



Janssen Pharmaceutical Products, LP

Overview

Country or Region: Belgium

Industry: Pharmaceutical

Business Situation

To integrate control systems with higher-level business systems, optimize operations performance, reduce batch cycle time, streamline and electronicize quality assurance validation processes, move towards electronic batch reporting, and reduce the risk of not being able to sell product into regulated markets.

Solution

RLINK™ is unique in its ability to integrate plant and business systems; the RtReports™ tool offers configurable reporting that Janssen had been unable to obtain elsewhere.

Benefits

- Integration of business/manufacturing domains
- Improved communication enterprise-wide
- Fact-driven decision-making; no guesswork
- More accurate forecasting and budgeting
- Real-time cost accounting
- Reduction of cycle time
- Major reduction of Batch Book compliance documentation (from 100 pages to 4)
- Easier, faster validation reporting
- More process investigations/improvements
- Improved operating efficiencies

Integrating manufacturing data from the plant floor into SAP



“The biggest risk in this organization is that we lose the ability to sell our product into regulated markets. RtReports is directly addressing the number one risk we face.”

Vincent Walshe, Systems Integration Coordinator, Janssen Pharmaceutical

Like many companies, Janssen Pharmaceutical was implementing SAP as their Enterprise Resource Planning (ERP) system. In order to integrate manufacturing data from the plant floor into SAP, Janssen simultaneously installed the OSIsoft PI System. For the first time, financial people, who had never been able to link to the production floor, were now costing in real time. People in Operations, Engineering, Quality Assurance (QA), Environmental, and Security were able to obtain multiple views from one data source, resulting in better operational visibility, process improvement, and collaboration. The use of the PI System has led to better decisions and ongoing improvements such as: reduced cycle times, superior batch quality and releases, thorough incident investigations, decreased process variability, real-time costing, and better alarm management and security monitoring.

Now, with the implementation of OSIsoft's RtReports product, Janssen can provide QA with a tool that streamlines the validation process for faster and more accurate compliance monitoring and reporting. The reams of paper with sign-offs and manual inputs from production to QA have been replaced with a few targeted reports that include batch trends. Production is able to reduce cycle time with configurable, real-time batch performance reporting. Of significant importance to Janssen's business evolution is that RtReports has become a major part of Janssen's progression towards electronic batch records.

The PI System and RtReports give Janssen the ability to produce a higher-quality, compliant product that enables the company to continue selling into regulated markets — a challenge all pharmaceutical companies face.

Janssen Pharmaceutical Products, LP

Janssen Pharmaceutical Products, LP was founded in 1953 by Dr. Paul Janssen, a prominent researcher, pharmacologist, and physician, who grounded the company in science and the search for innovation. That focus and commitment are still nurtured today by a unique blend of “opposites” — a lean, entrepreneurial organization that allows it to be nimble and opportunistic, backed by the significant resources of Johnson & Johnson, its parent company and the world’s most comprehensive manufacturer of healthcare products. Janssen produces and markets prescription medications in therapeutic areas including central nervous system disorders, gastrointestinal health, pain management, and the treatment of fungal infections. Janssen’s Cork County, Ireland site employs over 230 people and manufactures active pharmaceutical ingredients for human use including Imodium, Risperdal, and Haldol.



Integrating business and manufacturing

“We had so many islands of information,” explains Barry

Higgins, one of Janssen’s automation and control engineers who has managed the company’s batch operations for over 12 years. “We had many separate sources of data from our labs, process control systems, the plant floor, engineering, and the business office. All of this information had to be combined in order for us to make quicker and more accurate decisions for faster release of our product.”

OSIsoft’s PI System was first introduced to the Ireland site in 1999 as part of an SAP integration project. With the PI System, Janssen was able to integrate data from different sources for access and display on desktop clients throughout the company. Through OSIsoft’s RLINK gateway to SAP, real-time data from the plant floor was integrated into the company’s higher-level business systems. “The importance of connecting the plant floor to our business systems was to enable us — from a financial point of view — to cost our equipment usage and down time,” says Higgins. “Using the PI System and RLINK gateway, we were able to directly integrate batch stop and start times, down time, and batch performance data into SAP. Our financial people, who had never before had any link to the production floor, were now costing in real time. The RLINK connection between the plant floor and SAP has enabled finance to cost activities as they happen in real time. Forecasting and budgets are now more accurate.”

From a costing point of view, the interface between SAP and the plant means that start and end times, as well as any phase, recipe, or step required in each batch are all integrated into SAP and can therefore be associated with a direct cost. This has saved Janssen’s finance people a huge amount of time. Previously, data had to be manually gathered, recorded, and integrated into reports with other information.

RLINK has enabled the business office to see the status of a batch immediately, at any given time. In the past, once materials left the warehouse, tracking their position in the supply chain had to be performed manually. The PI System delivers an enormous time savings. Now, supervisors need no longer wait for necessary information to make decisions. Adjustments to the plan can be carried out in real time at the desktop.

