

Laboratory Excellence Achieved with CaliberLIMS

Case Study

Case Overview

MSN aimed at achieving a paperless LIMS and complete audit-readiness while scaling up its laboratory operations. They wanted to automate their labs. With digitalization of processes, they aimed at functioning at their highest potential.

About MSN

MSN, founded in 2003, is a fast-growing pharmaceutical manufacturing company with headquarters in India, Myanmar, and the USA. It specializes in the production of life-saving drugs with 9 API facilities, 5 finished dosage facilities, and an integrated R&D center for formulation and API. They have bagged 836 patents to date and cater to more than 40 million patients globally. Their product portfolio features over 450+ APIs and 300+ formulations.

MSN is backed by its mission to improve quality of life by manufacturing safe, innovative, affordable pharmaceuticals. The company invests in innovative R&D facilities, robust IP strategy, and insight-driven IT to create innovative solutions for tomorrow's healthcare requirements.

Paper-Related Process Inefficiencies Restricted Progress

Engaged in critical manufacturing, laboratories have complicated processes and stringent regulatory requirements. While cutting-edge science and state-of-the-art technology kept MSN abreast of technological innovations, some issues restricted operational efficiencies.

With a paper-based laboratory, MSN faced major challenges that limited its operations in today's technology-driven industry. Paper-based entries and manual data management at the MSN labs led to process limitations and huge racks with piles of paper documents made it difficult to fetch accurate data when needed.

Challenges faced with paper-based laboratory systems.

Data integrity was at a high risk of being compromised with manual intervention in maintaining data records. With large heaps of data generated, data management, recording, and analysis became difficult. Data was scattered and could not be accessed easily. Manual intervention in each of the processes was time-consuming, resource-intensive, and posed integrity issues. Approval from analysts took longer as everything had to be reviewed manually. Periodic review of samples, analysis, and release was subjected to the availability and approval of the analysts. This increased dependency led to longer release times. Material and inventory management had risks to data integrity as all the inward/outward samples were recorded on paper. Audit trails couldn't be managed efficiently as the records were difficult to fetch the required data for inspection.

Looking beyond operational limitations

With the goal to enhance lab processes and efficiency, MSN labs decided to look beyond the limitations of paper and explore the full potential of their lab processes through digitalization. Among the options in the market, the leadership chose CaliberLIMS as it had simple functionality, user-friendly views, scalability options, and robust compliance processes.



Caliber's Solution for Automated Labs at MSN

CaliberLIMS was introduced to structure the digital transformation roadmap for MSN. After starting without instrument connectivity, MSN strategically introduced integrated systems in 2018. CaliberLIMS proved to be a significant step in achieving their business goals through automated lab processes.

CaliberLIMS Modules Implemented

Chemical Management

Environmental Monitoring

Reference Standards

Reserve Sample

Culture Management

Reference Management

Analyst Qualification

Working Standards

Label Management

Media Management

Instrument Management

Volumetric Solution

SAP Interface

Configured COA

Column Management

Glassware

Stability Management

Solution Management

Laboratory Document Management system

Instruments integrated with CaliberLIMS:

- Instrument(s) that provide output, such as a single result per reading, in Non-File based format (Balances, pH, Tap Density, etc.)
- Instrument(s) that operate through the computer program (Non-CDS) and generate an output as a file or report (FTIR, UV, Titrators, Atomic Absorption Spectrometer etc.)
- Instrument(s) that are connected/operated by the CDS software such as Empower

With the implementation of CaliberLIMS across the formulation units, MSN could achieve a zero-paper lab information management system. Seamless instrument connectivity with CaliberLIMS brought in more authenticate data and processes. Along with it came process efficiencies. This ultimately helped with regulatory compliance and efficiency. With a compliant system, data integrity is easily achievable. Perusing through 100–200-page documents for one analysis became a thing of the past for MSN. Automated systems instilled auditors' confidence in the operations with back-to-back successful audits.

Audit-Ready and More Efficient Teams

After implementing CaliberLIMS, MSN could successfully face European and USFDA audits. The officials also appreciated the authorities for having a digital platform that keeps them audit-ready always.

CaliberLIMS implementation at MSN Labs streamlined collaboration across teams. System-generated records significantly eliminated data integrity issues. Built-in electronic laboratory notebook (ELN) recorded the lab's activities effortlessly. CaliberLIMS automated workflows and demonstrated them on the screen. This helped analysts at MSN to get a holistic view of the status of the samples, resources involved, and estimated timelines. Having every detail recorded and ready-to-use in the software, the management investigations of sample test failure became easy.

With digital SOPs and standard workflows in place, CaliberLIMS empowered the management to investigate any discrepancies in the manufacturing process with precision. The inventory management module within the CaliberLIMS software helped users track the status of the inventory efficiently. Thus, delays due to the unavailability of materials were reduced. Instant prompts at minimum stock levels of raw materials prevented production delays. CaliberLIMS maintained complete audit trails from sample analysis to Certificate of Analysis (COA). So, analysts could generate multiple reports for each module to understand processes better and take necessary corrective actions.

Process benefits to MSN with CaliberLIMS implementation

- Standard workflows defined
- Transcription errors eliminated
- Increased process efficiencies
- Single electronic repository for all operational data
- Increased productivity and reduced costs
- 336 instruments integrated
- Adherence to regulatory compliance including ISO17025, FDA 21 CFR Part 11, GxP
- Quantum of document storage reduced by 90%
- Enhanced decision-making with trend analysis and reports

From the management's desk

MSN Raju, QA Head at MSN noted, "CaliberLIMS has contributed majorly to structuring the digital transformation roadmap at MSN. With more than 500 people working in a lab unit, the implementation of a robust LIMS without hampering production efficiency is quite a remarkable achievement. The application has tremendously helped us achieve production efficiency."

Other senior officials also conceded that CaliberLIMS was very user-friendly when compared to other software. The team feels empowered with the robust LIMS application as it can be used by any of their analysts and end users even with minimum computer knowledge. With practically no paper, MSN labs are functioning at their highest potential.

Exceptional team spirit made things possible

MSN had a vision; Caliber had the solution. Caliber and MSN collaborated on the implementation of CaliberLIMS during the COVID-19 lockdown. Despite unprecedented challenges, the solution was implemented without any delays. After the successful implementation at Unit 2 (MSN Laboratories Private Limited-Nandigama), CaliberLIMS was extended to Unit 4 (MSN Laboratories Private Limited- Mekaguda – a newly constructed lab) which was completely paperless from day 1.

Future plans for a Tomorrow-ready lab

As CaliberLIMS continues to empower the MSN leadership with its efficiency to deliver lab excellence, they have plans to implement CaliberLIMS at other facilities too. Their experience with our products and the team has been positive, and Caliber's extended support post-implementation and dedicated team to address issues have opened many avenues to collaborate with MSN labs in the future.