal

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