OSIsoft®

SUMMARY

Shire

Industry

Pharmaceuticals

Business Value

- Operational Insight
- Data Centralization
- Data Integrity
- Employee Productivity
- Time To Market

PI System™ Components

- PI Server™
  - Data Archive
  - Asset Framework
  - Event Frames
  - Notifications
- PI Interface for Universal File and Stream Loading (UFL)
- PI WebParts™
- PI Vision™

Shire: Turning Data into Knowledge with the PI System

Over the past several years, biopharmaceutical developer Shire has been working to implement a major overhaul of the way data is handled at their pilot plant in Lexington, Massachusetts. Before implementing the PI System, the company was generating, processing, and storing data in a complicated series of networks and standalone data islands and relying heavily on spreadsheets and manual data entry. One by one, Shire is integrating all of these diverse data sources into a single solution, the PI System. At the OSIsoft's 2016 Users Conference in San Francisco, Paul Turvey and Brad Ebel of Shire, presented how this project has streamlined the flow of information, improved user access to data, reduced errors, and had a substantial impact on the bottom line.

Bringing Order to a Complex System

Like any pharmaceutical development facility, Shire's Lexington plant is a complex organism. More than 300 data sources feed into the plant's data architecture. Many of the components of the plant's system, both hardware and software, have lifespans – so the plant's data management system must be robust enough not only to handle a diverse array of existing data sources from different vendors, each with their own operating software, but also to integrate with future sources that will replace equipment as it becomes obsolete. "When you're in R&D you're not talking about four or five sources from a building management system and a process control system. You've got this whole ecosystem you're going to have to contend with," Turvey said who heads Shire's laboratory operations.

For Shire, the real value in implementing the PI System lies in taming this jungle of data so that information can be accessed and acted upon. "We want to enable any scientist to analyze an experiment in 10 minutes or less," Turvey said.

PI Vision[1] allows plant operators to pull up a rich and easy-to-read information screen showing the data output of a bioreactor over a full 24-hour time period. By looking at a full day's worth of data at once – rather than, for instance, spot-checking to see what the pH of the reactor was at one point in time – an operator can spot potential problems or unusual variations even if they don't rise to the level of triggering a system alarm.

The information interface also allows plant operators to explore data without worrying about interfering with plant operations. "With this screen you can

click on anything and everything and you can't mess anything up," said Ebel, who manages operations at the pilot plant. "This was a very happy moment for me, when I realized I no longer had to worry about people making changes to my reactor."

Event Frames has also enabled Shire to remove potential sources of human error from batch processes. Triggers are set off automatically that track a batch's movement from one phase to the next, ensuring that the accuracy of the batch data no longer relies on an operator remembering to enter contextual batch data at the right time.

PI System Saves on Costs and Drug Development Time

Since Shire began streamlining and centralizing their data in the PI System, the company has realized cost savings on several fronts. For one, the company is moving away from reliance on manual data entry and spreadsheets, freeing up valuable employee time that could be better put to other uses. "You've these got highly trained, highly educated employees that you're paying hundreds of thousands of dollars, and they're sitting at their computer wondering what the pH value for a reactor was," said Ebel. "It's ludicrous to be doing that."

Managing data through the PI System has also improved data integrity at the plant, which is helping Shire reduce the frequency of audit findings. According to a cost-benefit analysis of the project, Turvey said, the PI System is expected to spare Shire a potentially expensive audit finding approximately once every two years.

Most importantly, data reform has cut down the amount of time it takes to get a new drug through the pipeline from conception to clinical trials. In research and development, time is money: getting to market first can gain you a lasting advantage over your competitors.

In 2013, the plant was completing an average of about four research programs a year. That number rose steadily over the next few years as new data infrastructure reforms were put in place. In 2015, with the same level of staffing, the plant ran six research programs from start to finish, a 50 percent increase over their previous rate of drug development. "Every drug has a low probability of making it all the way to a success, but you've got to get shots on goal. Going from four to six in a few years -- I think that's a reflection of the investment in PI and some of our other partners," Turvey said.

"In pharmaceutical development, knowledge doesn't only define our product – it is our product… You need a single source of truth. OSI's PI has been very valuable for that for us."

– Paul Turvey
Associate Director of
Shire Laboratory
Operations

[1] PI Coresight was renamed to PI Vision in 2017.

Ebel, Brad and Turvey, Paul. *A Knowledge Management Model for Pharmaceutical Development.* OSIsoft.com. 6 Apr. 2016. Web. 03 August 2017. <http://www.osisoft.com/Presentations/A-Knowledge-Management-Model-for-Pharmaceutical-Development/>.