

CUSTOMER SUCCESS STORY



Otsuka Pharmaceutical Co.
Healthcare
www.otsuka-us.com

OVERVIEW

+ Challenges

- Complying with diverse regulatory standards across 30 international markets
- Accelerating development and delivery of periodic clinical trial reports to authorities
- Reducing risk of compliance failure while increasing operating efficiency

+ Solution

Otsuka Pharmaceuticals Co. is using JReport to create an end-to-end reporting platform for its drug and medical devices practice.

Take As Prescribed

Global pharmaceuticals manufacturer increases productivity by 300% and improves regulatory compliance with JReport.

CREATING MODERN MIRACLES

Miracle medicines don't just happen overnight. The pharmaceuticals that save lives and improve quality of life go through rigorous research, development, and testing for years before ever hitting shelves. For Otsuka Pharmaceuticals, the lengthy and arduous process is just a fact of life and a cost of doing business.

The company has spent nearly a century focusing on creating solutions for better health worldwide. Today, Otsuka delivers innovative neuroscience, oncology, and cardio-renal medicines, and medical devices to more than 30 countries. But as its business footprint has grown, so have the challenges of delivering new products to an ever-growing list of global markets.

"Each country has its own authority that oversees product safety testing, reporting, and the decision about whether or not a product can go to market," says Rajesh Pandey, Associate Director of the Safety Data Management (SDM) Group at Otsuka. "We wanted to find a way to collect and organize the required data for each country's regulators faster and make sure that the information we reported is as accurate as possible."

OVERVIEW CONTINUED

+ Benefits

- Delivered timely, verified clinical trials reports to more than 30 international regulatory agencies
- Increased productivity by more than 300% by eliminating manual reporting processes
- Generated more than 300 unique data outputs for internal and external audiences
- Reduced report development time from two months to less than two weeks

+ Technologies at a Glance

- JReport Server Live
- Ad Hoc Reporting
- JReport Designer
- JDashboard

“JReport is an easy and light tool that lets anyone in our organization become a report designer with very little training. With just a handful of resources, we're able to push out nearly 300 different outputs for internal use and create more thorough reports for external audiences from a single platform.”

+ Rajesh Pandey, Associate Director of the SDM Group, Otsuka

THE COMPLEX WORLD OF GLOBAL COMPLIANCE

Getting a new product to market—and keeping it there—is a lengthy and time-consuming process. Otsuka must put all its products through rigorous clinical trials and testing for safety and efficacy, compiling data from patients participating in trials around the world and meticulously recording each outcome—positive or adverse—for regulators to evaluate.

Data must be aggregated, analyzed, and organized into specific reporting formats for government authorities in every market in weekly, monthly, and annual intervals. In the past, Otsuka relied on manually driven, disparate processes to aggregate the data required of the various governing and regulatory bodies.

“We had colleagues in each region of the world collecting and building as many as 60 different reports, lists, and tables for every governing body,” Pandey says. “The sheer volume of work and the fact that our data has to be accurate made it extremely difficult to continuously meet deadlines to remain fully compliant.”

Pandey says that regulators occasionally granted extensions for extenuating circumstances, and Otsuka regularly contracted additional resources to help manage the workload. “Extensions and hiring more people were short-term solutions to a long-term challenge,” he says. “With the number of reports we have to produce, it became imperative to find ways to bring greater efficiency, cost-effectiveness, and consistency to our operations.”

ESSENTIAL REPORTS WITHOUT DELAY

Eager for a new approach to meeting its varying compliance standards, the Otsuka team gathered consultants and colleagues to brainstorm ways to consolidate and streamline data collection and reporting.

After developing new data collection processes, the team needed a software solution to put it into action and standardize its reporting activities. The company evaluated solutions from several well-known vendors, but chose to deploy JReport because of its compatibility with legacy data systems, intuitive setup, and automated operations.

JReport seamlessly integrates with Otsuka's Oracle database and Argus pharmacovigilance platform application to greatly accelerate reporting time-to-delivery and help to ensure that data the company uses for reports is completely accurate. Unlike other solutions, JReport doesn't require intermediate data-modeling processes to create reports, which can jeopardize data integrity while also adding critical hours or days to the reporting function.

