



Regulatory and Medical Writing

Providing strategic solutions to address the industry's greatest regulatory challenges

Nonclinical | Clinical | CMC | Drug Safety and Aggregate Reporting

Strategic writing and compliance is key to successful drug development

High quality medical and regulatory writing is an essential part of any successful drug development program. Pharmaceutical and biotech companies need a trusted, agile, and experienced partner not only to write these documents, but also to be a strategic partner and address key issues. Synchrogenix has developed the right combination of seasoned regulatory and medical writers and editors along with artificial intelligence (AI) technology-enabled solutions to be that partner. Our rigorous and proven quality control processes ensure documents of the highest caliber. Resourcing is scalable, and knowledge is shared, so quality and integrity is maintained regardless of fluctuations in workload or changes in your organization.

Global teams of experienced medical and regulatory writers

Working with a great team is a prerequisite to success in any venture. With over 30 years of regulatory writing and document support experience, Synchrogenix has honed a unique methodology and built a team of over 300 writers who are leaders in their field. The over 50 drug applications we've supported in recent years proves our impact. With flexible and scalable solutions, expertise across therapies and the entire drug development life cycle, and unique technology-enabled solutions, Synchrogenix offers a complete outsourcing capability to address all medical and regulatory writing needs.

Solutions from R&D through life cycle management

An astonishing number of documents, communications, and presentations must be produced at every stage of drug development. We provide all of the benefits of in-house writers—with the experience and perspective of industry insiders—without increased overhead and while managing fluctuating workloads. Synchrogenix can provide strategic expertise to augment your in-house team or lead all of your writing needs.

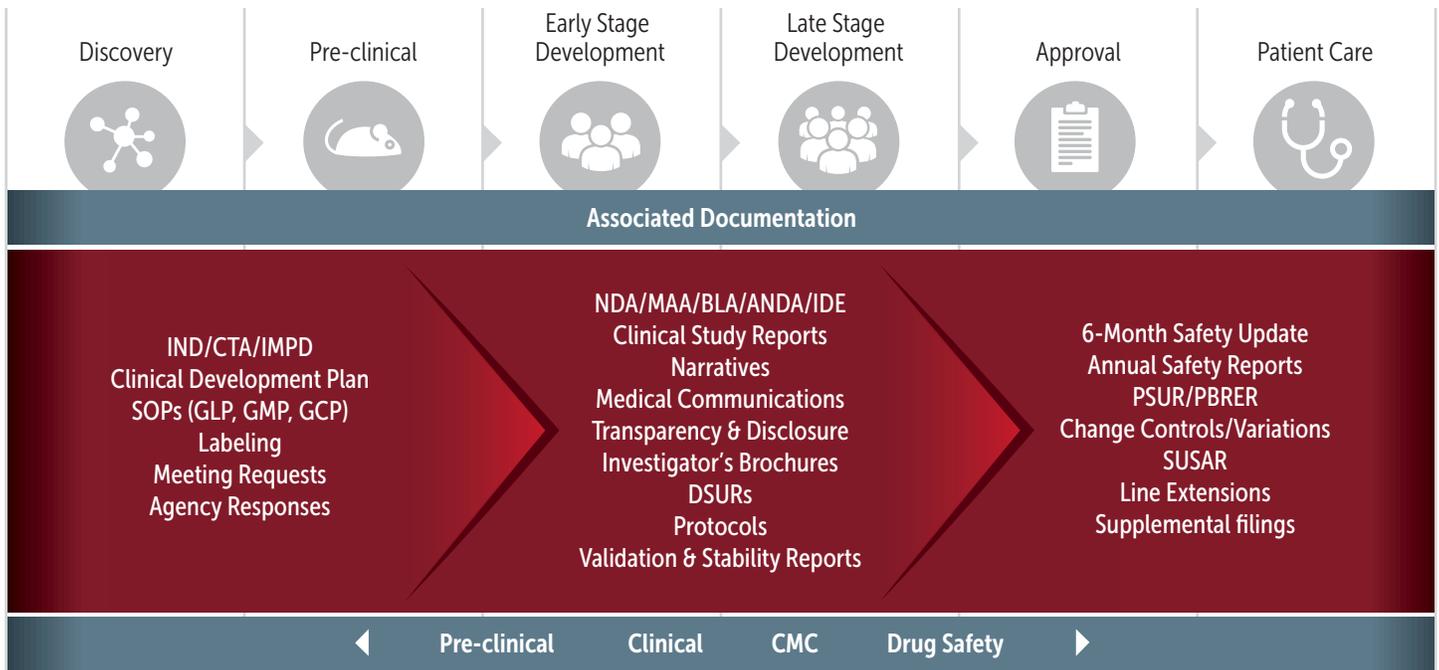
Our team is highly skilled in managing the transition from pre-clinical trials to clinical development, through submission and approval to post marketing, and know how to enhance the presentation of your program. Our writers are fully conversant in industry guidelines such as those issued by the

Benefits of partnering with Synchrogenix:

- Largest consultancy of regulatory and medical writers in the industry
- Proven expertise in developing global strategies to support regulatory documentation
- Allows your team to focus on interpreting data and driving new drug development, business development, and commercial activities
- Increased momentum for developing documents to meet required submission deadlines
- Increased efficiency and reduced risk when disclosing sensitive information with AI-enabled technology

International Council of Harmonisation (ICH) and the International Committee of Medical Journal Editors (ICMJE) while adapting to individual sponsor preferences and procedures.

Regulatory and Medical Writing Solutions that Span the Drug Development Cycle



Commercial and medical information

Synchrogenix also offers a range of commercial and medical information writing services with proven expertise in developing global strategies to support timely and accurate release of scientific and medical information.

