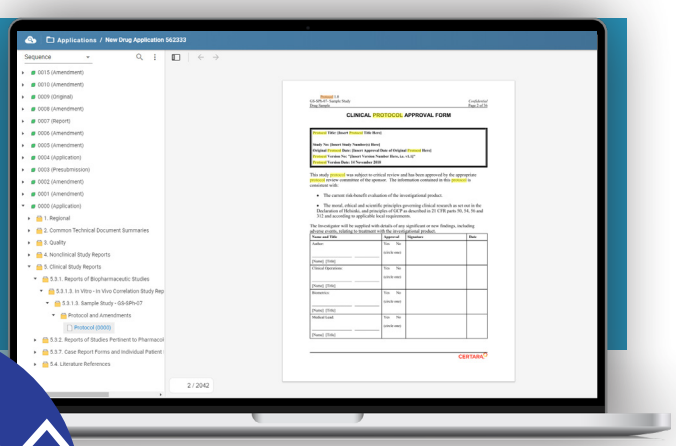
CERTARA | SYNCHROGENIX

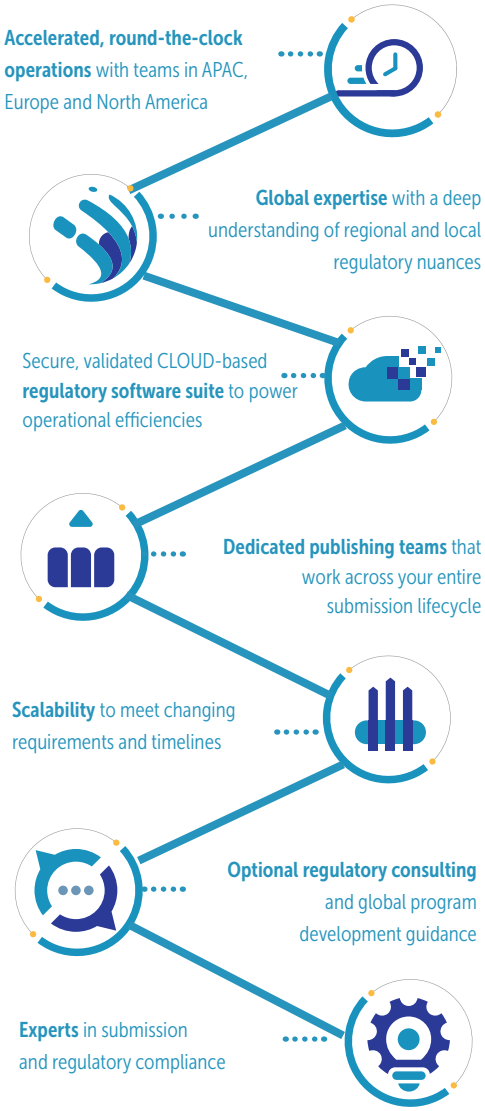
Regulatory Operations Services

Assure Regulatory Success with Customized Submission Support that Accelerates and Anticipates



Accelerate submission success with unrivaled expertise, advanced technology and round-the-clock operational flexibility.

Synchrogenix supports sponsor submissions to all major global agencies.



> **"Working with Synchrogenix was the next best thing to having a fully staffed and seasoned RegOps team on site."**
>
> *Vice President, Regulatory Affairs | Gritstone Oncology*

Anticipating Challenges Helps Accelerate Submissions & Mitigates Risks of Costly Delays

- Proactive management of project timelines
- Deep regulatory knowledge enables fast responses to changed regulatory requirements and mandates
- Proven track record in rare/orphan diseases and gene therapy
- Flexibility to meet changing requirements and timelines
- Simplified submission review

Track record with large and medium-sized pharma and biotech sponsors

Services

- Investigational and marketing application submissions
- Lifecycle maintenance submissions
- Master file submissions
- Dossier management
- U.S. agent services
- Electronic transmission
- Regulatory affairs

GlobalSubmit eCTD Submissions Management Software

- PUBLISH for more efficient PDF document publishing and QC
- VALIDATE for assessing the technical validity of your submission
- WebReview for simplified anytime, anywhere submission review

GlobalSubmit WebReview

A simple, secure solution with anytime, anywhere access

WebReview eCTD viewer ensures easy access to your applications. Cloud-powered, web-hosted technology requires no installations and eliminates the need for IT overhead. WebReview's browser-based access is also platform and browser agnostic, so it is fully functioning on all operating systems and browsers.

> *"WebReview is such a convenient tool for viewing and navigating through regulatory submissions. I also use it to search and view archived regulatory submissions."*
>
> *Elena Spanjaard, Global Head of Regulatory Affairs, Celyad*

Synchrogenix.com

For more information, please contact us at +1 302-892-4800 or contactus@synchrogenix.com