



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.

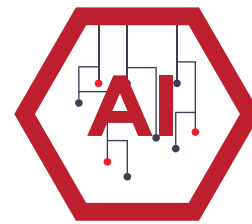


THE WRITING IMPERATIVE

Why Medical Writing Matters Now

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

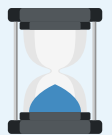
- Speed to Approval – Submissions delayed by incomplete or inconsistent documents cost millions in lost revenue
- Regulatory Success – First-pass approval rates hinge on clarity, accuracy, and compliance
- Scientific Credibility – Publications and disclosures shape physician adoption and market confidence
- 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



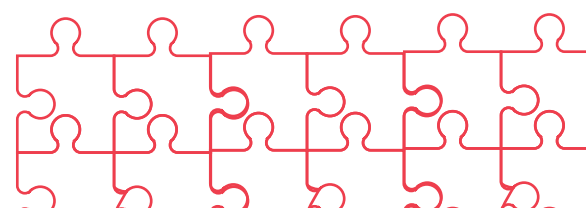
Quality Demands

- 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





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

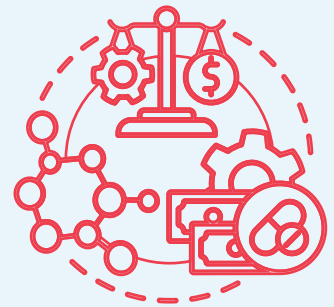
- Clinical Study Reports (CSR) – Full & Synoptic
- Protocols & Protocol Amendments
- Statistical Analysis Plans (SAP)
- Informed Consent Forms (ICF)
- Case Report Forms (CRF)

Safety & Compliance

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

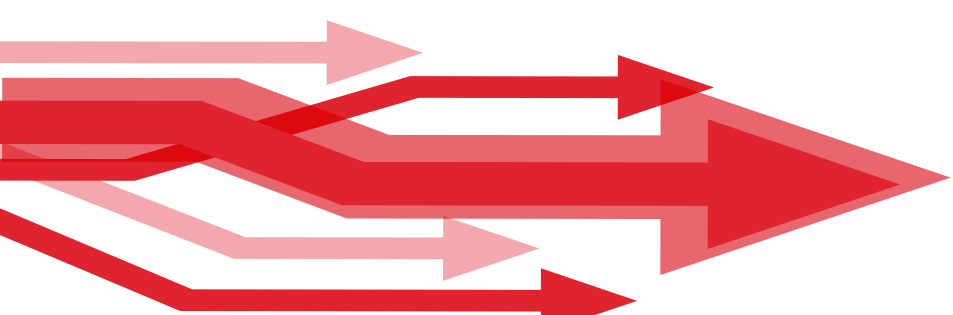
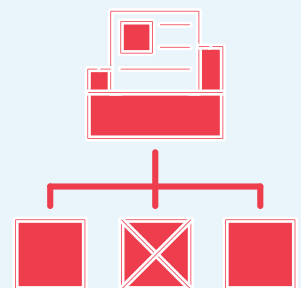
Publications & Disclosures

- 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)





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



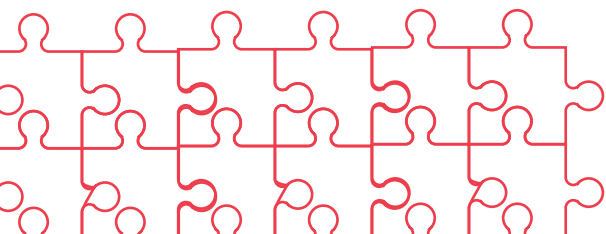
Global Regulatory Fluency

- 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





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.



GENBIOCA
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Our Offices



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