Syner-G

Case study highlight

How a medical writing partnership drives regulatory success.

A timeline of achievement in marketing submissions.

Navigating regulatory approvals demands precision, expertise, and collaboration. Our long-standing partnership with a global biopharmaceutical leader has driven success across multiple therapeutic areas, accelerating submissions and ensuring timely approvals worldwide.

2013

Initiated medical writing support under a master services agreement.

2016

Approval for a treatment for chronic respiratory disease

2017

Approval secured for a biologic therapy in a severe respiratory condition

2019

Authorization granted for a biologic therapy self administration option

Expanded collaboration to support vaccine submissions

2020

Approval achieved for a treatment for chronic respiratory disease.

2021

Regulatory approval for an emergency vaccination program

2023

Adopted an accelerated regulatory submission document authoring model

2024 - 25

Approval obtained for a treatment targeting rare inflammatory disease

Continued contributions to global marketing applications and document authoring strategies

Contributions to regulatory success

Document authoring across clinical development lifecycle

- Clinical study protocols
- Investigator's brochures
- Clinical study reports
- Paediatric investigation plans / pediatric study plans
- Agency briefing documents

Innovative Authoring Approaches

- Collaborate with sponsor teams to extensively pre-plan key messages, fostering stakeholder buy-in and ensuring cross-document consistency
- Adopt practives of lean authoring and strategic review to streamline document development
- Work with statistical programming teams to accelerate creation of in-text data displays

Multi-market regulatory submission development

- Common technical document
- Clinical summaries of efficacy, safety, & immunogenicity
- Risk management plans
- Responses to health authority queries
- Post-marketing updates

Expert Medical Writing Leadership

- Project management for large-scale regulatory submissions
- Quality control & compliance with regulatory standards
- Cross-functional collaboration with product teams

Why our expertise matters

1. **Document authoring across clinical development lifecyle**
   Seamless integration into regulatory workflows.
2. **Cross-functional collaboration**
   Active engagement with industry-leading teams
3. **Technical System Expertise**
   Facility with Electronic Document Management Systems and collaborative authoring tools. Ability to quickly learn and adapt to new technologies and processes
4. **Strategic Messaging & Clarity**
   Production of cohesive, high-impact regulatory documentation

With a proven track record in in regulatory medical writing, our expertise accelerates the approval of groundbreaking therapies, bringing innovative treatments to patients faster.

Advancing human health faster, together