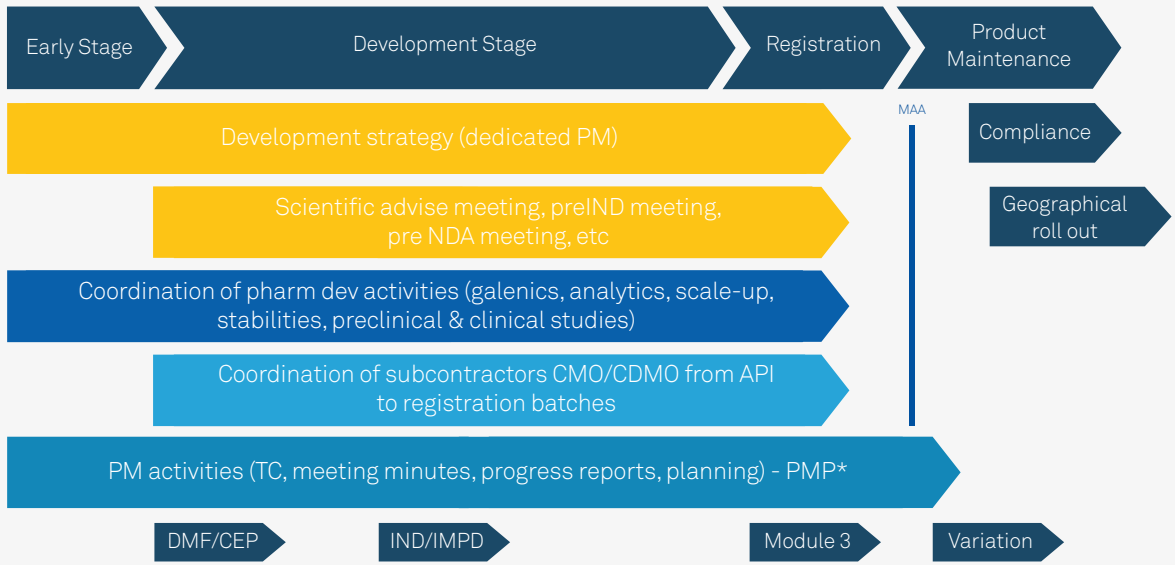
Global CMC business solutions : Pharmaceutical Development, CMC Regulatory Affairs & CMC Project Management

Blue Reg has a team of CMC experts and PMP® project managers dedicated to supporting your company through the full lifecycle of your medicinal products (small molecules, peptides, biologics, ATMP), medical devices and consumer health care products.
From product development, through registration and launch into maintenance, we provide flexible solutions or operational platforms to meet your company's needs.

BlueReg
PHARMA CONSULTING

www.bluereg-group.com

INTERNATIONAL ENVIRONMENT



Our services

Pharmaceutical development: Supporting the development of the best product while ensuring quality compliance

- Strategic consultancy during global pharmaceutical development and lifecycle management
- Expertise in all types of API (chemical, biological, herbals) – Development of ASMF, DMF, CEP
- Strategic advices in drug product development and coordination of activities as formulation, process, analytical development and validation, specifications, stability studies design, setting of shelf life
- Decision making to drive investments: due diligence, gap analysis and experts reviews

CMC Regulatory support: Interacting with authorities at every stage of development and generating associated CMC documentation

- CMC regulatory strategy: identify the scientific package needed at each development stage, check consistency between available data and regulatory requirements, perform gap analysis
- Scientific advice meetings with health authorities (US/Eur/Export)
- Assessment and preparation of regulatory documents : ASMF, DMF, CEP, IND, IMPD, MAA and NDA / BLA module 3, responses to agency questions.
- Maintenance of products on market : Post MAA/ lifecycle management with CMC variations

Project management : Coordination of all activities in pharmaceutical development from product development to registration and geographical roll out

- Establish project objectives whith client and define strategy for managing the project
- Manage risks, control schedule, cost, resources, quality
- Manage teams, workstreams, communication (meeting minutes, review of deliverables), changes
- Identify, Manage and coordinate analytical or manufacturing subcontractors

When work with us ?

The team can cover any step of the product development process, registration as well as product maintenance activities, providing consultancy or hands-on operational support. Interest to have an experienced PM to manage all pharmaceutical activities.

The team

Coming from pharmaceutical industry, our CMC experts and senior project managers certified PMP® have a flexible skill set from product development strategy to operational execution, as well as leading and managing projects. We have extensive knowledge of CMC regulatory requirements in an evolving environment. We are flexible and responsive, used to working in an international environment.

Among our latest missions

- Subject matter expert for impurities and other analytical activities
- Response strategy to health authorities
- CMC expert for the development of a synthetic peptide
- CMC variations with groupings
- Gap analysis for a Phase III in Europe considering existing IND for Phase II