versiondog:

Indispensable for the efficient development and production of pharmaceuticals

Yichang Humanwell Pharmazeutika

For Yichang Humanwell Pharmaceuticals, China's largest pharmaceuticals manufacturer, attention to detail is key. To ensure that the entire production process runs smoothly, versiondog accompanies the strictly regulated production processes.

The use of narcotics can make the difference between life and death. The specifications that must be complied with in the manufacturing of anesthetic drugs are correspondingly strict.

From the selection and the dosing of the raw materials, the speed of the machines, the temperature in the production hall, the duration of production to packaging, storage and transport - every step of the manufacturing process requires a high degree of stability and precision.



A single mistake can result in the disposal of an entire batch of medicines worth millions of RMB. Since 2020, versiondog software from AUVESY has been reducing the risk of failure and errors at Yichang Humanwell Pharmaceuticals, the largest manufacturer of anesthetic drugs in China.

Centralized data management for secure production compliance

For pharmaceutical companies, safe and lawful production is a priority. In particular, the production of narcotics is not only result-oriented, but must be strictly controlled.



This includes that all plant parameters must be set very carefully during the production process and executed in strict accordance with the process recipe. In the past, these processes had to be carried out manually at Yichang Humanwell and every small change had to be checked, manually recorded and documented at several levels. To make matters worse, it is difficult to control whether and which system parameters change in the actual production process.

Yichang Humanwell was therefore looking for a solution to simplify compliance with production regulations. In 2019, the head of the information center at Yichang Humanwell came across versiondog, a software that centrally manages various devices, automatically backs up data and records all program changes. In 2020, Yichang Humanwell introduced versiondog.

The software from AUVESY is used in a new production line for freeze-dried emulsions, which was built in 2021 with a total investment of more than 200 million RMB and includes about 70 machines.

From 2022 it is planned to gradually expand versiondog to all production lines in the newly built global headquarters.



Production line for freeze-dried emulsions equipped with versiondog

Ensuring Compliance

When all pharmaceutical process recipes and equipment formulas are entered into the system, versiondog can manage them centrally and ensure regulatory compliance more efficiently.

It can also be used to determine whether the device parameters were changed during the production process and what they looked like before and after the change. This function significantly increases the efficiency of quality assurance officers.

Instead of having to check the operation of the individual machines and test the production conditions on site, they can access the change log of the devices from the office with versiondog.

In the event of a problem with a product, they can visually check whether and which changes have been made to the relevant parameters and, if needed, quickly trace the problem back to the source of the error.

"By introducing versiondog, we are minimizing the risk of PLC failures that affect the quality of the medicines and empowering us to fix the failures as soon as possible and resume production."

Yichang Humanwell Pharmaceutical Co.

Responsible for the research and development laboratory, the quality management laboratory and all information in production.

Storage of multiple versions for more efficient research and development

Versiondog accelerates the development of new products in a safe and compliant manner. The recorded device parameters such as temperature, pressure or speed at which the system is operated can be compared simply and easily.

During drug development or process validation, these device parameters are constantly being adjusted. With versiondog, the version comparison takes place directly in the software.

A technician from the Smart-Manufacturing team sums up the advantage as follows: "As soon as the test product that best corresponds to the original design has been found, we use versiondog to immediately access the saved recipe to find the most suitable parameter ratios. This increases the efficiency of our research considerably."



"Having a full record of all equipment information and our pharmaceutical formulations, as well as any changes made during production, increases the efficiency of our QA colleagues. You can track and compare device parameters more easily, allowing you to find the most suitable recipe faster."

Yichang Humanwell Pharmaceutical Co.

Responsible for the research and development laboratory, the quality management laboratory and all information in production.

Rolled out on all production lines

Due to versiondog's great potential for ensuring safe and legally compliant production and increasing the efficiency of research and development, all production lines and facilities at Yichang Humanwell will be secured and centrally managed with versiondog in the future.

According to Yichang Humanwell's experience, companies that want to implement versiondog should consider three points:

1.

Clarification and protection of rights for pharma companies. When buying equipment, they should get the source code of their own machines. This enables better access to versiondog.

2.

Not only the IT staff should be trained. Even those involved in various aspects of production safety, such as QA and R&D staff should know how to use versiondog extensively for their projects.

Yichang Humanwell's R&D staff



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Customers from the same industry should meet regularly with the software engineers from AUVESY-MDT in order to comprehensively discuss and exchange experiences using versiondog.

AUVESY-MDT

AUVESY-MDT is the global market and technology leader for versioning and backup solutions in industrial automation. With its octoplant software platform, the company secures the automation of production processes through strong end-point management, where it consistently records and monitors changes to configurations, programming and project statuses in production. This minimizes downtime, increases efficiency, quality and safety standards, and saves costs as well as resources. As a modular solution, octoplant can be linked to different automation technologies and devices, regardless of the manufacturer.

AUVESY-MDT was formed in 2022 from the merger of the two established market leaders AUVESY GmbH and MDT Software Inc. The company is headquartered in Landau, Pfalz, Germany, with additional locations in the USA and China. The company works with more than 100 partners on all continents and serves over 2,800 customers worldwide.

More Information at: <u>auvesy-mdt.com</u>







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