

THOMSON PHARMACEUTICAL SERVICES

PHARMACEUTICAL CONSULTANCY AND WRITING SERVICES



AREAS OF EXPERTISE

- Regulatory writing support
- Regulatory strategy and consulting
- Quality assurance auditing
- Publication planning
- Integrated communication programs
- Product awareness and understanding

WE CAN HELP YOU TO

- Write INDs and CTDs
- Design and validate regulatory strategies
- Assure consistency and quality of submissions
- Design integrated publication plans
- Prepare manuscripts for publication
- Create posters and presentations

IMPROVE THE PLANNING AND EXECUTION OF YOUR COMMUNICATIONS

Thomson Reuters can provide a comprehensive range of pharmaceutical communication support, from publication planning to medical writing, all tailored to the needs of the global pharmaceutical community. Our services span drugs, devices and biologics.

Our industry experts can help you fashion your clinical and non-clinical data — no matter what the scope and quantity — into concise, industry-standard formats that communicate the essential information to your target audience quickly, accurately, and in the language they expect.

Since 1990, we have focused on supporting the pharmaceutical development process. We are able to draw on the best available scientific information, and apply unique evidence-based analysis.

All our writers are skilled scientists, able to handle all aspects of preparing and executing successful and relevant communication programs.

We can save your company time, and work within your budgets, by identifying time and cost-saving opportunities early in the product development process. Our commitment to meeting your internal goals, and our attention to personal service, can provide a cost-effective alternative for your industry outsourcing needs.

REGULATORY WRITING AND CONSULTING

We can help you to navigate the regulatory hurdles associated with product development and to facilitate approval of submissions by international regulatory authorities. We have participated in the design and preparation of more than 125 submissions, spanning even the most complex therapeutic areas.

Our Regulatory Affairs Certified specialists have extensive experience with submissions to regulatory agencies including the United States Food and Drug Administration (US FDA), the European Agency for the Evaluation of Medicinal Products (EMA), and other ICH parties.

We work closely with companies around the world, from multinational pharmaceutical corporations to emerging discovery companies.

We can help you to achieve the objectives set forth by the ICH, by helping you to present information to support the development and registration of safe and effective therapies clearly and effectively.

Our writers can prepare documents using your in-house templates or our own e-submission tools to facilitate electronic filings.



SPECIFIC REGULATORY SERVICES

Our regulatory affairs specialists and writers can work with you to:

- Develop regulatory strategies and identify submission options
- Design preclinical and clinical documentation
- Plan and prepare for regulatory authority meetings
- Prepare, document and maintain clinical and regulatory Standard Operating Procedures (SOPs)
- Provide support for chemistry, manufacturing, and controls documentation and compliance
- Develop protocols, case report forms and consent forms
- Prepare and e-file all components of Investigational New Drug (IND) applications, including non-clinical and clinical summaries, investigator brochures and updates

- Prepare and e-file all components of the Common Technical Document (CTD)
- Prepare overviews and tabulated and written summaries
- Write clinical study reports and safety event narratives
- Prepare and file Abbreviated New Drug Applications (ANDA), 505(b)2, and related submissions
- Undertake quality assurance audits of source documents, regulatory submissions (print and electronic)
- Develop databases, data entry, validation and coding, conversion and output.

We can serve as US agents for non-US sponsors.

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