“In my opinion,” says Brian Corcoran, an analyst and programmer working closely with the RLINK product, “integration is the greatest benefit of RLINK. We’ve

reduced the number of duplicate entries, increased the number of data systems we can incorporate into one data archive, and gained more production information in SAP. Without RLINK, there would be a lack of information in SAP. But with batch data integrated into SAP, we can look at all the different pieces of equipment within the batch and determine what material has passed through a particular piece of equipment during any given time period. This supports inventory control and costing. Also, integrating SAP with all plant systems allows us to report in real time at the campaign level, rather than at the batch level only. We can now look at yields over a particular batch or an entire campaign.”

“RLINK provided a bridge between our control systems and business systems with integration that wasn’t possible before,” says Phil Vaughan, Director of I.S. & Materials. “It is integrating activities happening on the plant floor with our high-level business applications, and we’re getting a more realistic picture of our total business.”

The real-time batch

“Our one data source is the batch,” Higgins explains. “The batch includes the start and end and everything that happens in between. Because we are a batch site, we are concerned with what happens within that period of time. But different people have varying information needs. We were looking for a way that non-batch information could be made available to different people.” The batch component of the Pi System is used across the site to track batch progress through the plant. Plant managers, production, and QA people are able to view information in a batch context. Users need only know the batch ID in order to access all properties and information associated with a particular batch.

“We are able to track the entire progression of each batch — what equipment a batch has gone through, digital states, whether a pump has come on or come off, our critical parameters, critical limits, and any exceptions to those limits,” says Higgins. “Across the site, critical functions such as Production, QA, and Finance are now interconnected; all of the data is combined into one source where users easily access the data they need in a form that relates to what they’re doing.”

“The ability to associate data in a batch context has

reduced our batch release cycle time,” says Higgins. “It also gives the operators more power and the ability to get targeted data about the process. It’s allowed our process development people to compare batches historically and work towards determining a “golden batch” that they can compare against all other batches. By finding our golden batch, we can get closer to optimizing our batch processes and running on-spec batches more of the time.”

RtReports: not just the typical quality reports

As with most pharmaceutical companies, Janssen was dealing with overwhelming amounts of paperwork, sign-offs, and reporting to validate and meet compliance regulations. “We had a hybrid batch record with three separate pieces — reams of paper had to be submitted to our QA department so they could review all the information associated with a batch and determine where and why deviations occurred,” says Higgins.

Janssen’s paper “batch book” required over 600 handwritten operator inputs and sign-offs for each step. With every batch requiring its own batch book, handling the paperwork and sign-offs required immense time and energy — as well as opening up a significant potential for error. In addition to the batch book, operators were required to print system reports and trends to send to QA in one package for sign-offs. QA would then go through reams of paper to spot deviations and identify how and why these occurred. At the end of the day, all this activity added to the cycle time of a batch.

In order to decrease the number of manual inputs, reduce errors, and streamline the validation process, Janssen joined the Early Adopter Program for OSIsoft’s RtReports product. “We look at RtReports as a strategic development for Janssen, and that’s why we have been very keen to move the implementation forward as quickly as possible,” says Higgins.

As an early adopter, Janssen’s first activity was to sit down with QA and Production to determine what data and types of reports were required by each group. The second activity was to make sure that the batch structure was set up correctly in OSIsoft’s Module Database.™ RtReports is fully integrated with the rest of the PI System and works directly from the equipment

lists and batch-tracking structures stored in the Module Database. Third on the list was the installation of RtReports, which went so quickly that Janssen was generating reports by the end of the first day.

"We certainly have seen added value in RtReports that we haven't seen elsewhere. It's a major part of our progression towards electronic batch records," says Vaughan. "QA now has a tool that helps them more quickly and accurately to validate batches."

"RtReports is a secure, flexible, Web-based batch reporting tool. You can build reports that are based on plant configuration, specifications, and production data. We were literally generating reports within hours — and when we saw what data we could get out of our 'closed' DCS systems, we were blown away. We quickly configured more RtReports to extract other data that we needed from our batches," says Higgins.

RtReports acts as an enhanced batch book taking out all information that is not required and reporting only information that specific departments need to see," says Vincent Walshe, Systems Integration Coordinator. Getting reports that have only targeted information simplifies the release process. Eventually, RtReports will be the definitive electronic batch report for Janssen, but for now, using RtReports, with an electronic batch record in place, reduces a 100-page batch book to four pages.

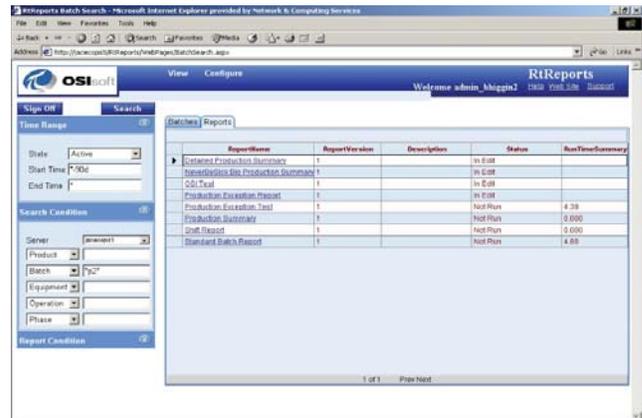
"The biggest risk in this organization is that we lose the ability to sell our product into regulated markets. RtReports is directly addressing the number one risk we face," says Walshe. "We've got something that we as a company want, rather than something that a vendor has pushed on us that's preconfigured to what they think we need. One of the most valuable benefits to us is the partnership with OSIsoft, wherein we've developed RtReports to be a truly valuable tool that we can use to deal with our challenges and inherent risks."

