

# **How Logilab ELN helped Megafine with Sample Management**

## **Background**

Megafine Pharma (P) Ltd, founded in 1995, is a pharmaceutical manufacturing company with offices in India. They have approved facilities by the US Food & Drug Administration (FDA), BGVFHH Germany (EMA EU-GMP), Japan PMDA, Health Canada, TGA Australia, COFEPRIS Mexico, & Korea MFDS.

Megafine Pharma (P) Ltd is involved in manufacturing active pharmaceutical ingredients (APIs) & advanced intermediates and is a trusted partner for research, serving as a contract manufacturer for numerous innovators & global pharmaceutical companies.

## **Business & Operational Challenges**

Megafine's laboratory processes are complicated, and they deal with a high volume of samples daily. They need to maintain comprehensive logs of samples which enter and leave the facility. Once the samples are registered and tests are conducted on them, they need to also maintain a record of the in-process & finished product samples. Being a laboratory in the pharmaceutical industry, it is very important that the complete integrity of data is always maintained using audit trails and that the system they are managing the samples with is fully 21 CFR part 11 compliant.

## **Why did Megafine choose Logilab ELN?**

Megafine wanted to overcome the challenges they face in their current process of sample management, sample traceability and sample reconciliation during drug manufacturing. Their main goal was to overcome the challenge of maintaining quality control in the different stages of sample management. They identified Agaram Technologies' Logilab ELN, a multi-tenant SaaS-based solution to help with this. They found Logilab ELN to be an appropriate system to achieve their lab process in a paperless and error-free

environment. These are the following reason leading to Megafine choosing Logilab ELN for their laboratory:

- Fully **21 CFR Part 11** compliant - with comprehensive time-stamped audit trails, e-signatures, & auto versioning to view changes made.
- Excellent built-in search functionality allowing users to identify samples quickly.
- Tracking the consumption levels of samples using the inventory module.
- Ability to provide role-based rights & privileges to configure review & approval workflows & protect confidential data.
- Auto versioning of changes made for full data traceability - to stay compliant with US FDA regulations.
- Megafine lab personnel work in multiple shifts. As all data is stored securely on a dedicated server on the cloud, collaborating on projects & sharing data is seamless.

## **Implementation**

Megafine chose to implement the SaaS model of the cloud-hosted Logilab ELN due to its advantages in terms of cost-effectiveness, scalability, accessibility, & security. The existing sample registration logs which they were using in excel were easily imported into Logilab ELN as sheet templates & designed with the additional fields provided by them. **Inward sample registers** were created for maintaining quality in each department, along with e-signatures to indicate which lab personnel handled the result entry, review, and approval. Designing their existing logs as templates for result entry is a one-time process as long as the log's design remains the same.

## **Improved Processes in Megafine after implementing Logilab ELN**

- Efficient & accurate sample management processes due to controlled data capture with labsheets.
- Simple & accurate way of monitoring inventory consumption levels, reorder levels & expiry dates resulting in better compliance with good laboratory practices.
- Availability of the latest version of the file with the ability to compare with previous versions & track changes.
- Due to the implementation of the cloud-based system, data security, accessibility & collaboration became much easier.
- Megafine can auto-generate summary reports which provide insights on key lab parameters, allowing them to make proactive data-driven decisions.
- Audit trails and e-signatures ensured that the laboratory operations fully comply with statutory regulations such as FDA's 21 CFR Part 11.

### **Streamlining Large Scale Sample Management Processes with Logilab ELN**

Organisations which have implemented Electronic Lab Notebooks have achieved easy and accurate data capture, data integrity & high-quality standards. It improves lab connectivity, scalability, and efficiency. The demand for powerful, versatile, and flexible laboratory sample management systems will see a surge in the future. Solutions such as Logilab ELN will provide proactive data insights, improve sample management, and assist laboratories in better managing their tasks. A combination of efficiency, security, and regulatory factors will lead to the decision to use an ELN. Megafine is one such company which was able to achieve its primary goal of large-scale sample management, by implementing Logilab ELN.