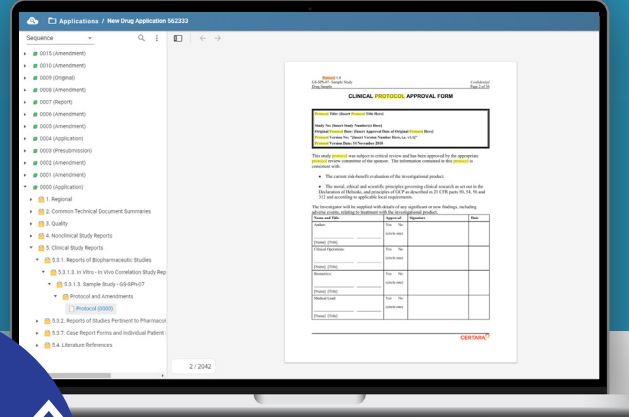


# Regulatory Operations Services

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

Accelerated, round-the-clock operations with teams in APAC, Europe and North America



Global expertise with a deep understanding of regional and local regulatory nuances

Secure, validated CLOUD-based regulatory software suite to power operational efficiencies



Dedicated publishing teams that work across your entire submission lifecycle

Scalability to meet changing requirements and timelines



Optional regulatory consulting and global program development guidance

Experts in submission and regulatory compliance



## 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