CERTARA | SYNCHROGENIX

Regulatory Writing

Writing your submission documents the right way

Expedite your submissions

Your drug development program has overcome many challenges and required a substantial investment to get to this point. Now your submission documents require regulatory writing expertise across the full drug or medical device development lifecycle. Regulatory submissions from early stage INDs, NDAs, and MAAs require CMC, nonclinical and clinical expertise. Most importantly, your submission programs require the coordinated technology-enabled expertise that Synchrogenix offers.

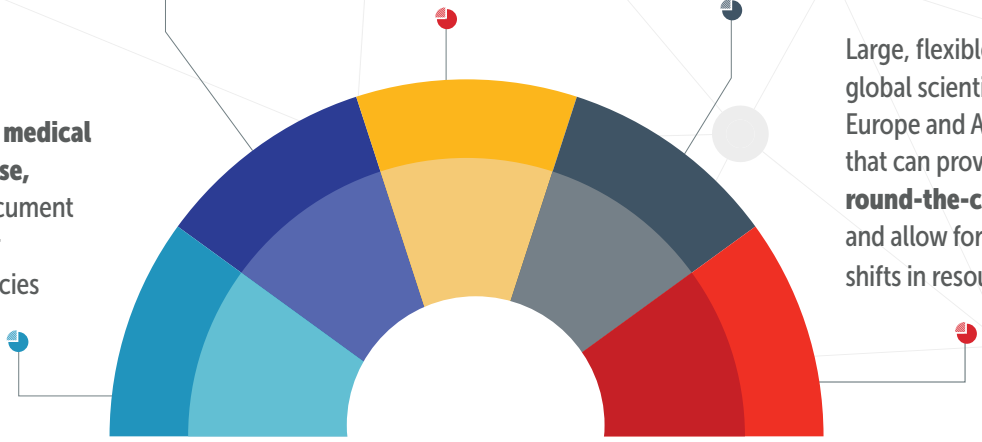
Process and people excellence drives quality deliverables that reduces reviewer comments and speeds time to completion

Enabling technologies that drive efficiency, accuracy and speed time to completion

Successful 30+ year track record leading all aspects of **high stakes submissions and scientific publications** – from writing, project management to publishing

Full spectrum regulatory and medical writing expertise, spanning all document types and major regulatory agencies

Large, flexible base of global scientific talent in NA, Europe and APAC that can provide **round-the-clock support** and allow for dynamic shifts in resourcing

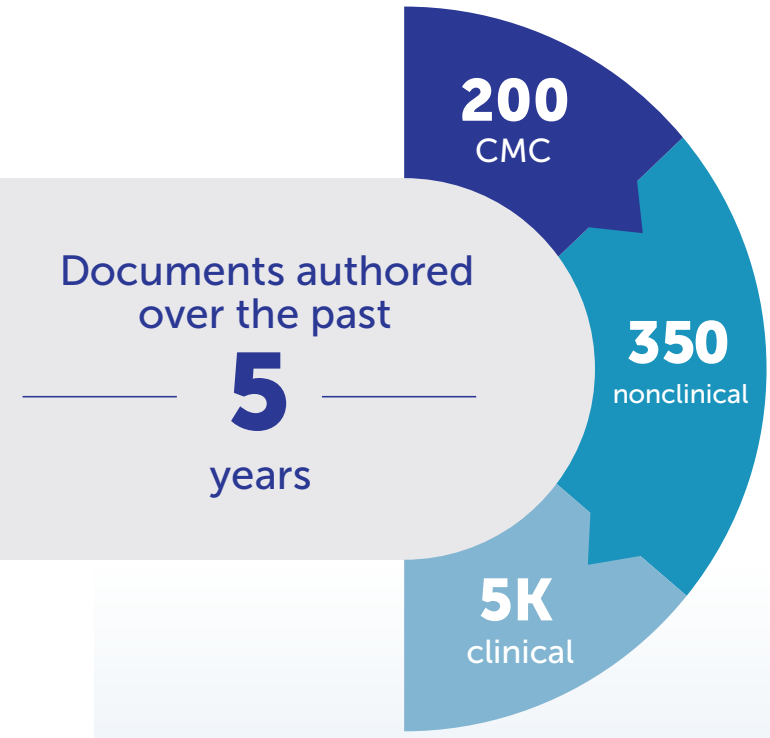


> **"Thank you so much for all the hard work on the protocol. I know we had a lot of changes and adaptations often on short timelines through the development process (so it probably wasn't the easiest document to work on). We really appreciate the flexibility you gave us and the great job you did on the protocol!"**
>
> – Senior Director, Clinical Science | Clinical stage biopharmaceutical company

Proven track record of success in regulatory process and medical writing

Our highly qualified team of writers author CMC, nonclinical and clinical documents required throughout the full drug development lifecycle, including:

- **Investigator brochures**
- **Clinical study protocols**
- **Clinical study reports**
- **Briefing documents**
- **All CTD Module 1-5 components**
- **Pediatric study plans/pediatric investigational plans**
- **Patient Narratives and Safety Reporting**
- **Annual Reports/DSURs/PBRERs**



Medical Device Clinical and Performance Evaluations

Since the introduction of MEDDEV 2.7/1 Rev 4, EU Medical Device Regulation (MDR) 2017/745, and In Vitro Diagnostic Regulation (IVDR) 2017/746, clinical and performance evaluations have been scrutinized by the notified bodies to ensure compliance with these regulations. Manufacturers have noticed that the bar has been raised for author qualifications, equivalence, literature reviews, clinical data, frequency of reports, and post-market clinical follow-up.

Our experts will work with you to ensure that you are prepared to meet the new regulations. Our medical device team consists of the following:

- **Experienced experts who have performed gap analysis, written, reviewed, and amended hundreds of clinical evaluation reports spanning all classes of device**
- **Qualified medical writers, physicians, PhDs, nurses, and librarians**
- **Skilled staff to perform methodologically sound literature reviews to support your clinical data**

Synchrogenix eCTD Authoring Template Suite

We've paired our technical experts with our team of qualified professionals in regulatory process and regulatory writing to create a comprehensive eCTD authoring template suite that contains:

- **Specialized toolbar**
- **Proper formatting**
- **Document granularity**
- **Agency-specific guidance in hidden text offering expert advice**
- **Best practices to guide sponsors to a successful submission**

Our authoring templates are the only templates built by regulatory writers for regulatory writers based on decades of experience planning, writing, and editing hundreds of global submissions.