ASPHALION
Knowledge from experience

BUSINESS CASE

Case Study: GMO Submission Support in EU and Non-EU Territories for Clinical Trial Initiation

CHALLENGE

A major pharmaceutical company requested regulatory support to manage **simultaneous GMO submissions across multiple EU and non-EU territories,** ensuring the timely initiation of its clinical trial. The project involved significant variations in territory-specific regulatory requirements, documentation expectations, and predefined timelines.

- Each territory requires separate **country-specific submission packages** reflecting specific local **GMO requirements and regulations**.
- Some territories required GMO submissions linked to clinical trial application (CTA) timelines, while others followed independent pathways. Both required careful **regulatory assessment and planning**.
- Submission timelines had to be aligned across countries to avoid delays to **clinical trial start-up**.
- Aligning parallel GMO submissions across territories with varying review schedules, while balancing **regulatory disclosure requirements and the protection of confidential information**.

SOLUTION

Asphalion rapidly established and deployed a dedicated **strategic framework** to coordinate synchronized GMO submissions across multiple territories, each with distinct regulatory requirements, timelines, and disclosure expectations:

- Defining a territory-specific roadmap and **submission strategy aligned** with global CTA timelines.
- Establishing a **priority submission order** based on **country evaluation times**.
- **Mapping each country** according to its GMO pathway and regulatory requirements, maintaining proactive interactions with local authorities to clarify expectations.
- Providing dedicated **project management** and **writing support** to coordinate parallel submissions.
- Developing and maintaining territory-specific GMO submission packages while ensuring **consistency** of the core data set **across all EU and non-EU territories**.

OUTCOME

Regulatory Clarity, Coordination and Confidence

The client **gained a clear, territory-by-territory understanding** of applicable GMO requirements and their interdependencies with CTA activities.

Submission planning became more predictable through ongoing regulatory assessment and proactive communication with local authorities.

Achievement of Key Milestones

Timely GMO submissions and approvals across relevant EU and non-EU territories.

Maintenance of critical CT milestones and timelines by avoiding country-specific regulatory delays.

Streamlined Clinical Trial Start-Up

The risk of local GMO requirements becoming a bottleneck for clinical trial initiation **was reduced**.

Smoother country activation was facilitated through coordinated documentation planning, submission management, and interactions with local authorities.