STARLIMS HELPS DOUGLAS PHARMACEUTICALS ON ITS LEAN JOURNEY TO SMART LABS

Douglas Pharmaceuticals, located in New Zealand, is a rapidly expanding pharmaceutical company with a reputation for high manufacturing standards, quality products and outstanding client service. The company researches, develops, manufactures, markets and distributes prescription and over-the-counter pharmaceutical, nutraceutical, and consumer healthcare products. Today Douglas Pharmaceuticals exports to 40 countries around the world.

LEAN TRANSFORMATION

Douglas' targeted growth and expansion was predicted to have enormous impact on their laboratory operations. Information automation management was identified as a necessity for their regulated New Zealand Quality Control Department to support the corporate strategy.

A "Smart Labs" program was established, and based on capacity and utilization studies, the opportunity for over 20% efficiency gains was identified, including the introduction of a lean initiative, organizational structure review, and centralization of services. However these benefit opportunities could not be fully realized if not supported by automation and the implementation of a LIMS system.

To minimize immediate headcount increases and unsustainable ongoing increases, the lean journey of which LIMS was an integral component began.

There were also other tangible benefits:

- Improved quality assurance and GMP compliance.
- Spare capacity freed up for other value add lab activities.
- Reduced printing, stationery and storage costs.
- Improved competitiveness and security in the market.

"STARLIMS delivered significant efficiencies via standardized workflow, QC, stability and microbiology sample management, custom reporting, instrument and wider enterprise systems integration."

David Hipperson, Quality Engineering Manager

PARTERNING WITH STARLIMS

Over 200 vendors were narrowed down to 5 from which business cases were developed. There was in-depth review and analysis for vendor selection to arrive at true differentiation. During vendor assessment, STARLIMS outperformed other competitors on a functional scorecard which included compliance, laboratory management, external interfaces, configuration, user interface and ease of use, etc. In the end, STARLIMS was chosen.

IMPLEMENTATION

The STARLIMS implementation was a catalyst for process improvement and optimization, capability enhancement, a shift from teams to shared services, elimination of non-core, non-value activities as part of the wider "Smart" laboratory journey. The journey continues as Douglas enhances and extends the use of STARLIMS to other laboratory sites in addition to applying the learnings from this implementation to other computerization and connectivity projects.

RESULTS

Douglas has received from STARLIMS implementation, support and training required for them to manage and configure the system. STARLIMS has delivered significant e fficiencies via sta ndardized wor kflow, QC, stability and microbiology sample management, custom reporting, instrument, and wider enterprise systems integration. On average, DIFOT (Delivery In Full, On Time) has increased from 50% to 95%, while LIRs (Laboratory Investigation Reports) have reduced by 50%.

DOUGLAS CHALLENGES	STARLIMS SOLUTION	DOUGLAS RESULTS
Paper-based, manual and inefficient systems. Minimal visibility of product quality data. Time consuming paper-based data review, batch approval processes and retrieval of data for audits. High rates of laboratory investigation due to poor data entry.	• Fully automated sample lifecycle and electronic data capture system. • Microbiological module • Full audit trails	• Review of hand-written entries and calculation spreadsheets no longer required. • Staff performing manual checking re-assigned to other value add improvement activities. 2 FTE equivalents redirected to other value add activities. • Review by exception with full audit trail. 1 FTE equivalent saved. • Time consuming issue and reconciliation of paper calculation sheets no longer required. 1 FTE equivalent saved. • Clear visibility of all data for trending, audit readiness. • Eliminated transcription errors.
Complex calculations involved in the test.	• Instrument integration. • Automated tests	• Reduction of lab errors, elimination of missing steps in a procedure. • Removal of manual calculation and review of complex tests.
Manual logging of batches and tracking of reduced testing programs onto paper receival sheets. Manual entry of data into SAP with follow up quality status and inventory transactions for batch release.	• SAP/ERP integration. • Skip lot rules.	• Automated logging of batches and automated assignment of tests via SAP inspection lots. • Less time spent in the release process and SAP status transactions.
Results must be peer reviewed against a paper specification. Reliant on analysts to report OOS and OOT results to their supervisor.	• Lab Investigation module	• OOS and OOT results are flagged automatically in the system. • Retest results are linked electronically, and outcomes are easily traceable / reportable.
Complex processes for ordering chemicals resulting in shortfalls and test delays. Complex processes for traceability of equipment and chemical usage.	• Electronic inventory management. • Assignment of instruments and chemicals to tests.	• Simplified ordering of materials and reduced risks of out of stock items. • Enhanced visibility of chemical usage patterns. • Improved visibility of instrument availability and utilization. • Simplified traceability and review of all instruments and chemicals used in a test.
Spreadsheets are maintained for Stability programs to track pull dates and all test results are manually transcribed into excel tables. Maintaining an inventory of all samples kept in each stability chamber is manual and prone to inaccuracy.	• Stability module	• The status of all stability programs is clearly visible. • Reduction in time spent manually generating summary tables and improved accuracy. • Stability chamber inventory reports easily produced.
Scheduling (sample / instrument / analyst) is time consuming. Often opportunities for efficiency are missed. Reviewer must check manually that analysts are trained to perform the tests they are assigned.	• Service groups • Analyst certification	• Scheduling of tasks in the lab is simplified and efficiency gains made by grouping samples together (campaigning). • Analysts cannot perform tests that they are not certified to perform.
There are many different systems currently controlled via spreadsheet, to manage specifications, test methods and procedures to ensure the current revision is used.	• SDMS and document repository	• Document review requirements reduced. • Information in a centralized location. • Procedures to issue and control paper copies of methods eliminated.

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