CFR
labeling
data evaluation
IB
regulatory
CSR
approval
multidisciplinary
clinical trials
simultaneous submission
investigators
placebo-controlled
double-blind
DSUR
adverse events
risk/benefit ratio
IRB
mg/dL
pharmacokinetic
peer-review
mmHg
protocol
FDA
statistical analysis
ICH

Augment your regulatory writing process

PharmaWrite®

Concise • Strategic • Experienced

PharmaWrite®

Stay ahead of an ever-changing regulatory environment, by augmenting your team with our team.

We are your end-to-end regulatory writing solution, with the expertise and resources to provide writing services from preclinical through all phases of clinical research and registration, as well as post-approval.

- Experienced, professional scientific writers who can effectively summarize and integrate data and statistical analyses, presenting information accurately and clearly
- Key documentation in all phases in the life-cycle of drug/device development
- Flexibility to provide "a la carte" or full-service partnership to enhance with your teams' organizational experience, expertise, and resources
- Devices, pharmaceuticals, *in vitro* diagnostics, vaccines, Orphan Drug designation, literature-based applications, Special Protocol Assessments

Pre-Clinical Development

At the discovery phase we help you develop an effective regulatory documentation strategy. Working in partnership with your staff experts, we prepare preclinical reports and summaries. Our experts analyze and interpret data and with our medical writers, we help you pave the way through the regulatory approval process.

- Preclinical reports and summaries
- Pharmcokinetic, pharmacodynamic and toxicology analysis
- ADME, including drug interactions and toxicokinetics
- Literature searches and reviews

Meetings with Regulatory Authorities

At critical points in the product development and registration lifecycle, it is important to consult with regulatory authorities and to present proposals for the next stage in the process. Preparation for these meetings requires the distillation of key issues and questions into a concise "Briefing Package" that will be used to guide discussion and feedback from regulators. It also serves to focus the Sponsor on the more effective pathway to market approval, identifying opportunities, barriers to success, and enhanced benefit-risk perspectives.

PharmaWrite can help prepare these critical documents and with our experience in conducting regulatory meetings, provide meeting preparation and logistical support.

Our writers will collaborate with your team or manage the document development process to ensure compliance with regulatory guidance and industry best practices.

We understand the importance of well-written Clinical Study Reports (CSRs) as a core document in any regulatory submission. We work closely with your in-house experts to ensure accurate data presentation and interpretation, strict adherence to regulations, guidelines, current industry standards, and your company-specific preferences. Our team of experienced medical writers quickly analyze data and present these clearly and accurately. In addition, we involve an independent Quality Assurance team to ensure that the highest standards are met in producing all of our documents.

Research results positive. Being fast-tracked for clinical trials. You need to submit your INDs and IDEs documents...yesterday.

- We assess based on your clinical trial development needs, worldwide protocols, product type and class, and innovation level
- Team expertise, coordination, literature search, review process and submission protocols and scheduling are determined and documents initiated
- Data and documents reviewed and completed, with formal submission to regulatory authorities

Clinical Development

To initiate clinical trials, regulatory authorities in most countries require evidence that investigational products demonstrate potential therapeutic value and an acceptable safety profile, based on preclinical studies and literature references. This evidence must be provided in formal submissions to the authorities for approval prior to initiating the clinical studies.

At PharmaWrite we can provide these specific formal submission documents to initiate clinical trials. We help map out your regulatory needs and provide accurate documentation compliant with applicable regulations and guidelines. Our team of knowledgable scientific and medical writers produces fit-for-purpose documents consistent with your specifications through all phases of your clinical development process. Our expertise in data interpretation, organization, and presentation enable us to provide high-quality:

- INDs, IDEs, (FDA)
- ITAs (Devices for Health Canada)
- CTAs (EU and Health Canada)
- Investigators' Brochures (including preclinical and CMC sections)
- Protocols
- Literature Reviews
- Posting to clinical trials registry
- Informed Consent Documents
- Investigational Product Labels
- Clinical Safety and Efficacy Study Reports (all phases)
- Patient Narratives

Marketing Application and Post-Application

Once the clinical program has been completed, documents prepared are assembled into complex and multi-layered dossiers with integration of data across studies to represent aggregate results. PharmaWrite can construct and submit:

- Module 2 and 5 Common Technical Document (CTD) overviews and summaries
- Integrated Summaries of Safety (ISS), Integrated Summaries of Efficacy (ISE).

