

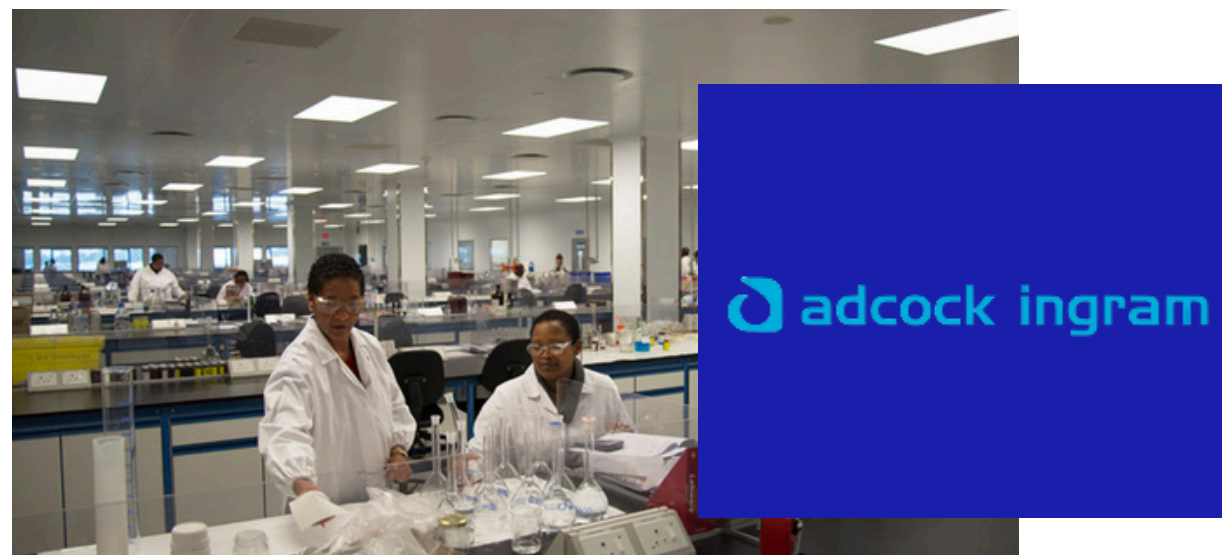
Adcock Ingram Becomes India's First 100% Paperless Lab

Case Study

Case Overview

As a manufacturing & marketing company, quality is an essential priority for Adcock. Our customer manufactures and exports capsules and tablets to South Africa, Australia & many other locations. They are required to follow the stringent quality guidelines set by US FDA. To ensure quality products are exported and efficiency is maintained, they partly automated their production processes and aimed to be a 100% paperless company.

Adcock Ingram met its challenge of becoming 100% paperless company with integration of 25 Instruments and electronic notebooks operated on handheld systems with CaliberLIMS.



About Adcock Ingram

Adcock Ingram is a pharma manufacturing and API company. They provide an extensive range of branded, generic prescription, and OTC products in a broad range of therapeutic classes such as: analgesics, cardiovascular, central nervous system, etc. as well as a selective range of personal care products.

In generics, Adcock markets a broad range of affordable products. In branded products, they market many well-recognised leading brands such as Adco Dol, Allergex®, Bioplus®, etc. They deal in Unique Formulations as well as a diverse range of brands on behalf of their international partners.

The Dream of a 100% Paperless Lab

Quality Control is at the heart of pharmaceuticals manufacturing, hence almost all regulatory auditors pay special focus to the quality control department. Manual documentation process, though followed through the ages, had its own limitations. Adcock was following manual documentation and faced the following challenges -

- Considering the volume and laborious process of documentation involved, correlation of results became a difficult task
- Strict controls, checks and balances throughout sample testing process to meet stringent regulatory guidelines was challenging with paper
- With increasing market demand, there was need for quick material quality certifications turnaround time
- Unavoidable human errors in a paper-based environment further caused bottlenecks in meeting GLP and GCP regulatory norms

Adcock had its vision set on a 100% Paperless Lab. This meant automating every single paper-dependent process in the lab. To meet the challenge of complete automation, Adcock was on the lookout for a best-fit LIMS that could effectively automate their processes with a good ROI. Adcock's focus and dedication towards their bold step towards complete lab automation became a driving factor for Caliber.

Big Step Towards Complete Automation

Adcock decided that they wanted to opt for full automation. To automate every single paper-dependent process, a plan was laid down.