With the support of our experts, sponsors can demonstrate their thought leadership at scientific conferences and in peer-reviewed journals without having to spend inordinate amounts of time assembling drafts, coordinating author reviews, managing journal and conference submissions, and performing galley checks.

Our team is experienced in a wide variety of project types, including posters, presentations, abstracts, slide sets, and manuscripts describing clinical trial data, PK/PD (i.e. modeling, bioavailability, gender/race differences, tissue penetration), meta-analysis, data-mining, health outcomes, and health economics.

Synchrogenix also provides graphic support and is experienced using many tools including Systat SigmaPlot, GraphPad Prism, and Adobe InDesign.

Regulatory

Synchrogenix has expertise across all functional areas. Our team is highly skilled in managing the transition from pre-clinical to clinical trials and development, including Chemistry Manufacturing, and Controls (CMC), through submission and approval, and on to post-marketing safety writing.

Our writers are fully conversant in International Conference on Harmonization (ICH) and other regulatory guidelines and were elected to sit on the driving committee for ICH E6. Our leadership is paramount within the industry for effectively creating documents or submissions that are accepted by global health authorities.

Non-clinical

As pressure increases to rapidly identify viable candidates, coupled with limitations of internal resources, companies are seeing the value of partners to provide streamlined and consistent documentation.

Synchrogenix has experienced writers who are familiar with the dynamics of your non-clinical team and who have a long history of preparing non-clinical documentation. Our writers average more than 10 years of experience with backgrounds in non-clinical pharmacokinetics, toxicology, and as research pharmacologists. Synchrogenix offers a single team and point of contact to coordinate activities and associated documentation across pharmacology, toxicology, and Drug Metabolism and Pharmacokinetics.

Clinical

Over the last 10 years, it has been recognized that the regulatory writing team is in a unique position to influence and guide clinical development teams toward success. Many companies have successfully developed processes to unify collective cross-functional agreement with Regulatory Writing leadership to ensure that teams progress smoothly toward goals, while other sponsors continue to struggle with optimal team engagement.

At Synchrogenix we see our role as an ambassador of transformation in our field, a leader and collaborator in strategy in support of drug development and regulatory filings. Collectively, we have supported our clients through many organizational and functional changes associated with in- and out-licensing, mergers, and acquisitions. This gives us a unique insight, and we are excited to share our experience with our clients.

At Synchrogenix it is our objective to understand your goals and help you meet them in a straight-forward and uneventful manner. We collaborate as a partner to develop robust essential processes, identify potential pitfalls, plan for contingencies, and introduce cutting edge technology and the latest regulatory thinking to the table. With the clinical contributions often as the key factor for meeting submission timelines, our leadership helps to proactively guide activities off critical path, successfully shortening timelines by two months on average.

CMC

Keeping up with the new guidance documents and current good manufacturing practices has been a challenge for the pharmaceutical industry for years. However with today's environment, it is even more challenging as global regulators issue new guidance and expectations for inspections, documentation, and submissions more frequently than ever before.

Synchrogenix is addressing these challenges by attending applicable industry meetings, reading new guidance documents, and considering the relevant nuances within these documents with our peers. We are also able to leverage our learnings and knowledge of best practices across the experience we gain from supporting numerous sponsors.

Drug safety and aggregate reporting

As more information is readily available in the post-marketing space, and as signals emerge, the impact for keeping products on the market, labeling, and potential future drug development is great. Also the impact of real world data is increasing, it is critical to communicate how the data support your current approval and proactively address agency concern. Coupled with challenging timelines, the requirements of the Pharmacovigilance Risk Assessment Committee, and other competing factors, document development in this arena can be daunting.

Synchrogenix has scalable, strategic, and well-organized processes that help ensure clients never miss an anniversary date for submitting safety documents; we are prepared to support urgent post-approval requests from health authorities. Our team members are knowledgeable regarding the Medical Dictionary for Regulatory Activities and EudraVigilance. Synchrogenix collaborates with client teams to bring efficiency to current processes or to establish new processes based on our collective experience.

Synchrogenix's drug safety team produces high-quality drug safety documents and aggregate reporting including; aggregate reports; bridging documents, narratives; Periodic Benefit Risk Evaluation Reports; and literature reviews.

Initial filings and global filings of approved products

Submissions and filings are make or break events in a drug's development process. Quality submission documents help sponsors to get drugs to market faster, conserve patent life, and maximize financial returns on investment. Our team members are well-versed in the requirements of global regulatory authorities and we create strategies not only for approval, but also for regional and life cycle management activities.

Synchrogenix's cohesive writing group collaborates with your team to develop strategic messaging across functional areas, ensuring that reviewers receive complete, consistent, and coherent submissions. By making documents clear and concise the first time, Synchrogenix reduces reviewers' questions and concerns and expedites the review process.

Transparency and disclosure services

Synchrogenix services include:

- Redaction and anonymization of Patient Protected Data and Company Confidential Information to address European Medicines Agency Policies 43 and 70
- Clinical trial lay summaries for study participants in partnership with the Center for Information and Study on Clinical Research Participation (CISCRP)
- Registration and disclosure on public registries, such as ClinicalTrials.gov and EudraCT.

Our ClinGenuity Redaction Management Service (CRMS™) is the only AI-enabled technology solution in the marketplace. It is the most effective and efficient approach to mitigate risk for meeting data transparency requirements. This technology is capable of automatically traversing thousands of pages and millions of words to accurately identify and redact sensitive information with more than 99% accuracy.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.