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Medical Writing Services

Including *ISIWriter™*



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Now You Have A Choice



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ISI Is Your Partner For Medical Writing

MEDICAL WRITING SERVICES: For Your Peace of Mind

ISI is the first in the industry to provide you with a unique approach to a service that is critical for your submission success. ISI's Medical Writing services bridge the gap between writing and publishing teams.

Our services include writing/editing of regulatory submission documents, consulting and training, and document template solutions. ISI's approach will ensure that your submission arrives at the regulatory agency on time, every time.

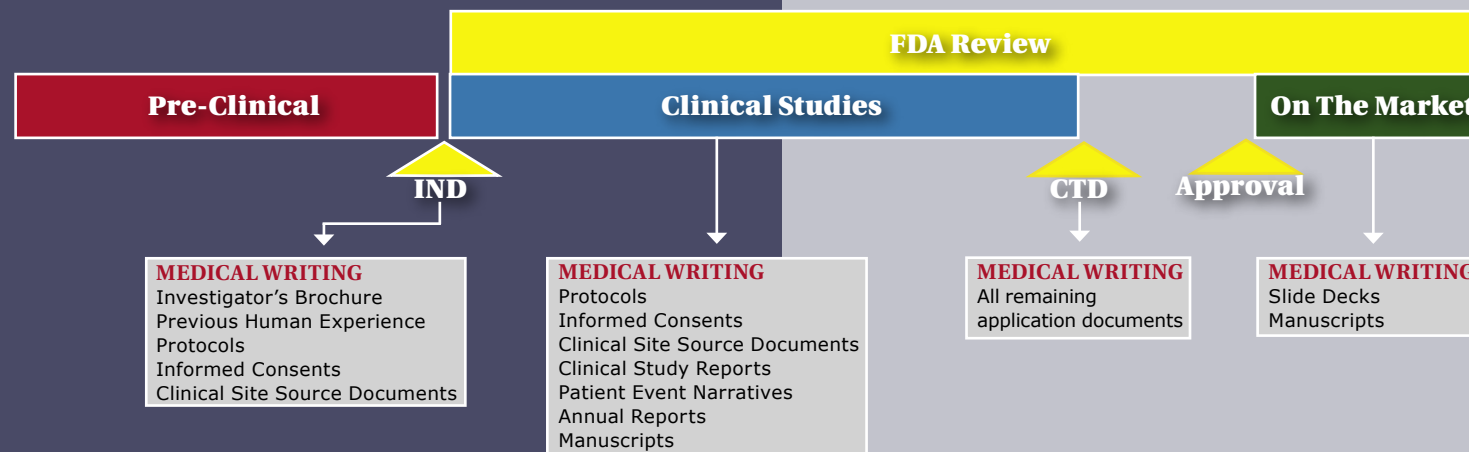
ISI's Medical Writers will give you the personal attention and objective perspectives you deserve. Our writers have many years of collective experience working with regulatory submission documents, and they understand current industry guidelines and requirements.

We can provide continuity and consistency across documents, helping to ensure an accurate, complete, and credible submission for your best chance of agency approval.

You can depend on ISI's Medical Writers to meet your needs. We can:

- Do all of the writing for you
- Supplement your internal resources
- Provide guidance as you build your own medical writing department

With our services, you can save time and money...and have peace of mind.



WRITING AND EDITING: It Suddenly Got Easier

ISI's close relationship with regulatory agencies means that our writers are on top of emerging technology and initiatives, such as the Continuous Marketing Application (CMA). We will make sure that your documents support the preferred submission format by aligning your resources with writers who can keep you on track throughout the process.

Our Medical Writers are equipped with state-of-the-art writing and publishing software not readily available to most writers. With ISIWriter™ Templates, our writers are able to focus on scientific content; the templates do the formatting for them. Since our Medical Writers understand the technology behind current initiatives, your documents will meet all technical agency specifications.

Teamwork and dedication to quality products and services are two of ISI's hallmarks of success. ISI's Medical Writing services are backed by ISI's quality guarantee – on time, in compliance, and of the highest quality – every time.

CONSULTING AND TRAINING: Experience Counts

ISI offers consulting and training on Medical Writing, Editing, and Template Development. Whether you represent a large company that needs help coordinating departments to meet a common goal or a small company that simply lacks the resources to develop internal processes, ISI's experienced Medical Writing and Product Development teams will be able to assist you with:

- Establishing efficient workflows between writers, editors, and publishers
- Training entry- and mid-level Medical Writers and Editors
- Writing or editing standard operating procedures
- Developing and customizing templates to meet the needs of your own writing, editing, and publishing teams
- Improving and expanding your existing processes

BENEFITS: What's In It for You?

ISI's reputation for innovative solutions continues with our value-added Medical Writing services, tailored to meet your specific Medical Writing needs. No other service provider can do all of this for you:

- Create documents and text based on current levels of granularity – a key step toward streamlining your writing processes for the future
- Provide continuity and consistency as your program progresses from investigation to final marketing application
- Maintain the personal attention and objective perspectives you deserve
- Ensure an accurate, compliant, and credible submission
- Significantly reduce writing and review times with state-of-the-art technology
- Provide current guidance on agency initiatives

ISI integrates the critical components for your regulatory submission: Medical Writing services, ISIWriter templates, and publishing software.

If you need Medical Writing services...we've got you covered.



TAKE CONTROL OF YOUR DOCUMENTS: ISIWriter™ Is the Solution

ISIWriter™ includes a Master Template programmed to save you time and money on document production. ISIWriter also includes a full set of Content Templates for writing an IND or eCTD Submission. With the ISIWriter Template package, your writers can focus on writing accurate, concise content, eliminating the hours typically spent formatting documents.

ISIWriter Templates represent the gold standard for creating submission documents with more user-friendly tools and features than any other product on the market, and they can also be customized by professionals at ISI to meet your specific needs. ISIWriter Templates are backed by ISI's reputation for providing reliable, quality products with customer satisfaction guarantees.

The Master Template includes functions that will:

- Significantly decrease writing, reviewing, and publishing time by improving productivity with automated tools
- Ensure that your documents are formatted to regulatory agency specifications for electronic or paper submission
- Meet your company's internal specifications through personalized customization
- Prevent or repair common problems that occur when using Microsoft Word software

The Content Templates include:

- Multiple documents covering every section of the Common Technical Document, based on the current eCTD levels of granularity
- Section headings compliant with ICH guidelines and agency guidances
- Instructional text and content suggestions --- there when you need them or hidden with the click of a button
- Formatting that is consistent, electronic submission compliant, and reviewer friendly