# The path to Industrie 4.0

In China, an integrated solution from Siemens is helping Jinyu Bio-technology to capitalize on digitalization by implementing an intelligent manufacturing facility. This emphasizes the company's position as China's leading animal vaccine manufacturer and will enable Jinyu Bio to expand into global markets.

A nimal vaccine manufacturer Jinyu Bio-technology Co., Ltd. (hereinafter referred to as Jinyu Bio) has developed a reputation in the biopharmaceutical industry for creating products with low impure protein, high antigen concentration, and minimal side effects. In addition to being the first company to successfully develop suspension culture technology for animal vaccines, Jinyu Bio has set industry standard for vaccines against foot-and-mouth disease. At the end of 2015, the company was named the No.1 animal vaccine manufacturer in China, and is now a leader in the country's animal protection pharmaceutical industry.

Continuous innovation and sensitivity to market needs enable Jinyu Bio to seize opportunities during times of industry change. Today, against the backdrop of China's reform of the supply front and the national strategy "Made in China 2025", Jinyu Bio is taking advantage of the potential Industrie 4.0 offers to the pharmaceutical sector.

## Maintaining an edge

Jinyu Bio understands that capitalizing on Industrie 4.0 will require the help of strategic partners. "Moving toward Industrie 4.0 requires collaboration between different players," says Zhang Chongyu, chairman and president of Jinyu Bio. "It can never be achieved by one company's efforts alone."

Jinyu Bio became the leading animal vaccine manufacturer in China thanks to more than a decade of hard work. Despite the leading position it currently holds in the animal vaccine industry, Jinyu Bio faces many questions, one of which is how to maintain its competitive edge in the years ahead.

At the same time, local biopharmaceutical companies still have to close a wide gap with their international counterparts. This has forced Jinyu Bio to decide how it will compete on the global market over the next decade. In response to these questions, the company set out to build a world-class digital pharmaceutical factory. With extensive experience in the digital factory field, Siemens was the ideal partner to help them accomplish this goal. Consulting-based services

## A new model

In the conventional business model for offering products, a supplier tells the customer what equipment, systems, and software are available, and what problems it can solve with them before the customer decides whether they will make a purchase. However, this method of engagement does not give the customer an in-depth understanding of how to address their issues, nor does it tell them what returns/benefits they can expect from implementing the new solution offered to them.

This was precisely Jinyu Bio's predicament. The company was trying to embrace digitalization as this is what the change process demanded, but it lacked effective and systematic implementation methods.

In an effort to overcome the limitations of traditional customer/supplier interaction, Siemens adopted a new business model – one that featured consultingbased services and an integrated solution for addressing Jinyu Bio's needs. Siemens held workshops discussing expectations, site surveys, and focus groups to fully understand the factory's status quo at Jinyu Bio and analyzed the existing problems in production, R&D, marketing, technology, operations, and maintenance. Siemens then delivered diagnostic and consulting reports before offering solutions to address Jinyu Bio's challenges.

## **Defining roles**

Overall planning group, 6 expert teams

Siemens communicated with the customer throughout the consulting process. To identify Jinyu Bio's pain points, Siemens appointed an overall planning group and six expert teams.

These Siemens experts worked with Jinyu Bio employees at all levels, including its leadership, management, team leaders, and shopfloor operators. Approaching Industrie 4.0 from different perspectives, Jinuy staff all had similar questions, such as what the digital pharmaceutical factory would consist of and how their roles should be defined.

To this end, Siemens organized a knowledgesharing session with all the employees at Jinyu Bio which focused on Industrie 4.0, the latest developments of smart factories and reference cases in various sectors in China. Taking Siemens Industrial Automation Products Ltd., Chengdu (SEWC) and Siemens Electronics Works Amberg (EWA) as examples, the elements of a smart factory were demonstrated. Siemens also gave a workshop for people in various functions at Jinyu Bio and encouraged them to communicate with each other and share their ideas and expectations.

Activities of this kind allowed Siemens not only to identify the actual needs of Jinyu Bio employees, but also generated enthusiasm for the digital transformation, setting the stage for later research and project execution. In focus

## In-depth analysis

## **Identifying issues**

After a comprehensive and in-depth analysis of the Jinyu Bio factory, Siemens identified several fields of optimization.

First and foremost, pieces of equipment were isolated from one another and there was no digital data flow. This problem is commonly encountered at pharmaceutical companies throughout the process industry. Unlike assembly lines deployed in discrete industries, medicinal products such as vaccines are manufactured in batches, that is, in a pharmaceutical factory where all processes and units including controllers are independent. This results in information silos, along with decentralized roles and responsibilities.

