GENBIOCA
Domain Led, Technology Services Company

WE ARE THE TRUSTED



Medical Writing Services Partner

Medical Writing Excellence

Precision in Every Word. Compliance in Every Line.

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THE WRITING IMPERATIVE

Why Medical Writing Matters Now

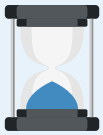
In an era of heightened regulatory scrutiny and complex science, the quality of your documentation directly determines:

- Speed to Approval — Submissions delayed by incomplete or inconsistent documents cost millions in lost revenue
- Regulatory Success — First-pass approval rates hinge on clarity, accuracy, and compliance
- Scientific Credibility — Publications and disclosures shape physician adoption and market confidence
- Risk Mitigation — Poor documentation invites regulatory queries, rejections, and compliance violations



The Challenges You Face

Time Pressure
- Tight deadlines for IND/IDE submissions, annual reports, and safety updates
- Competing priorities across multiple pipeline programs



Complexity Explosion
- Evolving ICH guidelines (E3, E6, M4, M8)
- Multi-regional requirements (FDA, EMA, NMPA, PMDA, Health Canada)
- Increasing demand for real-world evidence and patient-centric narratives



Quality Demands
- Zero-tolerance for errors in safety narratives and statistical reporting
- Consistency across hundreds of pages and multiple authors
- Integration of data from disparate sources (clinical, statistical, safety, regulatory)



Resource Constraints
- Specialized medical writers are scarce and expensive to retain in-house
- Peak workload periods exceed internal capacity
- Maintaining expertise across diverse therapeutic areas and document types



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The GenBioCa Solution

Regulatory Submissions

- Common Technical Documents (CTD/eCTD)
- Module 2 Summaries (2.5, 2.7)
- Investigator Brochures (IB)
- IND/NDA/BLA/MAA Submissions
- 510(k), PMA, De Novo (Devices)

Clinical Documentation

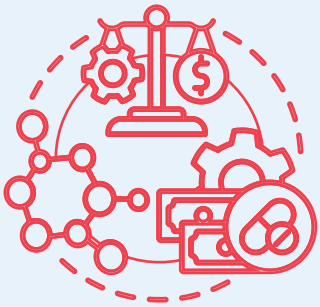
- Clinical Study Reports (CSR) — Full & Synoptic
- Protocols & Protocol Amendments
- Statistical Analysis Plans (SAP)
- Informed Consent Forms (ICF)
- Case Report Forms (CRF)

Safety & Compliance

- Safety Narratives (AE/SAE)
- DSMB Reports & Charters
- Periodic Safety Update Reports (PSUR/PBRER)
- Risk Management Plans (RMP)
- REMS Documents

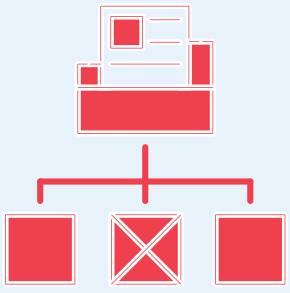
Publications & Disclosures

- Manuscripts for Peer-Reviewed Journals
- Abstracts & Posters for Congresses
- White Papers & Medical Education Materials
- HEOR & Market Access Documentation



Specialized Documents

- Clinical Overviews & Summaries
- Integrated Summaries of Safety/Efficacy (ISS/ISE)
- Response to Regulatory Queries
- Pediatric Investigation Plans (PIP)



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The GenBioCa Difference

Our Writing Philosophy

Scientific Rigor + Regulatory Intelligence + Reader Clarity

Every document we produce balances three imperatives:

1. Factual Accuracy — Meticulous data verification and cross-reference checking

2. Regulatory Compliance — Aligned with current guidelines and agency expectations

3. Narrative Coherence — Logical flow that tells your data's story convincingly

Capabilities That Deliver

Therapeutic Expertise



- Oncology, CNS/Neurology, Cardiovascular, Immunology, Infectious Diseases, Rare Diseases, Medical Devices/Diagnostics

Global Regulatory Fluency



- FDA (US), EMA (EU), PMDA (Japan), NMPA (China), Health Canada, TGA (Australia), MHRA (UK), and emerging markets

Operational Excellence

- Standardized Templates — Proprietary, agency-tested templates accelerate development
- Parallel Workflows — Statistical and medical writing teams collaborate from Day 1
- Quality Gates — Medical review, biostatistical verification, and QC at every milestone
- Technology-Enabled — AI-assisted literature review and consistency checking tools

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Flexible Engagement Models

Model	Best For
Project-Based	Discrete submissions, one-time needs
Dedicated FTE	Ongoing pipeline support, embedded teams
Functional Service Provider (FSP)	Long-term partnership, volume flexibility

Client Outcomes

Metric	GenBioCa Performance
First-Pass Regulatory Approval Rate	98.5%
On-Time Delivery	99%
Major Query Reduction vs. Industry Average	40%
Document Revision Cycles	≤2 (industry average: 4-6)

Why Partner With GenBioCa?

Writer Quality — Doctors + average 10+ years industry experience

Process Maturity — ISO-compliant QMS with documented SOPs and training programs

Scalability — Rapid team ramp-up for large submissions (NDA/MAA) without quality dilution

Cost Efficiency — Competitive rates with no compromise on expertise or turnaround

Confidentiality — Robust data security, GDPR compliance, and strict confidentiality protocols

Ready to Elevate Your Documentation?

Whether you're preparing your first IND, responding to a Complete Response Letter, or managing a portfolio of Phase III programs, GenBioCa delivers the writing excellence that advances your assets.

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Website

www.genbioca.com

Enquiry

gbc@genbioca.com