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KÖRBER SOLUTIONS

SUCCESS STORY SERIALIZATION

Serialization at Luye Pharma EU
in Miesbach, Germany



SERIALIZATION AT LUYE PHARMA EU IN MIESBACH, GERMANY

BACKGROUND

Luye Pharma EU in Miesbach, Germany, is part of the global Luye Life Science Group, with headquarters in Yantai, China. The primary focus in Miesbach is on development and production of Transdermal Therapeutic Systems (TTS). In addition, there is an on-site production of hormone patches. Miesbach Luye also produces for other marketing authorization holders (MAH) as a contract manufacturer (CMO), on top of their own production.

Due to this complex situation, Luye Pharma needs to monitor the legal situation of the EU directive on falsified medicinal products and tamper-evident packaging from both an MAH and a CMO point of view.

As a CMO, Luye must not only comply with the European directive 2016/161/EU, but also with the FDA guidance "Drug Supply Chain Security Act (DSCSA)" for the US-market, especially right now.

DSCSA was what drove this project, right from the start. There were only four months to release the first batch after the project's kick-off. This was mandatory in order to become compliant with regulatory requirements in the United States, and thus fully keep the ability to deliver to this market.

All involved project parties knew the pressure arising from the DSCSA from the beginning. First step: implement a stringent timetable. This was only going to work if all parties worked together and focused on a common goal.

Despite the pressure, the vendor was chosen very carefully. A major criterion during the selection of the Serialization Software solution was the ability of the solution to meet the

requirements with standard functionalities, so as to keep time spent on development and validation minimal. In addition, the solution had to be available as a hosted solution in order to avoid additional investment in IT support environment at Miesbach.



Luye Pharma EU

Luye Pharma AG, with its locations in Miesbach in southern Germany and Basel in north-east Switzerland, has been a worldwide partner of the pharmaceutical industry since 1997.

As part of the Chinese Luye Life Science Group, Luye Pharma is also developing the European branch of the globally and dynamically growing, demanding Luye Pharma Group which currently employs more than 4,000 people.

SOLUTION

The Luye Pharma team opted for the arvato CSDB solution hosted at Arvato Systems in Germany. The Arvato Systems team also maintains the solution which is constantly available and running on Arvato Systems server.

The arvato CSDB completely fulfills the Luye Pharma requirement for a customization-free solution, where no development efforts are required.

Together with Luye Pharma, Systec & Services split the project in two large phases. The required documentation was created in phase one, along with a test and a productive system. The common goal: to be ready for the US market!

IMPLEMENTATION

The Luye Pharma Project Team has taken the conscious decision to choose the standard solution arvato CSDB. During the project execution it was clear to everyone that there was only configuration, no development.

The Luye Pharma URS requirements were completely fulfilled by the arvato CSDB standard functions.

Seamless interaction between colleagues from Systec & Services, Luye Pharma, and Arvato Systems supported the success of the project.

Systec & Services demonstrated expertise in project management, functional consulting, and validation services. A big advantage was the close collaboration between the Systec &

SOLUTION HIGHLIGHTS

- Serialization & Aggregation
- Extreme short project duration
- Use of hosted solution

Services project team and the Arvato application engineers, which lead to quick decision making and fast processes. In phase II additional business partners will be included, as well as production for the European market. Looking back at how successful the first phase of the project was, everybody is looking forward to phase II.

RESULT

Due to the execution of phase 1 on time, Luye was in a position to deliver in full compliance with regulatory requirements to the US market. Therefore Luye Pharma is one of the few companies that do not need to take advantage of the FDA suspension of the “Drug Supply Chain Security Acts (DSCSA)”.

Bernd Wolke, Head of Engineering at Luye Pharma in Miesbach is looking forward to the Continuation of the collaboration: *“With a committed team like this, leading a project towards success means fun. Everybody knew about the amount of pressure on the project team. Being professional and authoritative in project execution, the Systec & Services colleagues set standards. I am confident that phase II will run just as well.”*

ADVANTAGES

- On-time execution under time pressure
- No need for additional IT support environment
- All requirements included in standard product

“We are happy about the compliments and are compelled to return them. In this project, the teaming between client and delivering organization worked extraordinarily well. A big thank you to Mr. Wolke and his team at Luye Pharma for the collaboration – we look forward to coming back!” added Dr. Martin Printz, Project Manager, Systec & Services.



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