synchrogenix

A CERTARA COMPANY

Regulatory Operations

Efficient, Timely Submissions

Synchrogenix ensures efficient, timely submissions through software and services solutions that break down barriers between strategy, dossier development and global transmissions. Through experience, expertise, and industry insight, Synchrogenix quickly responds to changes in global regulatory requirements and mandates, thus avoiding common issues that can lead to rejections.

Key Benefits

- Exclusive provider of eCTD viewing and validation software to FDA
- Experienced publishing experts backed by Synchrogenix subject matter experts
- U.S. Agent services for non-U.S. sponsors

Synchrogenix provides:

- Extended working hours due to regional office locations on U.S. East and West coasts
- Secure, validated CLOUD-based software suite
- Dedicated publishing teams
- Scalability to meet changing requirements and timelines
- Best practices training for authors
- Expert advice on regulatory standards and best practices for electronic submissions

Services:

- Drug Master File (DMF) submissions
- Paper to electronic common technical document (eCTD) conversions
- U.S. Agent
- Investigational and marketing application submissions
- Lifecycle maintenance submissions

Software:

- GlobalSubmit PUBLISH
- GlobalSubmit REVIEW
- GlobalSubmit VALIDATE
- GlobalSubmit CROSSCHECK
- GlobalSubmit LINK

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.