



SmartLab™ Technical Brief

Customer Implementation: Eli Lilly and Company

VelQuest's SmartLab as a Key Component of a Global LIMS System – An Update

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Global Lab Operations – Quality GMP

Eli Lilly and Company, Indianapolis, IN

Source: Proceedings of IMACS 2007, May 16, 2007, Princeton, NJ

Abstract: Global LIMS is a program of multiple business and information technology projects whose overall goal is to improve laboratory operations and replace the aging systems available in the labs today at Eli Lilly and Company. To meet this goal, this program will provide harmonized business processes enabled by a suite of software applications to improve laboratory information management, data integration, and data sharing. One key component of this program is VelQuest's SmartLab, which will provide laboratory procedure execution and electronic data acquisition and reporting capabilities for laboratory instrumentation. An update on the Global LIMS project and how the implementation of SmartLab is playing a key role in the scope and success of the project will be presented.

Key Presentation Points: The global cGMP informatics IT architecture is comprised of a three-tiered structure including ERP (SAP), LIMS, and SmartLab GMP Electronic Notebook System. The deployment plan is established and includes 35-40 sites worldwide. This implementation replaces two existing legacy LIMS systems and adds a suite of applications to improve laboratory information management.

The goals are to:

- drive global harmonization around business processes in manufacturing and laboratories
- improve laboratory operations
- focus on commercial solutions.

To accomplish these goals, SmartLab was chosen to be a "Lab Execution System" to introduce a common environment that provides:

- instrument run management
- instrument data capture (from all instruments, including CDS)
- procedure execution and electronic data capture
- Calculations
- replacement of current paper documents



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Figure 1: Projects and Applications

A three tiered IT architecture defines the cGMP informatics structure including SAP, a LIMS and SmartLab.

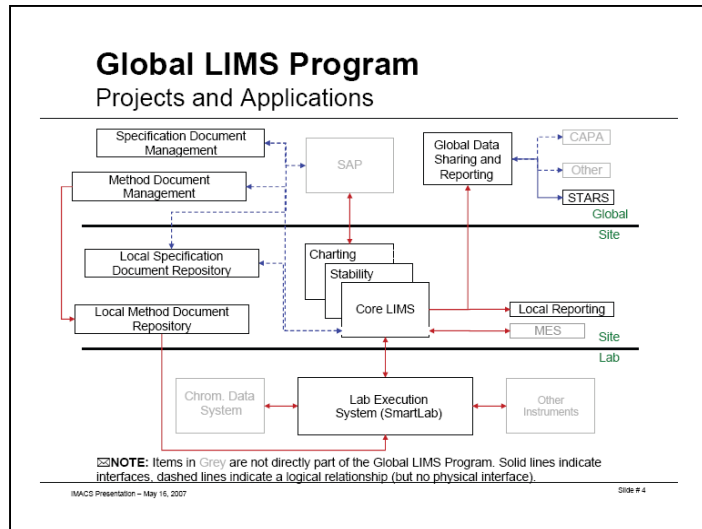


Figure 2: Business Process Overview

- SAP sends request for batch of material
- LIMS associates samples with a test and lab
- Samples labeled and sent to lab for testing.
- Analysts use SmartLab GMP ELN to execute tests on samples, export values to LIMS
- Analyst checks results against control charts and past values.
- Holistic review done and results released.
- P/I flag + potency values sent to SAP
- QA releases batch and makes market determination in SAP and LIMS.

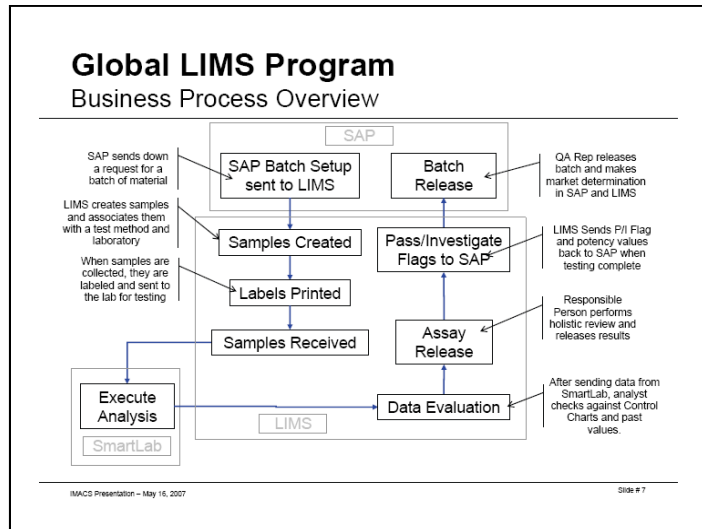


Figure 3: Laboratory Execution Process

Within the SmartLab "Laboratory Execution System" the following tasks are implemented:

- LIMS sends sample information and associated test method to SmartLab
- Analyst retrieves current version of test method from within SmartLab, saves a copy in SmartLab with the sample data.
- Procedure is executed, including:
 - * capture all data (PC and RS-232)
 - * perform all calculations automatically
 - * review and approve data and annotations
 - * forwards results to LIMS for evaluation
- Data is released to LIMS