- Provision of electronic worksheet for 100% Paperless Laboratory through method execution (LES)
- Instrument interfacing with different available modules that would enable information to sit in the system directly
- Integration of port-based instruments such as balance, PH meters, etc. where the data was not required to be printed. The data was automatically pulled into the LIMS system
- Integration of file-based standalone instruments. Values could be easily extracted from the produced report through parser technique for calibration
- Integration with third party software like Chromeleon, Empower, LabSolutions, etc. too to enable CDS-based instruments data to be pulled directly into LIMS
- Automation of various logbooks such as reference standard, working standard, chemicals, etc.
- Interface with ERP, SAP to reduce manual entries during lot registrations and other works
- Dashboard mechanisms, alert mechanisms to give notifications & controls to Adcock
- Automatic display of raw data with "Bypass" controls
- Audit trails of all transactions for compliance
- Partial save option to save data after every step of long duration analysis
- Compliance to regulations like GLP, GMP, 17025
- Access and Security norms as per 21CFR Part 11
- Integration with Quality Management Systems & Document Management System
- Easy retrieval of records/documents on the fly
- Integrate wherever possible to capture data without transcriptional errors and reduce manual intervention eventually leading to increase in productivity

Critical processes Automated

Adcock first discussed with the Caliber team about a semi-automated LIMS system. With this, they could easily get all the formulae and calculations related information back into the system. However, they had still had a few tasks with paper or print format for method or analysis related information.

In LIMS, the controlled worksheet could be shared once the QA approved a Master version. They had to take a printout and fill the details of analysis manually. They had to re-enter these details in the LIMS system. Thus discussions ensued around going 100% paperless.

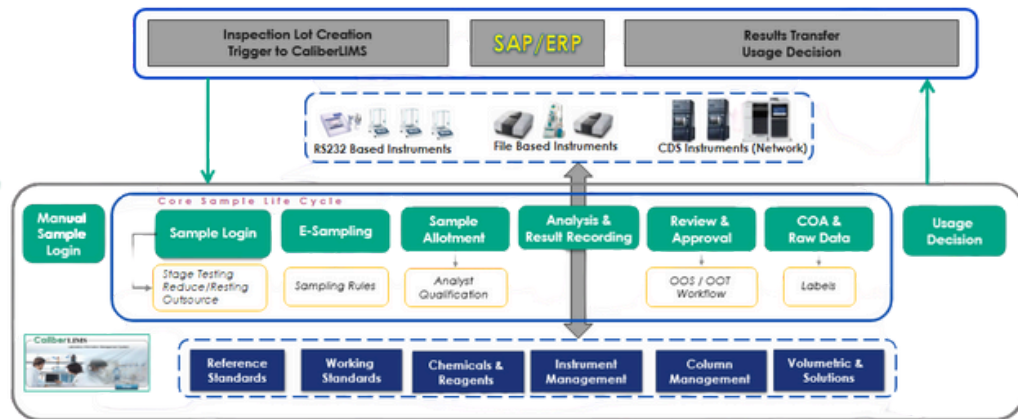
Caliber's Solution to Help Adcock Succeed

CaliberLIMS was implemented after a thorough requirements study, mapping processes, and software validation. CaliberLIMS 3.2.1E version was configured for the Adcock workflow process and formats of the final critical reports.

SAP-LIMS integration was put in place for seamless integration for material test requests and sampling process as per GMP. Instruments like CDS, file-based instruments, and port-based instruments were integrated through built-in Lab Execution System by completely eliminating paper notebooks and record keeping.

Critical processes Automated

Automation of the following processes saved huge amounts of time and efforts. CaliberLIMS helped Adcock improve throughput, achieve regulatory compliance, reduce errors, and obtain quick reports for a timely decision and completion of quality product manufacturing on time. Adcock now has the distinction of being a 100% paperless laboratory.



