Regulatory Medical Writing Services

With a deep knowledge of regulatory guidelines and what is expected by Health Authorities, the ProductLife team understands pharmaceutical industry constraints and can draft regulatory compliant scientifically credible documents in collaboration with the client.

ProductLife Group cumulatively has a total of 25+ years of experience as a service provider and can provide Medical and regulatory writing services to create the CTD clinical/non-clinical modules, documents required to support clinical trials (in Phase I-III projects), and other clinical/non-clinical documents required across the lifecycle of a product from development till the post-authorization phase as needed.

"Medical writing" involves writing scientific documents of different types, including regulatory and research-related documents and dossier, clinical trial related documents, disease or drug-related educational and promotional literature, publication articles like journal manuscripts and abstracts. The scientific information in these documents needs to be targeted to the audience, namely, patients or general public, physicians or the regulators. Efficient and high-quality medical writing requires deep knowledge of medical concepts and terminologies, thorough understanding of relevant regulatory guidelines, good scientific writing skills, and literature search expertise.

Scope of Services

Product Development BU PLG offer support and resources for the following services:

1. Common Technical Document

■ Clinical and Non-Clinical sections of the Common Technical Document (CTD) for EU, US and ROW Regulatory Authorities (Modules 2.4, 2.5, 2.6, 2.7, 4 and 5)*, following ICH M4 guideline and Volume 2B guidelines- Presentation and format of the CTD.

In details:

- Module 2.5 – 2.4 Clinical and pre-clinical overviews
- Module 2.7 – 2.6 Clinical and pre-clinical summaries
- Module 4 and Module 5 - Pre-clinical and clinical study reports
- Module 1: SmPC (CCDS – Company Core Data Sheet) and RMP Region-specific, PL and labelling

■ Reformatting of old application dossier to NeeS/e-CTD.

2. Drafting a BCS based biowaiver or drafting justification document/ scientific rationales to support regulatory queries

3. Clinical study protocol and report preparation

■ Phase I, Phase II, Phase III, and Phase IV studies, including bioequivalence and PK/PD studies.

4. Review/Approval Promotional tools

■ Scientific Support to production of promotional material.

■ Preparation and Medical/Scientific Review of advertising materials.

■ Training to Pharma Company.

5. Safety and toxicology

■ Permitted Daily Exposure (PDE): Assessment for Medicinal Products/Active Ingredients in shared facilities (EMA/CHMP/SWP/169430/2012/00).

■ Environmental Risk Assessment (ERA) for Medicinal Products for human use, as for EMEA/CHMP/SWP/4447/00.

■ Impurity Safety Assessment (ICH Q3A, ICH Q3B and ICH M7), Genotoxicity, Toxicity and Risk Assessment.

■ Elemental impurities evaluation (ICH Q3D), Genotoxicity, Toxicity and Risk Assessment: Risk-based control strategy to limit elemental impurities in the Drug Product.

6. Regulatory Writing

■ Investigators Brochure (IB) and Investigational Medicinal Product Dossier (IMPD) required for Clinical trial application.

■ Briefing document and presentation required for a scientific advice meeting with regulatory agencies.

■ Drafting orphan drug designation (ODD) dossier.

■ Drafting a Pediatric Investigation Plan (PIP).

■ Drafting Key Opinion Leaders as well as HAs' experts/Authority Communication, questionnaires and related reports.

Organization and Delivery model

In Product Development Business unit, the Medical Writing team is composed of scientifically qualified professionals with ~5-30 years of experience in Medical Writing services.

We also have a validated network of partners readily deployable for increased market reach in case of any special requirements. The medical writing team is scalable and ready to increase in size based on the work demand.

PLG's medical writing team works in close collaboration with the PLG's publishing team to offer if requested by the customers, the Nees/e-CTD formatting services.

Our team is composed of:

2 Medical Doctors,

1 Toxicologist,

1 bioanalytical chemist,

4 PHD holders,

8 Pharmacists or life science graduates/masters.

Delivery Model Options

The workflow comprises a description of the tasks with milestones and responsibilities.

For exploratory proposals, PLG proposes two different Delivery Models with a corresponding different approach.

OPTION 1: Strategic Approach

This option is a joined approach in the framework definition between PLG MW and the client. PLG act as strategic partner from the initial stage of MW activities to the final MA, e.g. reviewing customers' modules/study reports; finalizing appropriate legal basis; drafting the modules; addressing comments during assessment phase.

OPTION 2: Task Approach

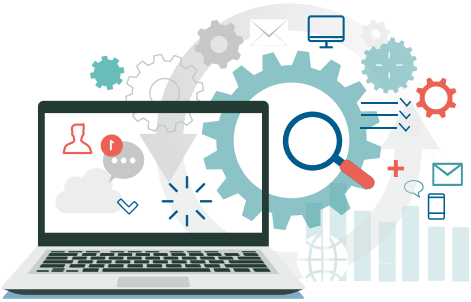
This approach follows client framework, and PLG is only responsible for the defined and agreed tasks, e.g. writing on demand one specific module.

Way of Working

Medical writing is an integral part of drug development. Our team of expert medical writers works closely with customers' nonclinical and clinical experts to deliver accurate, timely, and cost-effective documents. Meticulous attention to detail, strict adherence to timelines together with a flexible and friendly approach: this operational discipline is demonstrated following the below common practice.

Quality

Quality Management System in Place: document drafts are systematically reviewed in-house, and full quality control on the final document is performed. PLG IT system ensures the confidentiality and security of all data and documents with multiple regular backups, and the set-up of a secure BOX to upload the documents is also set-up by our IT.



Our Quality Management System ensures supervision of timelines, KPIs and deviation management: timelines are checked and monitored by appropriate tool and deviations (CAPAs) are managed and tracked by our Quality Assurance.

Communication and Flexibility

The in-depth collaborative discipline of ProductLife is demonstrated in regular communication before and throughout the duration of each project. Kick-off meeting, regular teleconferences and emails ensure that all team members have full access to relevant information throughout the project. PLG, as a service provider, can develop WPDs and working-style based on client's standards and SOPs.

Project management

In conjunction with other services provided by ProductLife, our project managers ensure that the scope, timelines, resources, and budget of each project are well-defined and realistic from the outset. They follow each project throughout its lifecycle and keep the client informed of progress.

Consolidated approach and quality control with our partners

Based upon client's requirement, PLG assembles a project team with the specific expertise to deliver an optimal solution tailored to the challenges of each product. The long-time relationship established with our validated partners guarantees the reliability, the timing, and the quality of the activities performed using the standard project management tools. The reports and the documents generated by our partners are reviewed for quality control by our internal senior medical writers, who have the final responsibilities of the scope, the quality and the timelines of the projects.