



Case Study

Operating as an Integrated Regulatory Writing and Submission Partner for Small and Mid-Size Pharma

Small and mid-size pharmaceutical companies often face heavy regulatory demands without sufficient internal expertise or infrastructure. MMS supports these sponsors by providing regulatory writing, project management, and submission services across Phase 2/3 programs, Fast Track designations, pediatric planning, and IND submissions. By augmenting lean teams with experienced professionals, MMS helps sponsors meet agency timelines, manage evolving requirements, and progress development programs without needing to build permanent in-house regulatory capabilities.

The Challenge

Advancing Regulatory Programs with Limited Internal Resources

Sponsors faced limited in-house regulatory capacity, evolving programs, and aggressive timelines driven by agencies and investors. Needs included End of Phase 2 preparation, Phase 3 planning, Fast Track requests, pediatric plans, and IND submissions. Many lacked document management systems and standardized processes, complicating reviews and submissions. To sustain progress, sponsors required a flexible partner to deliver hands-on regulatory support and scale efforts as program demands changed.

The Solution

Flexible Regulatory Writing and Submission Execution

MMS delivered tailored regulatory support by deploying project managers, writers, operations specialists, and document management resources. Teams handled clinical protocols, briefing documents, Fast Track requests, pediatric plans, and IND submissions. Where infrastructure was lacking, MMS implemented centralized document systems to streamline reviews. MMS also supported agency interactions and adapted to evolving strategies, enabling sponsors to manage parallel submissions efficiently without disrupting operations.



The Results

Regulatory Milestones Achieved and Programs Advanced

MMS enabled sponsors to achieve key regulatory milestones, including End of Phase 2 meetings, Fast Track approvals, pediatric plans, and multiple IND submissions. Sponsors gained clearer Phase 3 strategies, improved readiness, and reduced internal workload. MMS often extended support beyond initial projects. By delivering expert regulatory execution without adding permanent staff, MMS helped small and mid-size companies advance development programs efficiently and confidently.

Key Success Factors

- Flexible regulatory resourcing model aligned to sponsor size and program maturity
- Ability to support diverse regulatory deliverables, from INDs to Fast Track and pediatric plans
- Rapid onboarding to sponsor-specific processes and evolving program direction
- Practical document management solutions that improved efficiency and visibility
- Trusted partnership approach that extended beyond single submissions

Let's talk!

If you'd like to discuss this case study further or learn more on how our technology enabled services can support your development project, please visit mmsholdings.com or get in touch info@mmsholdings.com