synchrogenix

A CERTARA COMPANY

GlobalSubmit VALIDATE

Key Benefits

- More error checking than any other product
- FDA uses our software
- Integrates with all publishing applications

Key Features

- **Robust Validation Engine–** Supports over 200 error conditions including 40+ PDF checks
- **Regional Support–** Submissions validate according to applicable regional rules
- **REPORTS–** Includes guidance on locating and fixing errors
- **Incremental Loading–** System only reprocesses files that have changed

Eliminate the Risk of Rejection

Synchrogenix's GlobalSubmit VALIDATE is the industry's most robust software platform for assessing the technical validity of an electronic regulatory submission. VALIDATE is a web-based application that checks for over 200 error conditions of varying severity levels. No other program can provide such comprehensive error detection.

As the validation platform used exclusively by the US Food and Drug Administration (US FDA) to assess the validity of thousands of submissions annually passing through its gateway, VALIDATE is designed to successfully integrate with all existing publishing applications.

VALIDATE supports the most up-to-date criteria for US FDA, European Medicines Agency (EMA), Health Canada, NeeS, Swissmedic and numerous other regions.

Users can initiate the loading and validation process manually (using a browser based interface) or automatically (by launching a web service). Once a submission has been loaded and analyzed, REPORTS breaks down results across sequences and applications according to preferences selected by the end user.

The latest version of VALIDATE supports fully-automated submissions, a recent development at the US FDA engineered to speed the drug approval process. Sponsors using an outdated validation platform are now more vulnerable than ever to technical rejection.

Why Validate?

- VALIDATE not only supports submissions across multiple regions, it's ready for the next generation – Regulated Product Submissions (RPS).
- VALIDATE is the only validation solution that can build an RPS backbone. This solution supports medical device 510k's and other submission types as well. With VALIDATE, your success is all but assured.

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.