Secondly, the products lacked traceability with data manually recorded and there were potential data compliance risks. Currently, Jinyu Bio relies on paperwork to give production instructions and record production data, which can cause issues such as missing data and records, mistakes, and incomplete data retrieval. In the event of a quality problem, it was complicated to track down what went wrong. This is problematic because pharmaceutical products are subject to strict review and approval from relevant national regulators, including the China Food and Drug Administration (CFDA), which requires 100% traceability of the production process.

In addition, many critical production steps rely on the experience of frontline employees. Without systematic data management, important information is only known to senior operators but not written down. As a result, when personnel changes occur, there is often inconsistent knowledge transfer, which negatively impacts product quality. 3-to-5 year implementation plan, MES, Simatic IT eBR, ...

### A customized solution

After identifying issues and talking with Jinyu Bio personnel, it was determined that the factory's needs could not be met merely by traditional PLCs. So Siemens proposed a three-to-five year Industrie 4.0 implementation plan involving a number of hardware and software systems.

As part of this plan, Siemens will initially provide an integrated automation solution, with Simatic S7-1500 deployed for automation of individual equipment and Simatic PCS 7 as the overall process control system for production automation. Not only will it utilize industry networks for linking all equipment and production lines into a well-connected factory, but Jinyu Bio will also deploy a Manufacturing Execution System (MES) using Simatic IT eBR to enable pharma-specific documentation and release of the drugs. A key benefit of Simatic IT eBR is end-to-end material tracking and control from raw materials all the way to the finished product.

The customized solution will also feature a Siemens Comos platform to fully support the factory's future equipment operation and maintenance. With Comos, Jinyu Bio can comprehensively manage the progress and execution of the project in a transparent manner. Siemens will also provide its XHQ Operations Intelligence software to collect and manage Jinyu Bio's production, operation and maintenance data in a centralized system. This will include the use of powerful data interfaces for interaction with the commonly used database and conventional file systems in the market.

Data is the core of digital factory solutions. Based on the software systems to be implemented, Jinyu Bio can obtain mass data during the production process. Through further analysis, it can also define relationships between process parameters and First Pass Yield (FPY), thus significantly improving the production process and product yield.

Because this solution covers both management and digital improvements, Jinyu Bio accepted the proposed solution and signed the contracts for the MES and Comos systems. In the coming years, a series of digital factory solutions including Simatic PCS 7, XHQ, and Siemens Process Analytical Technology (SIPAT) will be strategically deployed. Vertical and horizontal integration

#### **Defining a blueprint**

Jinyu Bio's journey to Industrie 4.0 is also part of Siemens' deep exploration in the pharmaceutical industry. "Jinyu Bio-technology is a very important partner of Siemens in the pharmaceutical industry," says Lin Bin, executive VP of Siemens Ltd., China and general manager of the Process Industries and Drives Division. "Digitalization is key as we strive toward Industrie 4.0 and "Made in China 2025." I believe the digital factory we are about to build together with Jinyu Bio-technology will become a model in the pharmaceutical industry, and even in process industries, and will greatly facilitate the industrial transformation and upgrade of Jinyu Bio-technology."

The blueprint for the digital factory serves as a guide for Siemens' integrated solution design and helps determine the number of digital systems needed to support the business process. It also helps Siemens define the boundaries of digital systems and determine how crossteam business processes can be smoothly integrated with such systems.

The blueprint also maps out vertical integration from the shopfloor to management and horizontal integration from suppliers to customers. The overall planning and phased implementation enables Jinyu Bio to achieve Industrie 4.0 in a highly coordinated way.

"Technology drives production and lean manufacturing ensures product quality," says Zhang Chongyu. "The digital factory will help shape an intelligent manufacturing system. It will not only allow our company to take lead on the path to realize Industrie 4.0 and become a model in carrying out international standards in the industry, but also facilicate the upgrade and transformation of domestic bio-pharmaceutical industry." Best position for digitalization

## Setting the trend

As regulators worldwide attach more importance to data integrity in the pharmaceutical industry, digitalization has increasingly become a major concern and a necessary step for Chinese pharmaceutical companies to transform and upgrade their enterprises. The expertise of Siemens in the fields of automation, digitalization, and intelligence will play a critical role in helping Jinyu Bio achieve this.

Zhang Chongyu says: "Following the proposition of an innovation-inspired future, Jinyu Bio-technology will leverage Siemens' technical expertise to build a digital factory and intelligent manufacturing system. While better catering to customer requirements, this will best position us to set the trend in digitalization in the pharmaceutical industry."

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