



GVK BIO provides a full range of writing services for regulatory submissions, scientific communications and medico-marketing materials across diverse therapeutic areas for all phases of product life cycles, from pre-clinical development to post-marketing literature. We ensure timely delivery of accurate, consistent and regulatory compliant documents to our sponsors in a cost effective and flexible manner.

We organize our operations into integrated customer-centric units, to enhance customer-focus, and to drive operational agility that can result in delivery with quality, speed and value.

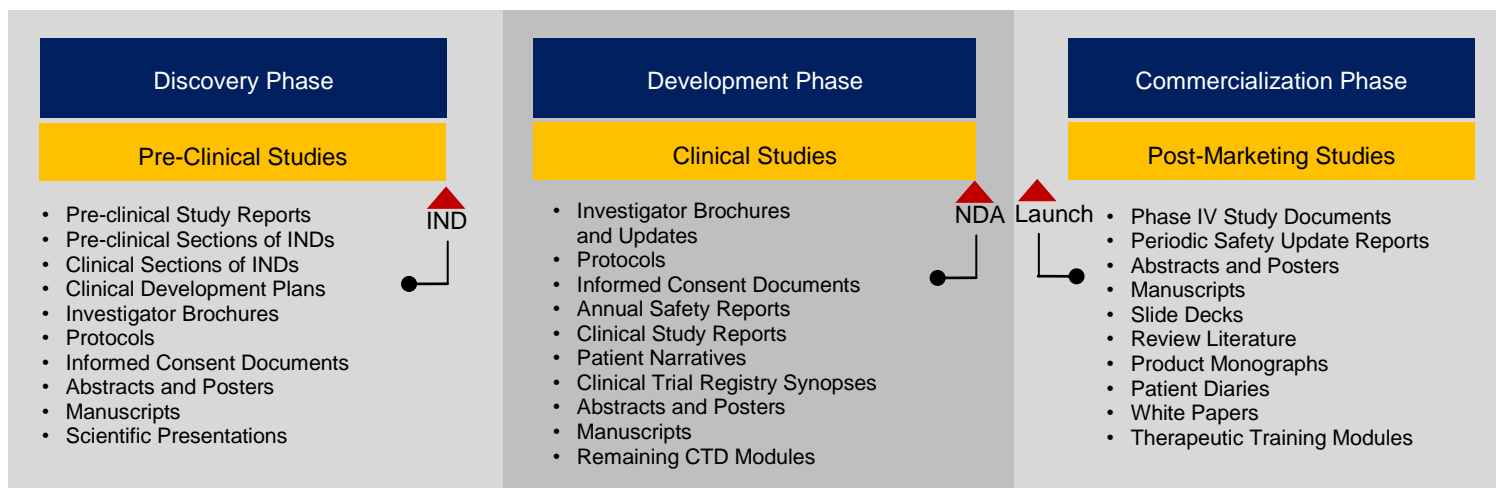
All GVK BIO medical writers undergo regular training to ensure uniform adherence to regulatory standards and to have consistency across writing processes.

Our medical writers are drug development scientists who have required scientific background, regulatory knowledge and professional attitude to get embedded in the sponsor's study teams during clinical development process of a molecule. We write quality scientific communications that are suitable for the sponsor's need, be it for its scientific disclosures or regulatory submissions.

Therapeutic Expertise

- Oncology
- Endocrinology
- Cardiovascular
- Gastroenterology
- Neurology
- Infectious Diseases
- Musculoskeletal
- Immunology and Vaccines

Medical Writing Services





Business Model

Functional Outsourcing:

Our flexible business models help Sponsors to choose GVK BIO as their virtual medical writing department for their consolidated writing services.

Transactional Outsourcing:

We offer writing services for standalone deliverables like manuscripts, patient narratives, CSRs and other documents detailed in the brochure.

Full Service Outsourcing:

As regulatory submissions require cross functional synergy between clinical operations, medical writing, data management and biostatistics, GVK BIO offers integrated end-to-end services in these functions as a one-stop shop.

GVK BIO offers customized services based on fee-for-service (FFS) and full-term-employee (FTE) basis.

Key Differentiators

- Knowledge of International and Indian regulatory requirements and experience in writing regulatory documents for USFDA, EMEA and DCGI submissions
- Expertise in clinical research, discovery and pre-clinical research
- Certificate training program in medical writing for external trainees
- Pool of trained buffer associates for quick ramp up and to overcome attrition, if any, to ensure continuity of ongoing projects
- Documents reviewed by therapeutic area experts from Medical Affairs Division (MDs)
- Learning Management System to meet continuous training needs of staff

Peer Review and Quality Check Process

At GVK BIO, each document goes through an extensive peer- and management review process. Before finalization, each document is reviewed by our medically qualified personnel from Medical Affairs Division. Document management is done under strict security measures to maintain data confidentiality. Documents are finalized after undergoing stringent quality control checks.

All documents conform to ICH guidelines.

Team Expertise

- The global head of Medical Writing has expertise in multiple therapeutic domains and experience of more than 13 years in USA in the field of medical/regulatory and academic writing
 - Spearheaded IND compilation for one of the Big Ten Pharma companies in USA
 - Wrote first human dose (FHD) protocol in Oncology and protocols for exploratory (Oncology and Endocrine) and Phase I studies (Oncology and Renal)
 - Wrote CSRs for psychiatry, endocrine, and renal molecules
 - Many peer reviewed publications
- GVK BIO medical writers (MD, M Pharm, MS) have expertise in writing and developing protocols, ICDs, IBs, CSRs, patient narratives, various modules of CTD and manuscripts
- Highly educated reviewers from Medical Affairs (MD) and Biostatistics (PhD) for scientific review

Success Stories

- Developed and wrote a Clinical Development Plan (CDP) with international scope for a US sponsor (trials in US and India)
 - Sponsor very impressed with our scientific expertise
 - Provided high level therapeutic and scientific expertise for multiple indications for their other molecules
- Successful full service Phase III study with Final Study Report completed for a European Sponsor and earned repeat business

About GVK BIO

GVK Biosciences, India's premier Contract Research Organization, delivers integrated research services.

The company accelerates the Drug Discovery and Development process of its customers through science and innovation.

Services

- Informatics
- Medicinal Chemistry
- Biology
- Process R&D and Custom Synthesis
- Clinical Research
- Clinical Pharmacology

Visit: www.gvkbio.com

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