synchrogenix

A CERTARA COMPANY

Regulatory and Medical Writing

Providing Strategic Solutions To Address The Industry's Greatest Regulatory Challenges

Nonclinical | Clinical | CMC | Safety and Pharmacovigilance

- Largest consultancy of regulatory and medical writers in the industry. Over 300 writers, including over 100 PhDs and MDs, in 17 global locations.
- Over 67 marketing applications since 2012, with 100% approval*

*for completed submissions for which the agency has reached a decision.

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.

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 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 or lead your in-house team for all 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 knows how to enhance the presentation of your program. Our writers are fully conversant in industry guidelines such as those issued by the International Council of Harmonisation (ICH) and the International Committee of Medical Journal Editors (ICMJE), while adapting to individual sponsor preferences and procedures.

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.

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 leadership is paramount within the industry for effectively creating documents or submissions that are accepted by global health authorities.

Non-clinical

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 ten 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

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 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 new guidance documents and current manufacturing practices is more challenging than ever for the pharmaceutical industry 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, the impact for keeping products on the market, labeling, and potential future drug development is great. Also, as 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, and collaborates with client teams to bring efficiency to current processes or to establish new processes based on our collective experience. Additionally, Synchrogenix's drug safety and pharmacovigilance team produces high-quality drug safety documents and reporting including; aggregate reports; bridging documents, narratives; Periodic Benefit Risk Evaluation Reports; and literature reviews.

For more information, visit our website at **www.synchrogenix.com** or email **contactus@synchrogenix.com.**

Synchrogenix - Regulatory and Communications Strategy, Science, and Solutions

Synchrogenix provides regulatory and communications strategy, science, and solutions to life science companies worldwide. Our regulatory expertise and innovative technology bridges the full regulatory continuum to propel treatments to the market by meeting the needs of all stakeholders and improving public health outcomes.

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