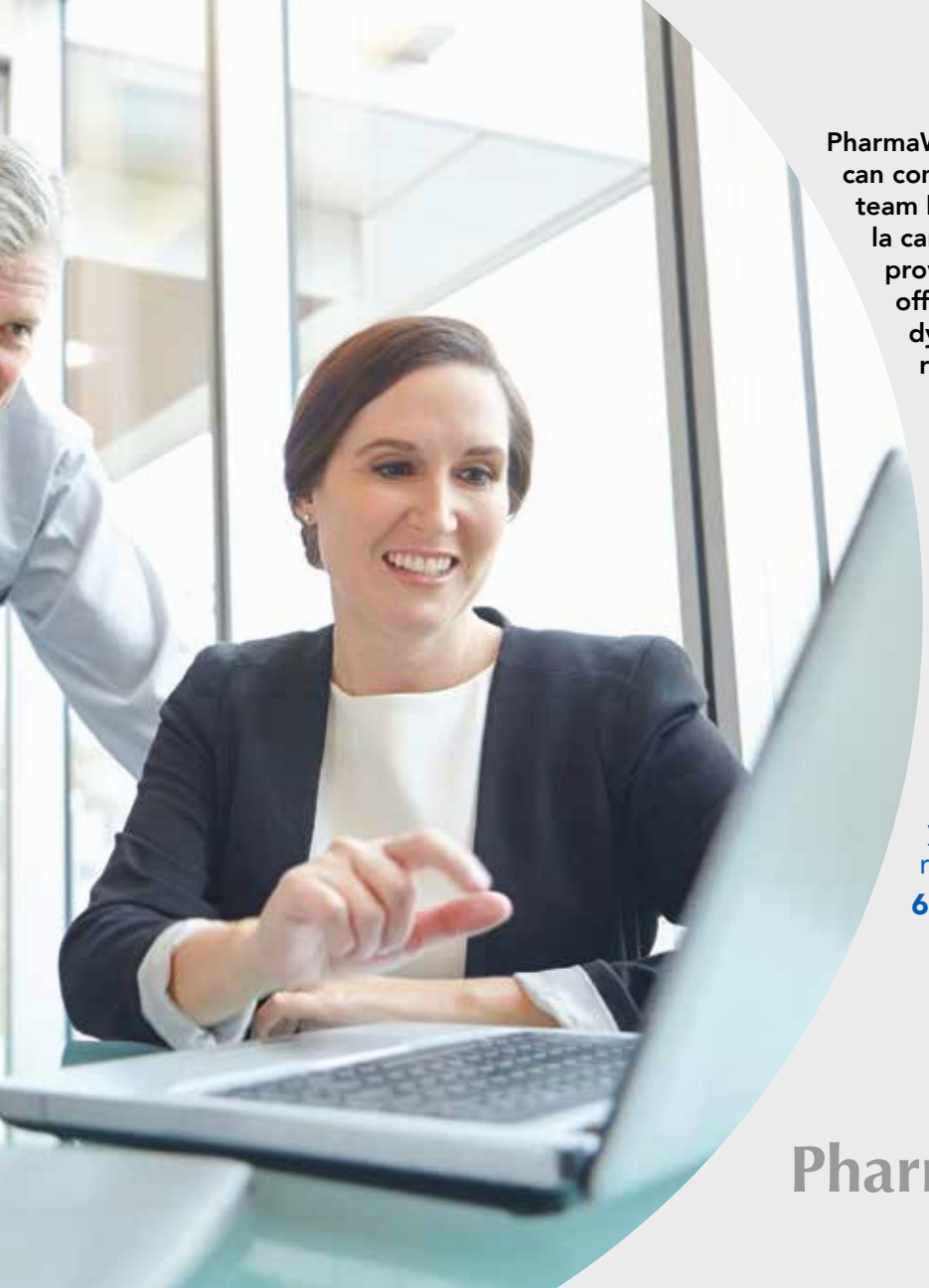
PharmaWrite, with its experience in preparing submissions, can guide you in crafting the registration documents in a way that most supports approvability. Types of dossiers include:

- NDAs, MAAs, BLAs, NDSs
- Orphan drug applications
- 505(b)(2) applications

Post-Application

The life-cycle of regulatory documentation doesn't end with marketing application. With product enhancement and continuing clinical studies and research, new and novel approaches require specialized documents:

- Regulatory response documents
- FDA Advisory committee briefing documents and presentation slides
- RMPs, RiskMAPs, and REMSs
- Clinical Trial Disclosure
- Post-marketing documents



PharmaWrite has a team that can complement your existing team by providing "a la carte" services or provide full-service offerings within the dynamic discipline of regulatory writing.

