

Implementing a GMP Electronic Notebook in QC Laboratory Operations

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*Source: Proceedings of IMACS 2006, May 17, 2006, Princeton, NJ and
the Canadian Information Productivity Award (CIPA) organizations
2006 award to GSK Canada.*

http://www.cipa.com/award_winners/winners_06/GlaxoSmKI.html



Abstract: QC laboratory operations are highly dependent on the accuracy of transcription of data from instruments to paper and from paper to computer systems. As these activities rely on human intervention the process is liable to human error and the paper-based nature of this activity makes it highly resource intensive.

This Presentation covers implementation of 'eLab' in a QC environment which includes:

- Implementation of SmartLab as a Laboratory Workflow application to link captured data, data sources, and analytical procedures with trained analysts.
- Intelligent conversion of paper methods to electronic procedure
- Integration of SmartLab GMP ELN with LIMS
- End to end data flow (SAP to LIMS to SmartLab, and back)
- Change management

Key Presentation Points: E-Lab's IT architecture includes ERP (SAP), LIMS, CDS (Atlas) and SmartLab GMP Electronic Notebook System.

Project Goals:

- Eliminate paper
- Increase efficiency by 18% which entailed automating review processes, building calculations into E-Lab worksheets, and integrating method and results;
- Increase compliance by prompting the tester at each step of a procedure;
- Eliminate transcription and calculation errors;
- Ensure unambiguous identification of author and reviewer;
- Increase job satisfaction by eliminating routine calculations;
- Increase focus on results;
- Decrease costs of buying and storing paper;
- Enable the swift retrieval of results, in the event of an audit;
- Facilitate the trending of test results.

Key Project Result: Savings of \$876,000/year! (see reverse page for details)

Figure 1: Data Flow

SAP initiates workflow with a process order for the inspection lot. LIMS creates the sample ID's, which is forwarded to SmartLab.

The analyst retrieves the required SOP from within SmartLab. Data is captured from lab instruments and cataloged automatically.

After review in SmartLab, test result data is forwarded to LIMS for final approval. Results posted to SAP.

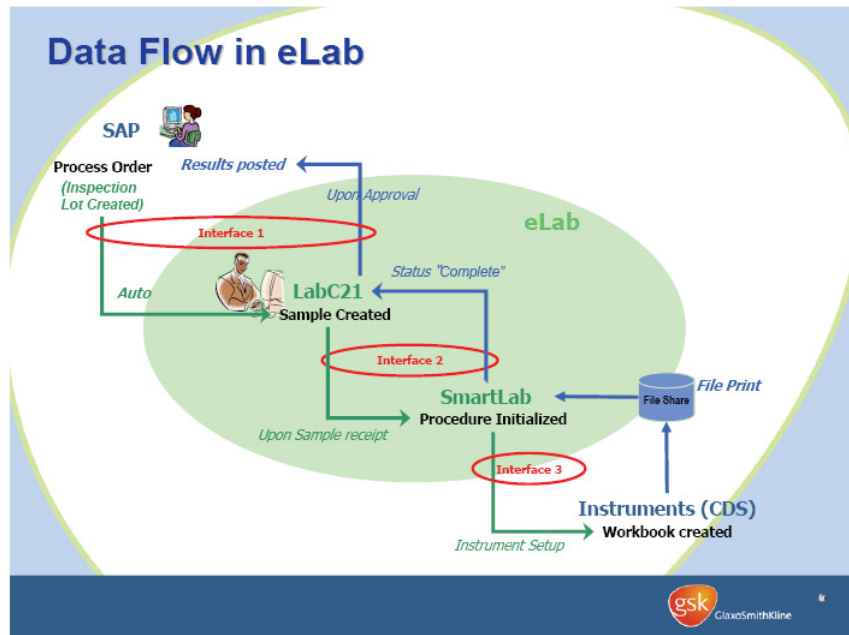
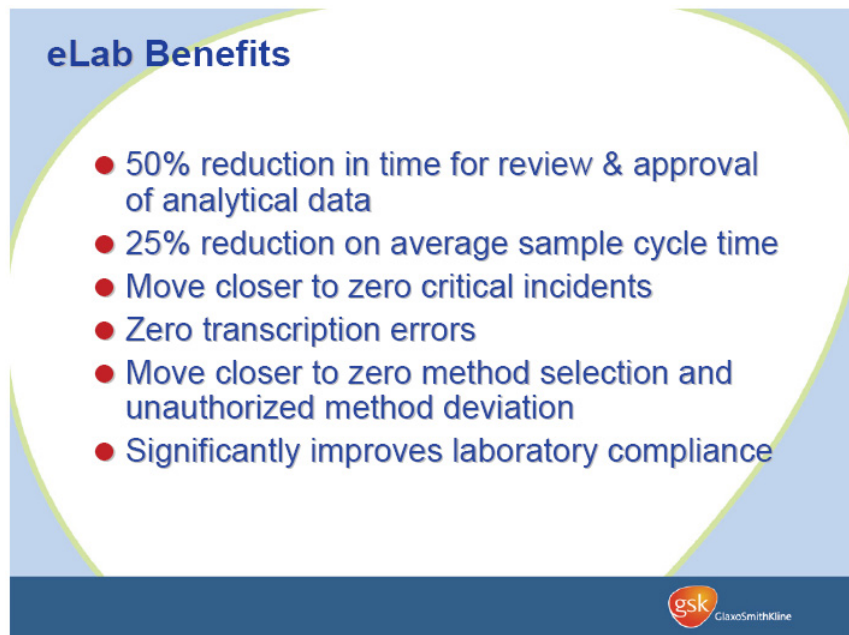


Figure 2: Organizational Benefits

Key benefits included significant reduction in data review and approval time, and 25% overall reduction in average sample cycle times. In addition, assured compliance documentation and "right first time" (zero critical incidents) were achieved.



Efforts on the project were recognized when GSK Canada received the 2006 C.I.P.A. Silver Award of Excellence in Organizational Transformation, For Profit category. As a result, other QC labs in GSK are following the example set by the Mississauga lab. The successful E-Lab project contributed to the Mississauga plant being awarded 22 new production mandates. To accommodate them, the facility is being expanded by 7,000 square feet and more than 150 permanent jobs are being created. (Source: <http://www.cipa.com/media/2006/Glaxosm.html>)

