synchrogenix

A CERTARA COMPANY

GlobalSubmit MANAGE

Solution Benefits

- Capture vital submission planning information and associated metadata
- Allocate resources to priority submissions based on workload data
- Anytime, anywhere access with Secure CLOUD
- Keep track of regulatory activity status for all active products world-wide (Approved, Pending, Clinical Hold, etc.)
- Integration with GlobalSubmit REVIEW

A Central System to Track Submission Data and Regulatory Activity Status

Synchrogenix's GlobalSubmit MANAGE gives regulatory operations teams the high-level data needed to manage present and future workloads so that resources can be allocated to the highest priority submissions. When a submission is filed, the system will transition to monitoring the status of each regulatory activity or decision you are waiting on from a global health authority.

MANAGE provides scalability as your organization develops new products and moves further along the lifecycle of active products.

In a typical scenario, a company has a number of active Investigational New Drug (IND) applications, but no active marketing applications. As the company matures, four of those active INDs become marketing applications to four separate countries. Planning, managing and reporting on submission and regulatory activities becomes virtually impossible if the correct system is not in place.

Layers of complexity can add up quickly in regulatory affairs. The design of MANAGE maintains its simplicity as your organization scales. Employees can tailor views to their job roles and easily locate data.

Built for How Regulatory Professionals Really Work

Synchrogenix's GlobalSubmit Regulatory Information Management (RIM) solution was designed to help regulatory professionals in the pharmaceutical industry meet their daily obligations without wasted motion.

By offering COMMUNICATE and MANAGE as standalone or integrated products, sponsors can realize a true return on investment by only utilizing functionality essential to each user role. Additional customization options such as filters allows each user to build views and create reports targeted to their individual responsibilities.

Submission Tracking

Spreadsheets do not suffice for managing everything that goes into a regulatory submission. Synchrogenix's GlobalSubmit MANAGE tool is a scalable system for tracking submission workload data. That data can then be used to allocate resources to high-priority submissions. Views can be customized to give each individual within a regulatory department only information relevant to their job role.

Regulatory Activity Status

Synchrogenix's GlobalSubmit MANAGE provides real-time awareness as to the regulatory status of each product in your global portfolio. What was approved and when?

Users are able to edit and run reports on their organization's historical and upcoming global regulatory activities filtered by region, product, time increment, etc. with just a few mouse clicks.

Other RIM Product Available—Integrated Solution

GlobalSubmit COMMUNICATE

Agency Correspondence

Agency Commitments

Challenges Addressed

- Stop gap use of spreadsheets to track submission deliverables and due dates for multiple products
- Frustration with inefficient systems where data entry and sharing are difficult
- Scalability, customization and access for each user
- Lack of real-time reporting based on submission activity and projections

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.

A **CERTARA** COMPANY