

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 – Approval obtained for a treatment targeting rare inflammatory disease.

2025 Continued contributions to global marketing applications and document authoring strategies.

Contributions to Regulatory Success

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

Document Authoring Across Clinical Development Lifecycle

- Clinical Study Protocols (CSPs)
- Investigator's Brochures
- Clinical Study Reports (CSRs)
- Paediatric Investigation Plans / Pediatric Study Plans
- Agency Briefing Documents

Multi-Market Regulatory Submission Development

- Common Technical Document (CTD)
- Clinical Summaries and Overviews
- Integrated Summaries of Efficacy, Safety, & Immunogenicity
- Risk Management Plans (RMPs)
- 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

Advancing Human Health Faster, Together

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

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