Zhongxi Sunve Automates and Enhances Pharmaceutical Quality Management

Overview
As a company directly owned by Shanghai Pharma, Shanghai Zhongxi Sunve Pharmaceutical Co. Ltd. ("Zhongxi Sunve") was created in June 2010 following the merge of two giants, the century-old former Shanghai Zhongxi Pharmaceutical Co. Ltd. and Shanghai Sunve Pharmaceutical Co. Ltd., one of China's leading pharmaceutical companies. Zhongxi Sunve bears the mission to develop specialty APIs and associated medicines for Shanghai Pharma.

The company has three production facilities. The Xinghuo facility is compliant with domestic and international cGMP and EHS standards, is used for mass production of specialty APIs and as a research incubator. The Waigang facility produces medicines compliant with domestic GMP standards, and the Jinhe facility produces plant-based anti-carcinogenic APIs in compliance with domestic and international cGMPs, with future plans to develop anti-carcinogenic drugs. The Xinghuo and Waigan facilities also house QC laboratories with more than 100 testers. The company focuses on developing treatments for psychiatric, neurological, rheumatic immune, tumorous and other conditions, and boasts key competitive medicines and influential brands for psycho-neurological and rheumatic immune treatments. Zhongxi Sunve has received approvals for 110 medicines, including 29 APIs and 82 drug products.

Business Challenges
In 2016, Zhongxi Sunve stressed the need to invest in digital systems for its laboratories. In doing so, the company introduced the concept of "smart medicine" which incorporated digitalization, networking, sustainability and environmental considerations. This was intended to drive informatics in production and quality management, and construct an intelligent manufacturing system to achieve "leaness, automation, information readiness, smartness and greenness". The purpose was to ensure successful business growth, build smart and "green" factories and develop high-end manufacturing facilities for quality generic medicines. In addition, the company wanted to implement the current cGMP management standards across the organization, provide continuous training for its employees, strengthen compliance awareness and constantly improve product and service quality. The bottom line was to produce medicines that comply with international pharmacopoeia,
meet personalized customer needs, and to continue as a strategic supplier for global pharmaceutical companies.

Historically, Zhongxi Sunve mainly relied on manual, paper-based processes including manually transcribed testing data, paper-based data storage and transmission, as well as manual task assignment and progress tracking. This led to vast quantities of error-prone manual transcription work for laboratory workers. It also caused problems like complex paperwork storage, difficulties in searching required data quickly and delays in processes through a lack of automation. All this made it very difficult for laboratory managers to do their jobs effectively.

The Laboratory Information Management System (LIMS) was introduced as an essential choice for business growth that addressed data storage complexities, inability to quickly locate data, high GM costs and high compliance risks.

Solution
Zhongxi Sunve decided to purchase a LIMS for several reasons. Firstly, it needed to track and trace data quickly to make its laboratories more compliant. Secondly, it wanted to quantitatively assess all laboratory resources through a digital system to achieve effective resource management. Finally, it wanted to access and statistically analyze QC data in real-time to enable scientific assessments of all laboratory resources through a digital system to achieve laboratories more compliant. Secondly, it wanted to quantitatively assess high QM costs and high compliance risks.

The Laboratory Information Management System (LIMS) was deployed centrally across Zhongxi Sunve using virtual platform technologies, with the server located at the computer center of the Xinghuo facility. The system covers management of the entire production sample process including registration, collection, reception, distribution, analysis, result entry/review and report preparation/review/sign off. SampleManager LIMS software was also fully integrated with the Manufacturing Execution System (MES), and managed stability inspection, environmental monitoring, personnel, instrumentation, methods, standards, reagent inventory, system security, data query and analysis.

The LIMS was implemented in two phases. Phase I focused on developing sample life cycle management and all elements of laboratory management. Phase II will cover electronic SOPs and instrument connectivity.

Before phase I of the implementation, the service team at Thermo Fisher Scientific worked with Zhongxi Sunve to complete a full range of preparatory tasks. They defined all business processes, such as sample testing, supplies/reagents, instruments management and specific coding rules. A project execution team was formed as well as ongoing software and hardware support resources, including system and IT administrators.

Benefits of Using SampleManager LIMS software
As a complete laboratory information management system, SampleManager LIMS software eliminated the need to select products from various vendors and integrate different technologies. There was no technical barrier and the cost of technical support was reduced. After the system was put into use, Zhongxi Sunve reduced repetitive manual work significantly, and improved efficiency in information transmission and sharing, in task workflows, data analysis and application as well as quality management.

The system enabled cost reduction through saving resources associated with paper-based recording, printing, storage and aggregation. Zhongxi Sunve were also able to optimize data sharing, improve efficiencies, reduce costs and avoid human errors while ensuring compliance.

Follow-up Steps
SampleManager LIMS software supports the addition of new business applications in line with business growth, such as new product lines, analyzing methods, testing standards, statements, workflows, personnel, instruments and devices. It can also be configured and scaled up to meet new business needs. The LIMS was integrated with the MES at its production facilities and achieved the goal of sample life cycle management. In Phase II of the implementation, further systems will be integrated with LIMS including ERP, Thermo Scientific™ Chromelon™ 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 Chromelon CDS software, 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.
Conclusion
SampleManager LIMS software leads the industry in terms of scale, flexibility, configurability and user friendliness. Thanks to its patented workflow technology, the system is able to map laboratory workflows through a flexible and intuitive interface. The flexibility of the LIMS and its ability to process huge amounts of data supports Zhongxi Sunve’s growing business needs. With its built-in instrument integration, SampleManager LIMS software improves productivity from the outset by supporting all aspects of the sample testing process and the tracking of relevant quality elements, effectively reducing repetitive manual tasks and human errors, ensuring data integrity, strengthening QM rules and standards. The flexibility of the system allows users to connect with other systems, such as the MES.

The LIMS was designed to meet the evolving needs of today’s laboratories and lay the groundwork for storing and processing vast quantities of data. Based on its reliable performance, adaptability and easily configurable features, SampleManager LIMS software is the laboratory solution of choice for many organizations around the globe.

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