

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.

- Approval for a treatment for chronic respiratory disease.

2016**2017**

- Approval secured for a biologic therapy in a severe respiratory condition.

- Authorization granted for a biologic therapy self-administration option.
- Expanded collaboration to support vaccine submissions.

2019**2020**

- Approval achieved for a treatment for chronic respiratory disease.

- Regulatory approval for an emergency vaccination program.

2021**2023**

- Adopted an accelerated regulatory submission document authoring model.

- Approval obtained for a treatment targeting rare inflammatory disease.
- Continued contributions to global marketing applications and document authoring strategies.

**2024-
2025**

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 practices 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 and Overviews
- Integrated 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

- 📍 **Regulatory & Compliance Mastery** – Seamless integration into regulatory workflows.
- 📍 **Cross-functional Collaboration** – Active engagement with industry-leading teams.
- 📍 **Technical System Expertise** – Facility with Electronic Document Management Systems and collaborative authoring tools. Ability to quickly learn and adapt to new technologies and processes.
- 📍 **Strategic Messaging & Clarity** – Production of cohesive, high-impact regulatory documentation.

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

Advancing Human Health Faster, Together