New LORENZ docuBridge Submission Management System enables a leading pharmaceutical company to deliver compliant drug dossiers to agencies around the globe

Existing submissions were automatically migrated to the new system using the LORENZ Automator.

The Situation

Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the worldwide Novartis Group, its purpose is to discover new ways to improve and extend people's lives. Sandoz contributes to society's ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Its portfolio of over 1000 molecules, covering all major therapeutic areas, accounted for 2015 sales of USD 10.1 billion. In 2015, Sandoz products reached more than 500 million patients and the company aspires to reach one billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Previously, Sandoz had a solution in place for publishing initial submissions and for maintaining submissions to the various national health authorities. However, the vendor of that solution stopped further development. In order to remain current and compliant with all updated Health Authority requirements, Sandoz had to replace their submission management system. A RfP was prepared and sent out to the leading software solution providers. After a thorough evaluation phase, Sandoz selected the LORENZ docuBridge solution together with the LORENZ Automator for the automatic migration of more than 100,000 submission sequences into docuBridge.

SANDOZ A Novartis Division

- Implementation of a **centralized Submission Management Solution**
- Connected to an **external DMS** and **Master Data System**
- Accessed by **250 users simultaneously**
- Managing submissions for a **portfolio of 1100 generic compounds** worldwide

LORENZ Products:

The Solution

LORENZ docuBridge is a software solution to create, maintain and publish drug submissions to all national and regional authorities around the globe. All required submission formats (eCTD, NeeS, Paper) can be generated from the same source. docuBridge connects to both the Sandoz Content Management System for documents and the Sandoz regulatory database (Master Data) in order to populate pick lists and other metadata required for the submission process. Based on the templates for each submission type, new submissions and submission updates can be created quickly and easily. docuBridge includes an integrated validation software component, the **LORENZ eValidator**, to verify that the published output complies with the latest regulatory requirements of the target agency.

For all existing submissions, **LORENZ Automator** and a Sandoz-built software component have been integrated to create an automated migration solution. Post-migration, Sandoz is able to continue the life cycle for all of the migrated applications, and can also use the existing documents and Master Data.

The solution was implemented in two phases: first, docuBridge was made available for new submissions, and in the second phase existing applications were migrated to the new system in a sequenced migration plan put together with Sandoz.

The Benefits

Sandoz has been creating and delivering submissions with the new system since March 2015, meeting all current compliance requirements. Sandoz has also experienced a 40% gain in efficiency with the new solution compared to the old one. "We are very pleased with the LORENZ software. When rare support issues do arise, LORENZ addresses them immediately. The system is being used heavily. The LORENZ implementation team was both professional and highly flexible in doing what was needed to simply get the job done. We made the right choice with LORENZ," says Elke Schydlo, Head of Global Regulatory Information Management & Systems at Sandoz.