cencora
PharmaLex

# Professional Medical Writing Services

## Accurate, clear, and compliant scientific content

The demands on scientific and regulatory documentation are continuously increasing. Pharma and biotech companies in Germany face the challenge of producing high-quality medical writing documents without overloading internal resources. Choose PharmaLex to reduce costs, navigate regulatory challenges, and respond flexibly to market changes.

### Why choose us?

Need clear, scientifically accurate, and compelling medical content? Our MEDICAL WRITING SERVICE delivers high-quality materials – from peer-reviewed articles and clinical study reports to patient educational and regulatory documents. With experts in medicine and science, we help you hone your message so it is precise, engaging, and compliant. Whether for pharmaceuticals, medical devices, or healthcare communication, we transform complex data into impactful content. Let us enhance your scientific communication!

- Expertise – Experienced medical writers with in-depth knowledge of German and European regulatory requirements, including the European Medicines Agency (EMA) Germany's Federal Institute for Drugs and Medical Devices (BfArM) and the Paul-Ehrlich-Institut (PEI), an agency of the German Federal Ministry of Health.
- Regulatory compliance – We review all documents in accordance with industry standards and regulations, including Food and Drug Administration (FDA), EMA, International Council of Harmonisation (ICH), and good clinical practice (GCP) guidelines.
- Clarity and precision – We deliver well-structured, scientifically accurate, and engaging content.
- Timely delivery – We adhere to strict deadlines without compromising quality.
- Supporting > 200 new registration procedures in Europe, the United States, and other countries worldwide per year
- Handling more than 50 special designation requests per year (e.g., orphan drug designation requests, Paediatric Investigation Plans (PIP))

# Our services

## Clinical writing

Clinical development plan, protocols, clinical study reports, investigator brochure, patient safety narratives, informed consent document, clinical evaluation report, protocol registration on Clinicatrials.gov, EudraCT, anonymization/redaction of clinical documents as per EMA's publication of clinical data for medicinal products for human use (Policy 0070) and Health Canada's Public Release of Clinical Information (PRCI) guideline

## Medical regulatory writing

Mod 2.4, 2.5, 2.6, 2.7, INDs, NDAs, 505b(2), well-established, 8(3), briefing documents for regulatory meetings/scientific advice, feasibility analysis, orphan drug designations, PIP/iPSP plans/waiver, integrated summaries of safety and effectiveness, labelling (CCDS/SmPC/PIL), environmental risk assessment, medical rationales

## Scientific writing

Systematic literature search (for medical device, market access, literature-based submission), medical launch packs, training materials, response to medical information queries, standard response letters, scientific publications (original research articles, review/meta-analysis), clinical background reports (epi, unmet need, burden of disease from a clinical, humanistic, and economic perspective)

Work with a trusted partner who understands the regulatory and linguistic requirements of the German market. Optimize your medical writing processes with us.

**25+**
years of industry experience and knowledge

**9/10**
of the top pharmaceutical companies are our clients

**50+%**
of our projects are global

**200+**
experienced and certified local representatives support our global coverage

PharmaLex is now part of Cencora, a leading global pharmaceutical solutions organization centered on improving lives around the world. Together, PharmaLex and Cencora become the premier global provider of end-to-end product commercialization, including global market access strategy and execution.

To learn more about how PharmaLex can accelerate patient's speed to therapy, visit us at **pharmalex.com**

## Contact us