RtReports: one source, multiple views

RtReports are configured to each user's specifications and show only the data relevant to that person. Users now have access to targeted data at the desktop. Reports can be generated while batches are running, so

if a manager wants to know the current status of any parameter, an entire batch, or the whole operation, a report can be run to show real numbers in real time.

Originally Janssen set up reports for only Production and QA, but once the company realized that reports could be used by other departments, these reports were configured to be used in areas such as engineering, utilities management, and energy management.



From one RtReports display, multiple report types can be accessed, including production summaries and exception, shift, and standard batch reports. This display was configured so that users can search by product, batch, equipment, operation, or phase.

"These are not just typical product quality reports," says Higgins. "This new capability is very exciting to our management. It enables them to build RtReports that show the standard time that any particular batch should run within. With that, if production goes off the standard, the problem can be immediately focused on and solved. This leads to a reduction in downtime and increased on-spec manufacturing."

Janssen generates different RtReports for respective users such as the following:

Production uses cycle time, as well as detailed and summary production reports to track the progress of a batch

Quality Assurance uses exception reports and batch trends in approving each batch release. This contributes to a streamlined approval process

Plant managers use shift activity reports to view the plant's current state at the start and end of a shift

Management uses RtReports to establish golden batch standards, reducing downtime and manufacture on spec

Security personnel can view the entire plant or a particular unit from a security console

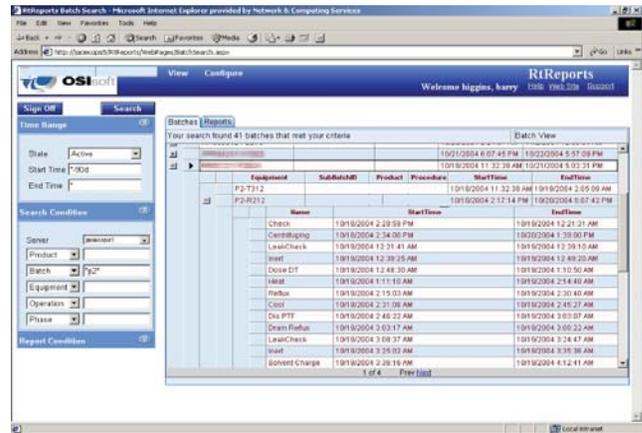
Everyone on the same page

The fact that the PI data originates from one source and is distributed throughout the company has enabled everyone to “read from the same page”. “I’ve noticed operators using it,” says Higgins. “Day by day people come to meetings with trends saying, ‘Look, this is what happened, let’s do something about it. How do we prevent this from happening again?’ It has enabled the company to communicate better, because we’re not going on hearsay or guesswork anymore.”

The company operates more efficiently because information is so readily accessible and available in a context that makes sense. “If we didn’t implement the PI System, we’d be back with multiple sources of unintegrated data. There’d be arguments and conflict over the meaning and validity of the data. And our company would have more paper with no context. The PI System has enabled us to work more efficiently: everyone’s reading from the same page; the same data is going to the same people; and they can apply a context to that data.”

A valuable partnership with many benefits

“Just because we have a lot of data doesn’t mean we can do anything with it,” explains Walshe. “To be able to give data context and use tools to run operations better is a valuable PI System benefit. The benefits we’ve seen are in yield and throughput improvement; streamlining of work practices; ability to attach a cost to an action; correlation of operations and business outcomes; a means of reporting on any given problem; and the streamlining of regulatory processes to make them easier, more efficient, and foolproof.”



Real-time and historical data can also be instantly accessed by individual batch — even as it’s running — such as raw material additions, leak checks, trace inlets and outlets, and solvent changes. Having all of the data easily available and well organized makes at-a-glance overviews and drill-down analysis more efficient.

“The fact that OSIsoft’s products are so incredibly versatile is a huge benefit,” continues Walshe. “We write one batch report and reuse it across our multi-purpose plant. It provides an extremely efficient method for generating batch reports at an almost zero cost of ownership.”

“Janssen is very keen on building partnerships with our suppliers,” says Vaughan, “and our relationship with OSIsoft is absolutely critical. It’s a two-way communication. We benefit from having OSIsoft tell us what technology is coming down the pipeline, and we tell OSIsoft what our business challenges are. It’s been a great advantage to be able to give OSIsoft our

requirements and have them take the feedback into building a product (RtReports) that works for us and our industry. OSIsoft is keenly aware of compliance-related issues and what the industry needs to meet validation and reporting requirements. It's a great benefit to have a technology partner that will work with you to give you the products that help you solve those challenges."