

# Zhongxi Sunve automates and enhances pharmaceutical quality management

In 2016, Zhongxi Sunve recognized the need to invest in digital systems for its laboratories to support their 'smart medicine' initiative, incorporating digitalization, networking, sustainability and environmental considerations. Historically, Zhongxi Sunve relied on too many manual, paper-based processes including manually-transcribed testing data, paper-based data storage and transmission, as well as manual task assignment and progress tracking. In addition to introducing the risk of transcription errors, it also made it difficult to search and process data quickly. All this made it very difficult for laboratory managers to do their jobs effectively.

Zhongxi Sunve needed to create a digitally connected ecosystem for several reasons, with the most important being the ability to track and trace data quickly to make its laboratories more compliant. They also wanted to quantitatively assess all laboratory resources through a digital system to achieve effective resource management. Finally, Zhongxi Sunve needed to access and statistically analyze QC data in real-time to enable scientific management of the data and achieve a paperless laboratory. Zhongxi Sunve selected Thermo Scientific™ SampleManager™ suite because of its integrated LIMS, SDMS, LES and ELN capabilities and developed a strategy to digitalize their lab and manufacturing environments.



## Delivering a Successful Informatics Implementation

SampleManager LIMS software was deployed centrally across Zhongxi Sunve using virtual platform technologies. The system utilizes a standard user interface and covers the management of the entire production sample process from registration to final approved results. The LIMS was implemented in two phases. Phase I has been completed and focused on developing sample life cycle management and all elements of laboratory management. Phase II, which is currently in progress, covers electronic SOPs and instrument connectivity.

For phase I, a key part of the project was integrating LIMS with the manufacturing environment. SampleManager LIMS was fully integrated with the Manufacturing Execution System (MES) to manage standard laboratory processes including: stability inspection, environmental monitoring, personnel, instrumentation, methods, standards, reagent inventory, system security, data query and analysis.

To ensure the project's success, Thermo Fisher Scientific's services team worked with Zhongxi Sunve to understand their business and laboratory processes, such as sample testing, supplies/reagents, instruments management and specific configuration rules. The team worked closely with Zhongxi Sunve's project execution team as well as ongoing software and hardware support resources, including system and IT administrators.



During the first phase, Thermo Fisher's service team held several meetings with Quality Directors, QC Managers and QC laboratory analysts at Zhongxi Sunve's Xinghuo and Waigang facilities to confirm project plans, arrange training and analyze and verify requirements. This was followed by system configuration and design, 'double-track' operation, User Acceptance Testing (UAT) confirmation, and validation. During a trial period, more than 150 users processed over 4,000 batches of finished products, raw/auxiliary materials, and intermediates along with purified water and samples of sedimentary and planktonic bacteria in environmental monitoring, in addition to the almost 7,000 reagents and reference materials that were used. Following this successful trial, Zhongxi Sunve went live with SampleManager LIMS software.



## Integration into Zhongxi Sunve's Informatics Ecosystem

Zhongxi Sunve has begun integration of the LIMS with their production and laboratory infrastructure. True sample life cycle management was already achieved by integrating the LIMS with the MES at its production facilities. In Phase II of the implementation, further systems are being integrated with LIMS including ERP, Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) software, the training system and the CAPA system. The company will also implement the Laboratory Execution System (LES) and instrument data collection capability within SampleManager LIMS software. Thermo Fisher will continue to provide technical support and services for system application and daily optimization, security, and computer-based system validation.

By incorporating the Laboratory Execution System (LES), instrument data collection and Chromeleon CDS, Zhongxi Sunve will achieve further paperless laboratory management and automation, lower management costs and ensure continuous improvement and mitigate compliance risks to bring its quality management process to a new level.

Thermo Fisher Scientific's reputation as a trusted informatics partner gave Zhongxi Sunve the confidence and support needed to move through the process. As Zhongxi Sunve grows, SampleManager LIMS software's flexible workflow will adapt to new business applications, such as new product lines and enable onboarding of new methods, testing standards, workflows, personnel, instruments, and devices.

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