

From Vision to Reality: Novast's Successful Lab Digitalization with CaliberLIMS

Case Study



About Novast

Novast is the only USFDA Company in Nantong, a Pharma belt in China. The company provides innovative pharmaceutical preparations and high-barrier-entry drugs for both domestic and international markets. With around 500 companies, the company is into manufacturing and formulations of effective prescription drugs. They predominantly export products to the US but have ventured in the local Chinese market too. They have 249 registered products and 100 final products of different strengths to their credit.

NOVAST maintains a critical focus on technological research and product development of drug-delivery systems. They follow stringent procedures to meet the set quality metrics. Providing quality products is an integral part of their growth strategy.

Speciality

Pharmaceutical preparations and high-barrier drugs for domestic and international markets.

Founded

2015

Location

Nantong, Jiangsu, China

Solution

CaliberLIMS

The Need for Choosing LIMS over Manual Data Maintenance

Novast could handle the first audit of USFDA well even though their lab data was manually kept. But the need for shifting to digital systems became more prominent. By the next audit, they wanted to have a better compliant system in place that could help them:

With a target to drive efficiency, quality, and compliance, Novast was looking for a robust LIMS application that would accommodate smooth transition from manual to digital system.

Novast implemented CaliberLIMS Version 3.3.0 in the year 2017. The following 17 standard modules of the system were adapted in place of manual procedures.

CaliberLIMS Modules Implemented



Among the several LIMS providers, Novast chose to go with Caliber due to:

- Availability of end-to-end sample management system
- Accessibility to a robust inventory management system apart from other effective modules
- Extensive and clear validation process

The Digital Journey

Novast faced a few initial hiccups during the implementation process. With determination and an able digital partner like CaliberLIMS, it could easily overcome the issues.

1. Overcame language barrier

Being a company with majority of Chinese speaking employees, Novast faced language barrier issues up to a certain extent during implementation process. However, they didn't find any issue in adapting to the system as CaliberLIMS is user-friendly. Novast's existing procedures were followed with no customizations. There were hardly a few configurations in the application.

2. Complex network system

Another challenge Novast faced was that of complex network used for their security systems. They had multiple networks in one lab with different instruments connecting to different networks. But by using the robust instrument interfacing platform of Caliber, they managed to connect to different complex networks at a time. The system could connect to 17 instruments and 1 CDS (Chromatography Data System) system during implementation.



Phase-wise Implementation for Smooth Manual to Digital Transition

The whole implementation process was completed in merely 5 months. Novast made a 5-member team – three from QC and two from QA. Three members created Masters and two members reviewed them. It took one and half month to finish the task.

In-process and finished products were implemented first followed by APIs as suggested by the Caliber team. Finished products were specifically picked for implementation process as Novast had to share COAs with customers.

CaliberLIMS Extensive Support

Thorough training

Novast staff underwent thorough training for 22 days including theory sessions and hands-on activities. With the use of scenario-based approach and real-time use cases, the Novast users could get acquainted with the system and use it to perfection very quickly.

Offsite validation

Novast chose to get the implementation done in a faster way through offsite validation. It is one of the multiple implementation methodologies followed at Caliber. Instead of having one or two on-site validation resources, Novast was provided with 3 to 4 offsite validation resources under offsite validation process. The resources were connected through secure VPN. The process of implementation was very elaborate and stringent as per the regulatory standards of GAMP5.

Remote support

Novast received remote support from Caliber. Major part was cleared and validated. They had a separate support portal through which they could track the time taken to resolve issues. A dedicated support team from Caliber provided them assistance.

The Result

1. Ease in Audits

Novast faced many FDA, NMPA (CFDA) audits so far. They are the only company in China that successfully completed 4 consecutive FDA audits with zero observations. The complete implementation process from the time of implementation to PQ document was explained to FDA and other auditors using CaliberLIMS system.

“CaliberLIMS COA created the best impression on our customers. At present all new products are directly implemented in CaliberLIMS. During audits, we could confidently trace and show the requested data within 30 seconds. It was amazing to see how weights can be pulled into the worksheet with a single click and how balance data calculations are done,”

-Dr. SasiKiran, QC Manager, Novast.

2. Increased efficiency of QA

There was a considerable reduction in the review time with review alerts, reduction in redundant and repeated data entry work, thus resulting in increased efficiency of QA. The review time for finished products could be completed in shorter durations. QA could see whether the chemist has used correct quantity of sample, working standard, chemical standard, etc.

Digitalization of lab with CaliberLIMS helped in reviewing a greater number of batches in less time resulting in increased production.

3. Reduction in time and effort of users and operators

The users and operators saved a lot of time and effort by using LIMS. To get the details of the chemical usage, they had to manually note down the details in a paper worksheet visiting respective chemical area earlier. But after CaliberLIMS implementation, the data was automatically fetched. Similarly, to perform analysis and transcript of a finished product sample, with an average of 12 to 13 tests, the turnover time for complete manual work from operator was 5 days which now reduced to 3 days.

4. Readily available trend analysis

Extracting data for APQR generation became quick and easy with CaliberLIMS. Earlier, manual entries were required to generate a trend. But now data could be easily pulled with product name and product code within half an hour.

5. No delay in work in the absence of chemist

Earlier, work would get affected in the absence of chemist and group leader due to lack of proper communication. But after digitalization, the system assists in transferring work to others in case someone is on leave. So, all the evidence details of who initially performed the tests, who transferred the tests, and who did it later are available. It helps in tracking the person who committed mistakes during an investigation process.

Further, in case a chemist leaves the company, the QC tests are transferred to others on the relieving date without any hassles.

6. Collation of important data

Novast could also benefit from the system in collecting data on number of samples received, number of COAs generated, deviations, OOS, CAPAs raised, etc. which were presented once every year to the management.

By improving the efficiency and helping to meet regulatory requirements stringently every time, Caliber has become a true robust digital partner of Novast over the years. This association instilled more confidence in Caliber and its products. Their journey together will help Novast foray into new markets and expand tremendously.

“Instead of our resources wasting time in redundant data entry work, they are able to focus on the analysis more,”

-Dr. Srinivas Reddy,
Quality Director, Novast.

Stronger relations for future implementations

With a smooth digital transformation with Caliber, Novast experienced a hassle-free journey. Rendering to this, our collaboration has grown stronger, and we ensure to support Novast relentlessly going forward. CaliberLIMS has proven to be an impactful service offering for Novast and we wish for a long-term association for other business aspects as well.

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