OSIsoft.

SUMMARY

Sandoz

Industry

Pharmaceuticals

Business Value

- Process Optimization
- Operational Visibility
- Data Quality
- Quality Control
- Regulatory Compliance

PI System™ Components

- PI Server™
  - Data Archive
  - Batch
  - Audit Trail
  - High Availability
- PI Interfaces
- PI Manual Logger™
- PI ProcessBook™
- PI DataLink™
- PI BatchView™

Sandoz Relies on the OSIsoft PI System for Data Integrity and Regulatory Compliance

Sandoz, a subsidiary of Novartis that manufactures generic drugs, is subject to regular inspections from multiple regulatory agencies. In recent years, those agencies have begun focusing more on data integrity and audit trails for all digital records. In a presentation at OSIsoft's 2015 EMEA Users Conference in Prague, Alexander Haimayer, Head of Data Systems at Sandoz, described how OSIsoft's PI System helps the company stay in compliance with rigorous data archiving and manufacturing procedures required by the U.S. FDA – just one of the many agencies with jurisdiction over Sandoz's operations.

The Importance of Data Quality in a Complex Regulatory Environment

Sandoz is subject to regular inspections from regulatory agencies around the world. At least once or twice a month, an agency will visit the facility, either for a routine compliance inspection or a directed inspection triggered by some discrete event, like a drug preapproval, recall, or complaint.

Sandoz has been running the PI System at their Austrian facilities in Kundl and Schaftenau since 1996. Their PI System implementation at these two facilities includes more than 150,000 PI Tags on five servers and 60 PI Interfaces. There are roughly 1,500 PI System users on site. "The PI Servers are dealing with about 2,000 events per second," Haimayer said.

With so much raw data being collected and stored, it takes a highly robust and stable system to ensure that all the data is accurate, trackable, and properly archived. Sandoz operates in one of the most highly regulated industries in the world, and the company places a high premium on the quality of their data.

Increasingly, Haimayer said, agencies like the FDA want to have direct access to Sandoz's data. "We had an inspection this year where we had to give the FDA access to the PI System. They took a laptop to the hotel and were really looking into the data," Haimayer said.

Using the PI System to Maintain cGMPs

To ensure that drugs are made properly and labeled accurately, the FDA requires companies under its regulatory purview to follow "Current Good Manufacturing Practices," or cGMPs. The concept of cGMPs dates back to the early 1940s, when a batch of sulfathiazole tablets made by a New York pharmaceutical company was contaminated with phenobarbital, causing hundreds of patients to fall ill and several to die. In the wake of the incident, the FDA began requiring pharmaceutical companies to follow controlled, tightly monitored procedures for manufacturing, processing and packing of all drugs. The regulations on cGMPs are meant to ensure the quality, strength and safety of all drugs under the FDA's authority.

As manufacturing has matured, so have the FDA's regulations. Current cGMP regulations include strict controls on not only the manufacturing process for making a drug, but also on the collection and storage of digital data at every step of that process. In recent years, Haimayer said, health agencies like the FDA have been increasing their focus on data integrity in the manufacturing process.

"Regulators don't want to see only the end result, they want to see the audit trail," he said. An audit trail, to the FDA and other regulators, is a time-stamped electronic record that shows not only the data associated with a process, but how that data was created, by whom, and for what purpose. An audit trail allows regulators to reconstruct the entire course of events that led to the creation of a data record. If the record was modified or deleted, the audit trail will show who modified or deleted the data, and why it was done.

According to a 2016 analysis by the Health Research Institute, the FDA has stepped up its efforts to ensure data integrity by the manufacturers it regulates, especially in the wake of the 2012 FDA Safety and Innovation Act. Between 2013 and 2015, the FDA cited 24 drug manufacturers for data integrity violations – a nearly five-fold increase over the number of citations between 2010 and 2012. The agency has also stepped up the number of drug quality inspections it conducts outside of the U.S. For manufacturers, the costs of improper data practices or incomplete audit trails can be very high. Problems with data integrity can trigger product recalls or cause drug approvals to be delayed or denied.

Because the PI System is "sophisticated and stable," Haimayer said, it is vital to Sandoz in their effort to stay in compliance with multiple agencies and a myriad of regulations. "We have really good inspection results," Haimayer said, "because we have a clear story of how we do data archiving."

"In the regulated production environment, data is the evidence to our patients and health authorities that our products are safe and effective. It tells the story of a product long after it is shipped."

– Alexander Haimayer
Head of Data Systems

Haimayer, Alexander. *How the PI System Helps Sandoz in Kundl with Regulatory Compliance*. OSIsoft.com. 14 Oct. 2015. Web. 21 July 2017. <http://www.osisoft.com/Presentations/How-the-PI-System-Helps-Sandoz-in-Kundl-with-Regulatory-Compliance/>.