

2007 ASUG Annual Conference



April 22-25

Georgia World
Congress Center

Atlanta, Georgia, USA

Replacing LIMS Systems with SAP QM

Michael Krug, QMS
Srini Nunugonda, ITSG Ilc



EDUCATING

NETWORKING

INFLUENCING

Learning Points

- History of LIMS, SAP QM and the QM-IDI (Instrument Data Interface)
- Evaluation of typical LIMS functionality and SAP's solution to address these requirements
- Additional functions that make the SAP software a complete Quality Solution (Notifications etc.)

History of LIMS & SAP QM

LIMS Systems

- Laboratory Information Management System (LIMS)
- Developed for Laboratories (developed specifically around testing)
- Typically found Pharmaceutical application
- Historically have incorporated more “Quality Control” capabilities along with reporting and statistical analysis
 - Sample Management
 - Calibrations
 - SPC
- Initially was the “Hands Down” choice for laboratories that needed to do a lot (> 1 million) samples per year

History of LIMS & SAP QM

SAP QM

- Been around since the R/3 3.0 Days
- Initially offered “Quality Assurance” functions
- Was enhanced significantly in 4.0b (calibrations), & 4.7 (stability studies)
- Strength was around COA generation because of its tight integration with other modules (SD, MM)
- Offered the QM-IDI which was leveraged by LIMS vendors to interface to SAP with the LIMS systems

History of LIMS & SAP QM

The “Best of Breed” Solution

- Use QM, a LIMS solution, and the QM-IDI
- QM for Quality Assurance
 - Product Testing Requirements repository
 - Ensures product isn't used or sold until it meets QA requirements
 - COA generation
 - Vendor evaluation
- LIMS for Quality Control
 - Test capturing
 - Calibration
 - Sample Management
 - Interfacing to Lab Equipment
 - Reporting and SPC

History of LIMS & SAP QM

What is the Right Answer now?

- Both systems offer “like” functionality
 - There is a lot of room for questioning which system to use for which one
- SAP markets QM as an enterprise LIMS (4.7)
 - System is a more complete quality package
- Interface problems have muddied the picture
 - The only way to eliminate interface problems is to eliminate the interface
- Many Companies are not taking advantage of both systems
 - Certification is not indicative of how well a LIMS vendor understands SAP
 - With “Best of Breed” solutions, companies focus more time and attention to the LIMS system instead of both
 - Interface is typically not “transparent”

LIMS & QM – A side by side comparison

- Areas that “historically” have been LIMS territory
 - Data entry – Ease of use
 - Sample Management
 - Calibration
 - Test Equipment Integration
 - Reporting – SPC

LIMS & QM – A side by side comparison

Data Entry

- **LIMS**

- Historically LIMS systems have been perceived to be more user friendly and an easier place to enter results
- Offered tabular displays
- Can be customized with macros to perform multiple things at the same time

- **SAP**

- SAP offers multiple tabular results recording functions – QE71, QE51n, QE01
- SAP's results recording ALV grid can be customized to only show relevant fields (simplifies the view)
- With SAP's Recording Configuration (4.7) basic macro functions can be activated without any code (automatic close, close on save, etc)

- **Comparison**

- The screens look about identical to SAP screens (sometimes not as pretty)
- The customization is typically built in LIMS using VB macros by programmers
- Lab users historically have been able to familiarize themselves with SAP just as quickly as a LIMS system

LIMS & QM – A side by side comparison

Calibration

- **LIMS**
 - Have standalone systems that offer some “scheduling” functionality
 - Are typically pretty basic
 - Offer functionality to capture typical calibration data (as-found/as-left readings, lab standards, etc)
- **SAP**
 - Introduced calibration functionality in 4.0b
 - Integration with PM to use technical objects and other shared data
 - Offers functionality to capture typical calibration data (as found/as left readings, lab standards, etc)
 - Offers Digital Signatures etc that help make it ISO 17.025 compliant
- **Comparison**
 - LIMS solutions are dependent on software vendor
 - SAP’s solution along with its integration to PM is a strong option
 - Many customers (including pharma customers) are starting to use SAP calibrations

LIMS & QM – A side by side comparison

Test Equipment Integration

- LIMS
 - LIMS packages can perform this out of the box IF (and only if) the LIMS vendor is the same vendor as the manufacturer of the equipment
 - LIMS systems typically interface to other packages that interface to the equipment
- SAP
 - SAP offers the QM-IDI (Instrument Data Interface) for test equipment integration
 - QM-IDI is based on several function modules
 - Several BAPIs also exist to extract and import data into SAP
 - This is an area some SAP customers are starting to explore
- Comparison
 - Interfacing to lab equipment is not easy and is typically not standard=
 - The complexity is dependent on the type and capabilities of the test equipment and not the software component that is interfacing to it
 - In either system additional programming and development is most likely necessary

LIMS & QM – A side by side comparison

Reporting - SPC

- LIMS
 - LIMS packages still strong in this area with the ability to chart 2 different tests at the same time
 - SPC charts are dynamic and can be changed to support ad hoc reporting
 - Offer data mining capabilities
- SAP
 - SAP offers great reporting tools
 - SPC (not as robust but a workable solution)
 - Run Charts & Histograms
 - Results History
 - QMIS (Quality Management Information System) & BW/BI
- Comparison
 - Many companies use a bolt-on statistical package like NWA
 - SAP supports dumping of data to statistical packages with the QM-STI
 - LIMS is still stronger option in this area, although SAP is typically workable

Additional functions offered by SAP

- Quality Notifications
 - Powerful tool to manage internal quality, customer/vendor complaints integrated with workflow
- End to end product traceability
 - Complete upstream and down stream product traceability i.e a raw material defect in a product can be tracked to customer who received it.
- Vendor Evaluations
- Stability studies
 - Shelf life studies conducted to track how different environmental conditions affect product over a period of time.
- Audit Management

Business reasons to replace LIMS with SAP QM

- Increased need for tight integration between quality, manufacturing and R&D throughout supply chain
- Quality testing is moving out of Laboratories. (Products are tested more on front end than later)
- Increased cost pressures are forcing companies to track quality costs more efficiently
- Global companies are trying to standardize testing practices to enforce consistent product quality.
- Increasing need for quick product recall situations requiring tight traceability.
- Increasing Issues with LIMS providers:
 - Stability of LIMS providers
 - Resources available to support and upgrade the product (Changing hardware, operating systems)
 - Increasing license costs

Thank you for participating.
Please remember to complete and
return your evaluation form following
this session.

For ongoing education on this area of
focus, visit the Year-Round Community
page at www.asug.com/ycr

Session Code:
Insert session code

EDUCATING

NETWORKING

INFLUENCING

