



Service Listing

Scientific Writing

Safety Writing

We typically author & compile a few hundred safety reports in one year. Aggregate reporting is closely aligned to our pharmacovigilance service of individual case processing and we often provide both these services in tandem to our clients.

we can either provide complete support on PSURs, from maintaining the schedule and sending out call for contributions all the way to submission of finalized document to the regulator through our QPPV, or we can author and compile the report once the client provides all the components to us.

The safety documents include:

- Post-marketing periodic safety reports - PSURs, NDA PRs/PADERS, Summary Bridging Reports & Ad-hoc Reports
- Pre-marketing safety reports - IND ARs, EU ASRs
- Safety case narratives
- Patient Medication Guides
- Risk Management Plans

Regulatory Writing

Certain documents that summarize the safety information for a product are often handled by regulatory affairs departments of companies and require specific understanding of the regulatory requirements around reporting & submission, especially the CTD/eCTD format.

We provide authoring and compilation services for the following regulatory documents:

- Company Core Data Sheets (CCDS)
- Summary of Product Characteristics (SmPC)
- Patient Information Leaflets
- Nonclinical & Clinical Overviews (Modules 2.4 & 2.5 of CTD)
- Bio-waivers

Clinical Writing

We write a variety of clinical study documents including:

- Clinical trial protocols
- Investigator's Brochure (IB)
- Clinical Study Reports (CSR) & web synopses
- Informed Consent Documents

Our clinical writing services also include

- Abstracts & Manuscripts
- Standard responses to medical queries
- Product-specific Web content

Majority of our writers have several years of experience in authoring clinical documents, especially for global clinical trials.

Sciformix is a knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.



For more information on how Sciformix Scientific Writing services can benefit your enterprise contact us at

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