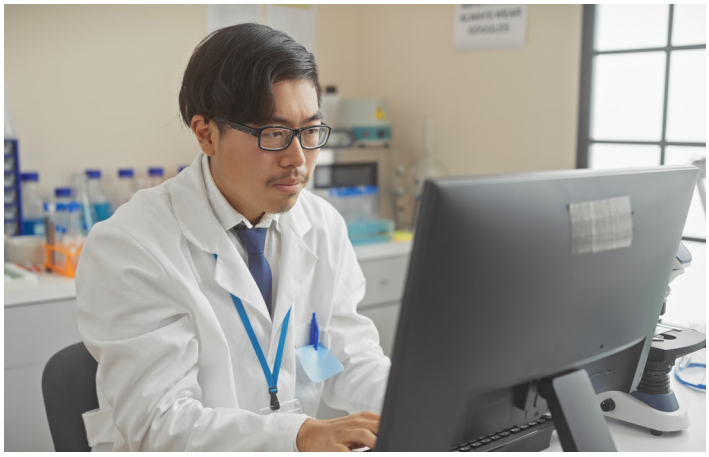
Case study

Watson LIMS software

Enhancing bioanalytical studies at Global Clinical Central Lab

Global Clinical Central Lab (GCCL) provides clinical trial sample analysis that goes beyond simple central lab services. With exclusive services tailored for clinical trials and a logistics system that adheres to global quality standards, GCCL has built trust with over 200 partners across Asia. Their services encompass the entire cycle of clinical trials, addressing customer demands with precision and reliability by operating two specialized labs:

- **A bioanalytical lab:** Focusing on small and large molecule pharmacokinetics (PK), including immunogenicity analysis
- **A central lab:** Providing safety and diagnostic testing, sample preparations (e.g., Peripheral Blood Mononuclear Cells [PBMC], DNA/RNA extraction from blood, Cerebrospinal Fluid [CSF], etc.) and logistics for large-scale clinical studies and sample storage



GCCL faced critical challenges due to the use of disparate analytical software and manual data recording associated with Microsoft Excel. This fragmented approach led to significant concerns, such as data inconsistency and uncertainty about the original data source. To address these issues, GCCL decided to implement a Laboratory Information Management System (LIMS), specifically Thermo Scientific™ Watson™ LIMS Software.

Challenges and motivation for change

Prior to implementing a LIMS, GCCL experienced inefficiencies and data integrity complications stemming from manual, paper-based processes, which were difficult to track and validate. GCCL's workflow involved multiple validation, approval, and planning steps, all done using different types of analytical software, often resulting in scattered data and deficiencies. Lab personnel frequently had difficulty determining which values were the originals and which had been adjusted against the concentration. The absence of a centralized system led to significant problems in managing data integrity, sample tracking and Quality Assurance (QA) within their bioanalytical studies.

Selecting Watson LIMS software

GCCL selected Watson LIMS software because of its strong track record in the global market and its ability to meet their specific needs for bioanalytical studies. It offered a solution where all data—from sample collection to analysis—could be centralized, easing data management and review. The LIMS software allowed for the integration of barcodes, improving trackability and sample management. GCCL noted that Watson LIMS software simplified the workflow, making it easier for execution personnel to handle data acquisition and for QA teams to conduct inspections. It eliminated the need for intermediate data processing, a significant bottleneck. Key, non-negotiable features for GCCL included custom ID and Import Study Protocol functionalities, which were critical for their operations. As Watson LIMS software could deliver these essential features, GCCL was confident in their decision to implement it into their labs.

Implementation

The transition to Watson LIMS software involved careful planning and execution with the GCCL and Thermo Fisher Scientific teams. The process involved running the system, learning its functionalities and training staff—all while continuing regular work. Notably, GCCL did not migrate old data, but maintained it in the original acquisition and Microsoft™ Excel™ systems, focusing on new data moving forward. Validation and approval processes were meticulously followed to comply with regulatory requirements. The six-month implementation period successfully streamlined workflows, reduced manual interventions and enhanced data integrity.

Training and adoption

The Thermo Fisher team worked closely with GCCL's R&D lead, Kyungmin In, Dr. rer. nat., to help ensure the training program was approachable and easy to digest for the lab staff. The two-month user training program featured in-person, role-based training sessions provided by key users to end users. During this period, lab personnel also attended workshops to finalize user manuals, complete standard operating procedures (SOPs) and conduct QA reviews. Additionally, they performed robustness testing, comparing the new and old systems to check if everything was functioning as expected.

The overall response from the lab personnel was initially hesitant, but after training and hands-on experience, lab staff found Watson LIMS software very helpful because it simplified their day-to-day work and made data management much more seamless. For example, using the templates from Watson LIMS software for the Import Study Protocol function, setting up a new study and importing samples all became easy, seamless tasks. In addition, the digital interface with Sciex™ Analyst™ software helped lab personnel reduce Quality Control (QC) checks while importing results from the instrument software.

Lab staff and directors quickly realized the transition to Watson LIMS software was crucial in helping ensure the integrity and reliability of their bioanalytical studies.

Valued results

The implementation of Watson LIMS software brought significant improvements to GCCL's bioanalytical operations, including:

- **Enhanced data integrity and traceability:** Centralized data management has eliminated dispersed paper records and Excel documents, helping ensure all data is consolidated in one system. It has also provided complete study records and reports, from study initiation through study closeout, including sample chain of custody, assay verification, and reconstruction events using the audit trail.
- **Advanced QA review and efficient reporting:** QA processes are now more efficient, with decisions and justifications easily accessible within the LIMS. Lab personnel can generate a full study report, including method validation experiments, assay performance and study data in formats required for submissions.
- **Improved compliance throughout the entire workflow:** With Watson LIMS software's ability to generate study-specific labels to meet necessary requirements, GCCL and principal investigators can move logically through each step in their workflow, complying with 21 CFR Part 11 and FDA guidance.
- **Optimized productivity and processes:** Watson LIMS software has reduced the risk of manual transcription errors by automating data capture and management processes. The time required for PK validation reporting was reduced to just one week, while Anti-Drug Antibodies (ADA) reporting is still in progress; it's currently taking two to three weeks. GCCL also benefits from real-time snapshots of data quality and the quick generation of various graphs, tables and statistical calculations from study data.
- **Enhanced data quality and consistency:** Instead of relying on disparate systems with their own calculations and reports, all data is now centralized within Watson LIMS software. This helps ensure uniform calculations and consistent reporting across the board, leading to higher-quality data and reliability.

Conclusion

The strategic implementation of Watson LIMS software at GCCL effectively addressed critical challenges related to data integrity, sample management and QA efficiency. By centralizing data and streamlining workflows, Watson LIMS software significantly enhanced GCCL's bioanalytical operations. The improved efficiency, trackability and compliance with regulatory standards have positioned GCCL for future growth and scalability, helping ensure they continue to deliver high-quality bioanalytical services. The transition to Watson LIMS software has improved data integrity and workflow efficiency and fostered a culture of continuous improvement and adaptation among the staff, setting the stage for sustained success in the competitive field of bioanalytical studies. Watson LIMS software also allows GCCL to expand its international operations by enabling it to share data directly with sponsors while maintaining Good Practice (GxP) compliance. This capability not only supports global collaboration but also helps generate additional revenue.

Implementing a LIMS can significantly enhance data integrity, streamline workflows and improve overall efficiency, positioning companies for growth and scalability.

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