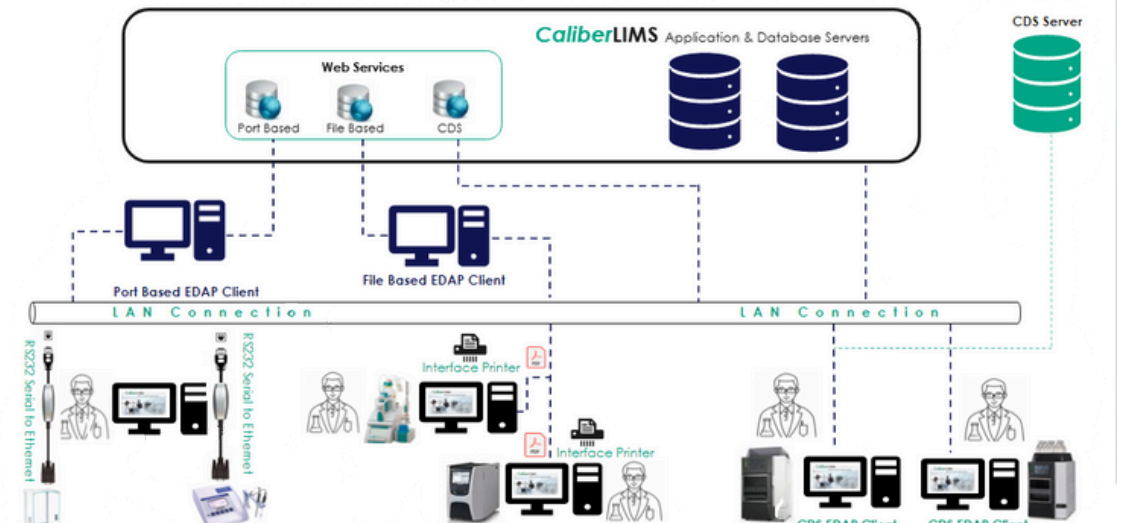
- Intimation for sampling of material from stores and production under test label printing
- Sample Login through SAP with complete automation and controls
- Sample registration and Sampling procedure of various material inspections from various sources like stores, production, and warehouse
- Assignment of tests to respective test categories like Chemical Analysis, Physical analysis, Microbiological analysis, etc.
- Protocol preparation, results evaluation and recording through electronic worksheets
- Advanced seamless bidirectional integration with Empower CDS. First of its kind in India!
- Inventory and usage recording of chemicals, reference standards, working standards, and Instruments through integrated electronic worksheets
- Results approval and certificate generation. Online review process by multiple levels of reviewers
- Material usage decision and intimation to stores and production
- Approved label printing on containers

Instrument Integration

The following instruments were integrated.

Balance/Instrument	Model	Solution
Mettler Toledo	AS204	R\$232
Mettler Toledo	AS105	R\$232
Mettler Toledo	P8302	R\$232
FTIR PerkinElmer	--	File Uploading
UV: Shimadzu	--	File Uploading
Polarimetry	Rudolph	R\$232
ERWEKA Tablet Testing Machine	TBH220	R\$232
Metrohm Titrator	794-Basic Titrino	File Uploading
VEEGO (Programmable Melting Point Apparatus)	--	R\$232
BrookField Viscometer	--	R\$232
TAP Density	--	R\$232
Mettler Toledo: Conductivity Meter	SevenEasy Conductivity Meter S30	R\$232
Mettler Toledo: pH meter	SevenEasy pH Meter S20	R\$232
HPLC	Waters: 8 Nos	Bidirectional CDS integration ----- Chromatogram View on LIMS side
UPLC	Waters: 3 NOs	Bidirectional CDS integration ----- Chromatogram View on LIMS side

CaliberLIMS was implemented on ML 150 HP server with Xeon processor and CAT5 LAN. 125 named users were registered. Instrument interfacing with Caliber EDAP engine made sure that data automatically got saved in the system eliminating human errors completely.



Adcock is Now Audit-Ready with Caliber

Upon completion of the project, Adcock attained the distinction of being the first 100% paperless lab in India. Adcock India has been successfully audited by international regulatory bodies post implementation, with appreciation for their automation vision. Adcock achieved zero deviations through the controls and automation. Now, they are Anytime Audit Ready!

Adcock's Achievements through their Paperless Journey

Since 2013, Adcock has achieved specific benefits with CaliberLIMS.

- Achieved minimum inter-department paperwork with integrated deviation handling system with QMS
- LIMS-SAP real-time integration made seamless integration between warehouse and QC/QA department possible
- Reviewers spent 60% less time on reviews and focused their saved time for other essential works
- 100% time was saved on COA preparations & approvals
- More than 20% of Senior QA time was saved in preparing material quality trends
- Good improvement in planning of the team and increase in quality performance with reduction in errors
- As a result, on an average 2000 samples per month were released from Caliber LIMS

All these achievements instilled great confidence on Caliber and increased their trust in Caliber's products. With the successful implementation of CaliberLIMS, Adcock also showed faith in automating its manufacturing process with CaliberBRM. Adcock's successful ongoing journey with Caliber speaks volumes on how much can be achieved with strong partnerships.

