CERTARA

FACT SHEET

Strategic Regulatory Affairs – a Core Function, Central to Business Success

Plan Globally and Act Locally – Regulatory Consulting and More

Global Strategic Regulatory Affairs are essential for businesses of all sizes, from small start-ups to large multinational corporations. They are central to a company's success and to effective product development. Early consideration of global registration needs provides a more efficient and cost-effective roadmap to product delivery.

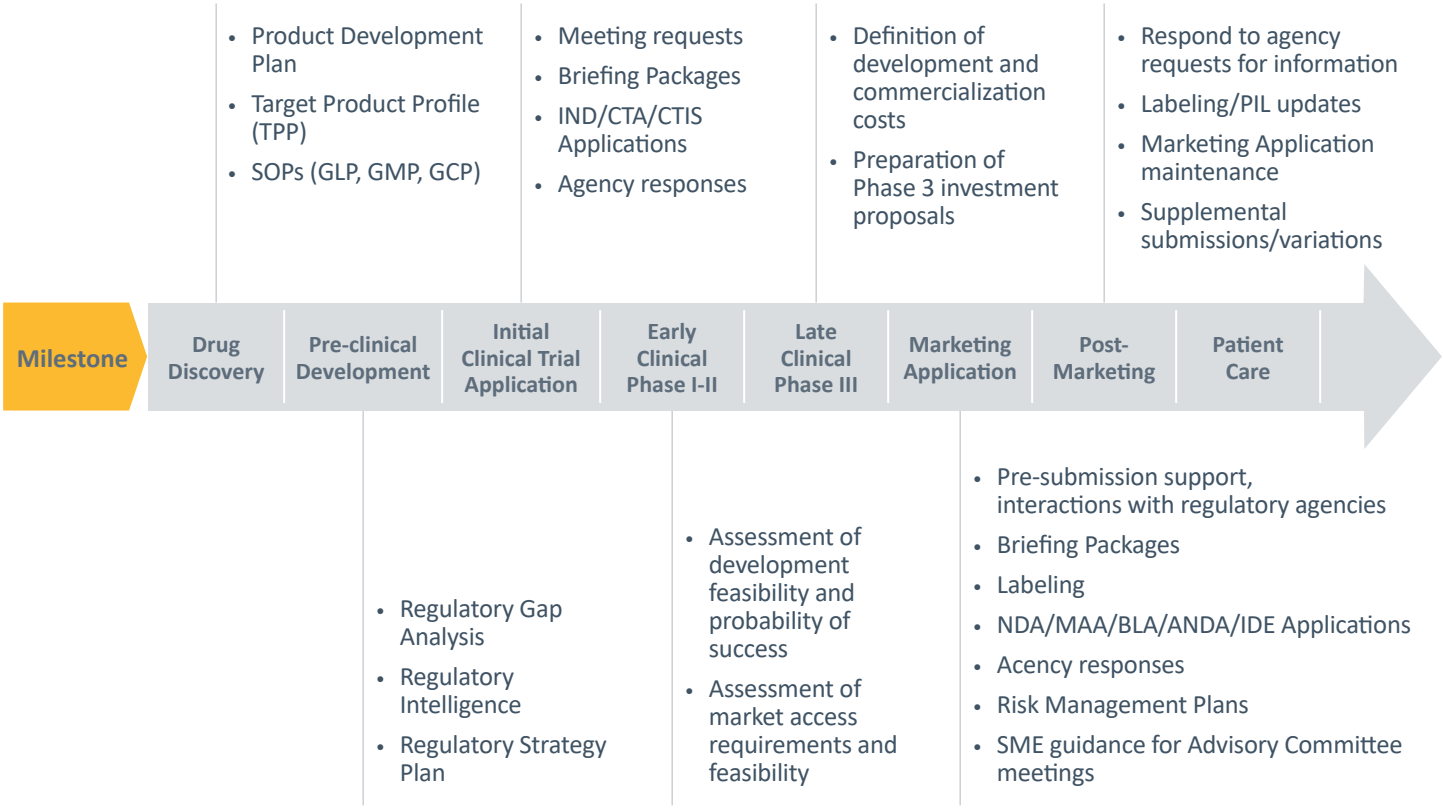
Product development demands a holistic approach encompassing all functional considerations to deliver success.

At Certara, our teams of regulatory experts help our clients optimise their global regulatory strategy from product concept through to commercial product maintenance, integrating the needs of all required functions to ensure a total development strategy as required.

Our Comprehensive Global Strategic Regulatory Affairs Expertise spans across the entire life cycle of the project, with emphasis on strategic consulting and regulatory advice.

Key Services | **Regulatory Strategy**

throughout the life-cycle of the project



CERTARA

Increase Program Success with Certara

Our Regulatory Consulting and Strategic Advice teams offer full global support in Asia Pacific, North America, Latin America, Europe, Africa, and the Middle East.

Our experts are skilled in navigating the complexities of non-standard projects by creating unique and novel solutions tailored to meet global regulatory requirements, which do not necessarily fit within the confines of standard guidance.

We thrive on innovation, leveraging deep expertise and strategic thinking to overcome unique challenges and expedite the approval process worldwide.

Whether dealing with novel therapies, unconventional study designs, or cross-border regulatory hurdles, we deliver customized strategies that ensure compliance and facilitate successful outcomes and regulatory support that adapts to the ever-evolving landscape of global healthcare.

Why Certara? Robust regulatory expertise with a proven record of success

Experience

Our Strategic Regulatory Affairs team has over 75 years combined experience in global regulatory affairs supporting projects from concept to post market support.

Strategic Regulatory Strategy Leadership

Geoff Fatzinger
VP, Regulatory Strategy

25+ years experience in pharmaceutical industry

Specialties include leading the complete product development life cycle

Expertise in many complex therapeutic areas

Questions? **Contact us for a complimentary consultation** to learn how Certara can help provide regulatory strategy, consulting, and submissions support to solve your regulatory challenges.

Contact: Geoff Fatzinger | **Geoff.Fatzinger@Certara.com**

About Certara

At Certara, we accelerate medicines to patients, partnering with life science innovators. Together we advance modern drug development with biosimulation, regulatory science, and market access solutions.
For more information visit certara.com