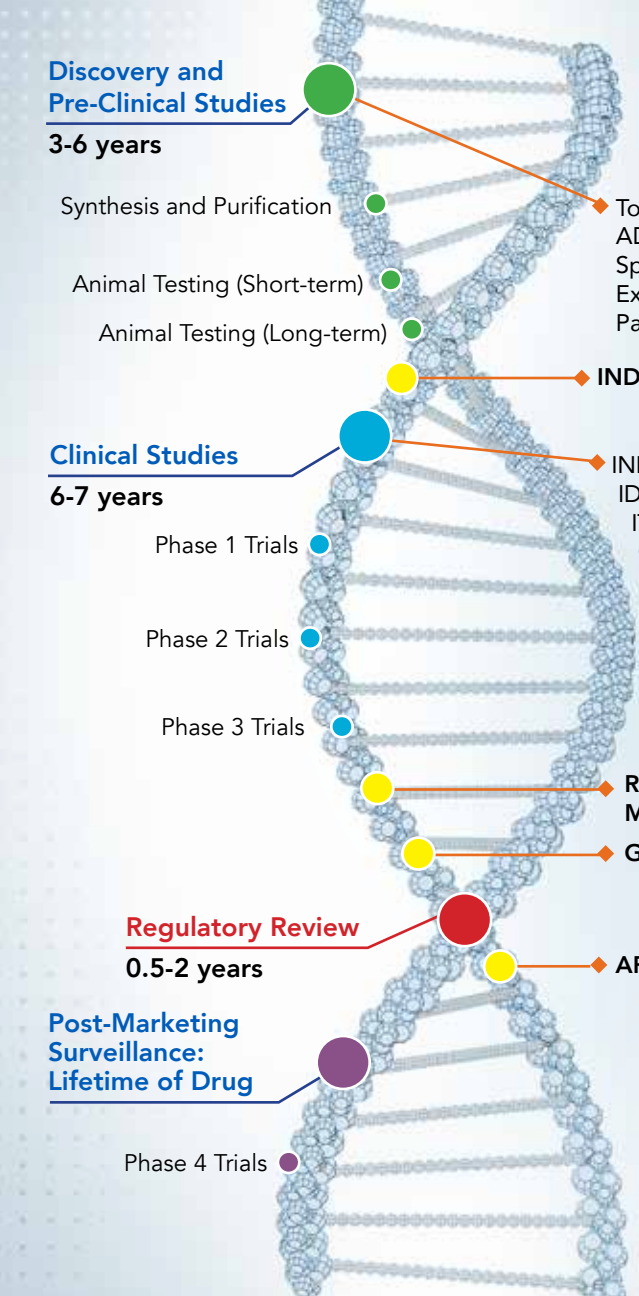
Please contact PharmaWrite to assist you with your next regulatory initiative.

609-924-4856

PharmaWrite®

Drug Development Process

Regulatory Writing/Consulting



Discovery and Pre-Clinical Studies

3-6 years

Synthesis and Purification

Animal Testing (Short-term)

Animal Testing (Long-term)

Toxicology reports
ADMEs (drug interactions, toxicokinetics
Specialized periodic reports
Expedited safety reports
Patient Narratives

IND submission to FDA (US) or EU Regulator

Clinical Studies

6-7 years

Phase 1 Trials

Phase 2 Trials

Phase 3 Trials

INDs (FDA)
IDEs (FDA)
ITAs (Devices for Health Canada)
CTAs (EU and Health Canada)
IB's (preclinical and CMC sections)
Protocols
Literature reviews
Clinical Trails registry posting
Informed Consent documents
Investigational Product Labels

Registation: NDA/BLA submission to FDA; MAA to submission EU regulator

Generics: ANDA submission to FDA

Regulatory Review

0.5-2 years

APPROVAL granted by regulator; marketing begins

Post-Marketing Surveillance: Lifetime of Drug

Phase 4 Trials

PharmaWrite®

Augment your regulatory application team with precision, expertise and experience

PharmaWrite®

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