

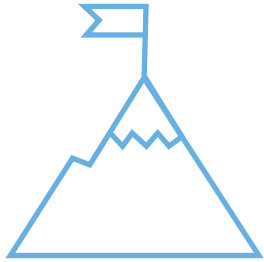


Case study

Enhanced Batch Quality Prediction Using Process Analytical Technology

Client

The client is a leading US-based multinational corporation that manufactures medical devices, pharmaceuticals, and consumer packaged goods.



Challenges

The challenges that the client faced in maintaining batch quality included:

- ☑ Insufficient information leading to delays in taking early corrective action for bad batches.
- ☑ Lacked ability to optimize production cycle times.
- ☑ Lacked insight on the external parameters that were impacting process and batch quality.
- ☑ Real-time process information was unavailable, affecting the timely release of batches.

LTIMindtree Solutions

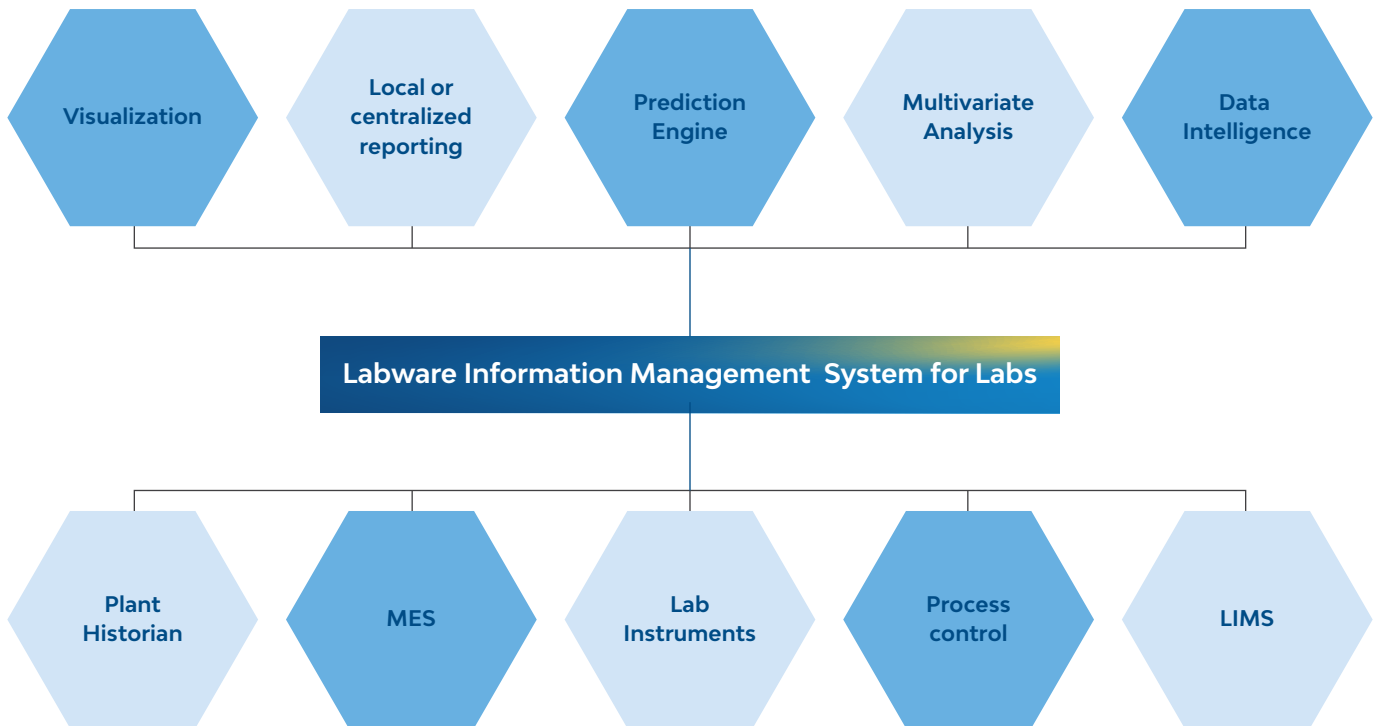
Automated reading and recording of process information using the Process Analytical Technology (PAT) framework.

Created digital replicas of the manufacturing process using data from spectral instruments and a range of Operational Technology (OT) systems.

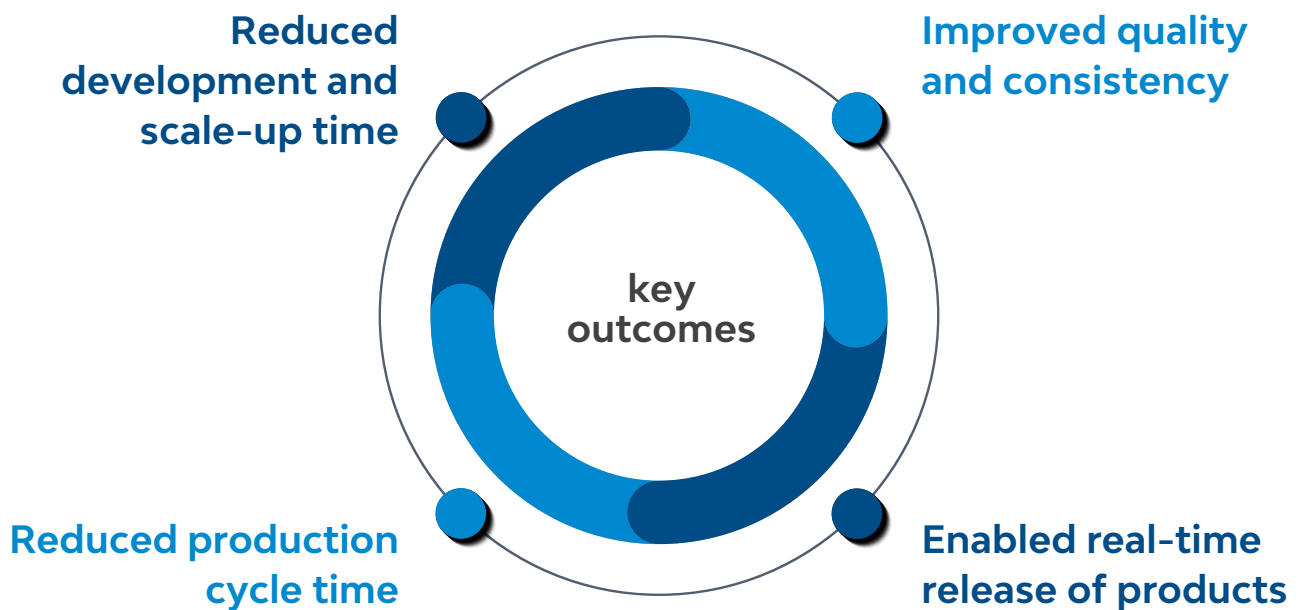
Introduced a data-model based real-time Multivariate Analysis (MVA) procedure to drive predictable outcomes for newer batches.

Equipped process engineers to execute preliminary Root Cause Analysis (RCA) for non-performing batches.

Enabled execution of focused RCAs along with necessary corrective action that helped manufacture good batches.



The key outcomes of the solution included:



Benefits

70% enhancement in the operational capacity.

100% compliance to Good Automated Manufacturing Practices (GAMP).

Strategically enabled Right First Time (RFT) processes.

Enabled continuous manufacturing with seamless transfers from laboratory to plant and facilitating global tracking and monitoring.

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