“JReport lets us skip data handling steps that add unnecessary time and risk to our operations,” Pandey says. “Not only can we be sure that the information we're providing is as accurate as possible, we're also able to schedule automatic report delivery and make sure we don't miss a reporting deadline that could result in a non-compliant status, costly audits, or even having to suspend operations in a particular market.”

NEW TOOLS OF THE TRADE

One of the biggest advantages to using JReport is the ease and speed with which Otsuka can create new reports and formats. Otsuka team members use JReport Designer, JDashboard, and ad hoc reporting with JReport Server to rapidly design and deploy a range of interactive, elegant reports to meet the individual requirements and demands of international regulators as well as internal stakeholders.

In the past, reports had to be created locally, with Otsuka employees in each region responsible for collecting information, collaborating with local authorities, and trying to organize them into specific report layouts as dictated by regulatory agencies. With JReport, those tasks are centralized. Pandey's team can generate an array of reports covering topics such as patient medication reactions and trial outcomes at the individual participant level and lay the data out to regulators' exact specifications for more than 30 markets.

“ Our productivity overall has increased by more than 300% since deploying JReport. Reports and presentations that used to take two months to compile now take less than two weeks because every aspect of the process is simpler and more straightforward.”

+ Rajesh Pandey, Associate Director of the SDM Group, Otsuka

JReport Designer and JReport Server's intuitive interface enables virtually any Otsuka employee to easily select the appropriate data sources, create specific queries, and design a layout to a governing agency's specifications. The software's drag-and-drop functionality lets the report developer choose from over 40 types of charts, tables, crosstabs, and other components to customize the look and feel of the reports and make essential information easier to read.

“JReport is an easy and light tool that lets anyone in our organization become a report designer with very little training,” Pandey says. “With just a handful of resources, we're able to push out nearly 300 different outputs for internal use and create more thorough reports for external audiences from a single platform.”



ENHANCED PRODUCTIVITY AND GREATER REPORTING TRANSPARENCY

Deploying JReport has helped Otsuka modernize and simplify its complex reporting responsibilities. In contrast to the disparate and disjointed manual processes of the past, JReport unifies and automates many of the most time-consuming data collection and reporting tasks. Now, Otsuka can remain compliant and competitive across its geographic centers of operation with less effort, in less time.

Pandey says that his team no longer requires extensions on report deadlines and has significantly improved its resource management. “Our productivity overall has increased by more than 300% since deploying JReport,” he says. “Reports and presentations that used to take two months to compile now take less than two weeks because every aspect of the process is simpler and more straightforward.”

The increased efficiency has not only saved Otsuka a lot of time, but has also helped the company avoid the financial calamity that comes with unverified data and failure to comply with regulatory standards. Pandey says that the consequences of non-compliance can devastate a company because of the cost to redo the work, hefty fines, and other penalties, which can easily reach tens or hundreds of millions of dollars.

“JReport makes it easier for us to validate data with less effort and make sure we're compliant with all the regulations in every country in ways we never could before,” he says. “We now have all the tools to carry out our most critical activities with the confidence, clarity, and efficiency needed to move our business forward for years to come.”



Otsuka America Pharmaceutical, Inc. (OAPI) is an innovative, fast-growing healthcare company that commercializes Otsuka-discovered and in-licensed products in the U.S., with a strong focus on neuroscience, oncology, cardio-renal, and medical devices.

www.otsuka-us.com



JReport

A LOGI ANALYTICS COMPANY

JReport is an embeddable Java-based BI solution for the enterprise that empowers users to create reports, dashboards, and data analysis on cloud, big data, and transactional databases. Through embedded data visualization, users can self-service their own reporting and data discovery all from within their applications. Self-service data analysis capabilities are enabled by in-memory technologies and easily transform business data into agile visualizations. Powerful, seamlessly embedded BI has never been easier.

www.jinfont.com