Bay Area Life Sciences organization builds Regulatory Information Management (RIM) solution to simplify regulatory submission tracking process

Customer

The customer is a research-based biopharmaceutical company focused on the discovery, development, and commercialization of medicines.

Business Challenge

A life sciences company partners with WinWire to address regulatory compliance challenges.

The company is required to track and meet compliance regulations for its products and take a new drug to the market faster.

The company was looking to build a **unified Regulatory Information Management (RIM) system** which can make regulatory compliance process more effective and efficient.

The significant impediments of Regulatory Affairs organizations included

- No holistic view of the regulatory process from clinical trial to approval
- Data silos across multiple systems and countries created lack of visibility
- Dependency on manual processes and excel files – inefficient, slow & error prone
- Changing the global submission tracking and license management mechanism
- No visibility into how data is tracked - e.g. submission timelines, expiry dates for licenses
- Need a submission tracking platform that provides real time updates on the product portfolio and pipeline

WinWire Solution

WinWire helped the life science company develop a robust Regulatory Information Management (RIM) solution that simplified regulatory submission tracking process.

RIM solution stitches the digital fabric through **"systems of intelligence"** by unifying all submission data from legacy systems and multiple data sources enabling organizations to be compliant and bring a new drug to the market in lesser time.

WinWire removed the **data silos** by bringing together enterprise-wide data to create a single source of information and created an intuitive platform for use across multiple global departments. RIM solution enables *submission planning and tracking with license lifecycle management.*

This has provided the senior leadership a bird's eye view of all the product pipeline across the globe which helps them plan their resources/efforts more efficiently and effectively.

Business Value

- Decreased legacy system maintenance cost
- Maximizes revenue and minimize compliance and quality costs
- Data quality improvement

WinWire Technologies