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THE PAPERLESS LAB

THE TARGET AND MEANS FOR OPERATIONAL EFFICIENCY

BY SOMNATH MUKHERJEE

WHITEPAPER

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TABLE OF CONTENTS

1.0 ABSTRACT

Today, the majority of laboratories are more or less automated—in the form of instrumentation and instrument data systems with LIMS being at the center. Typically, laboratories use many diverse types of software apart from LIMS. While LIMS is used to track sample lifecycle and related data management, result entry of the samples is performed through instruments interfacing. While trying to achieve "Paperless Flow" in laboratory, LIMS needs to be integrated with other enterprise software such as enterprise resource planning (ERP), electronic notebook (ELN), the scientific data management system (SDMS), chromatographic data systems (CDS), inventory management system, the training management system, the statistical package and so on. Though the intention is to have seamless interconnectivity between all these systems, in reality, many manual operations still prevail. Most of the organizations are now trying to reduce the extent of manual operations and thereby move closer to the ideal paperless laboratory. LabIMS™ from HCL Technologies is designed to work as a comprehensive sample information management system which has built-in functionalities to integrate with various applications as indicated above, and thereby enable end users to move closer to a paperless lab.

This paper tries to analyze practical problems involved in moving into a paperless lab and how LabIMS™ can help to mitigate those problems.

2.0 DO WE REALLY WANT TO MOVE AWAY FROM PAPER?

There are people who say: No, we really do not want to move away from paper. We like to retain paper. We feel very comfortable if we see papers or notebooks at our desk. There are scientists/technicians in Lab, who spend a long time to maintain these papers and can seem very productive with these papers.

But, why do they want to retain paper? Is it worth spending time to manage these papers, when there is no guarantee that these papers will be there for long duration? Unfortunately, there are no solid answers to these questions. This is a practice we have been following for years.

If we drill down, we will find two main reasons behind this attitude: paper-driven procedures and a lack of well integrated systems. Most organizations have procedures which were developed, keeping paper systems in mind. Now that the industry is moving towards electronic systems, organizations heavily depending on paper-driven procedures are forced to use the new system. Hence, there is a disconnect. What ideally needs to happen is to modify processes and ensure lesser dependency on papers. However, the modification of paper-driven procedures is not the only solution to achieve a Paperless Laboratory. Organizations also need to tackle the other significant root cause—the lack of an integrated system.

There is limited information available as how best to connect LIMS with Electronic Laboratory Notebook (ELN), Scientific Document Management System (SDMS), Enterprise Resource Planning (ERP), Chromatographic Data Systems (CDS) and so on. Most of the interfaces are supplied by product vendors and hence those are not flexible to connect any diverse systems. In order to drive towards paperless lab, it is important to use a technology-agnostic middleware which can connect with the above systems in a synchronous or asynchronous way. But that is not sufficient to achieve

a paperless lab. We need to continuously strive towards a comprehensive integrated system.

3.0 WHAT ARE THE DRIVERS?

Regulatory compliance and business transformation objectives are the two drivers for the paperless laboratory.

- Regulatory compliance: The FDA regulation CFR Part 11 is harmonized with ISO 8402:1994.

The European Medicines Agency (EMA) has announced its first revision of EU GMP — Annex 11 "Computerized Systems". These revisions came into operation on June 30, 2011. The Annex has been revised in response to the increased use and complexity of computerized systems, facilitating innovation and towards a paperless laboratory. The new Annex 11 adopts a risk-based approach in several areas which makes it generally aligned with current industry standards and practices (ICH Q9, ISPE GAMP 5).

For businesses which are governed by the Health Insurance Portability and Privacy Act (HIPAA), paperless records are a regulatory requirement. Hospitals across the nations are trading their once scattered medical charts, file folders, X-rays and other documents for comprehensive, unified, electronic records to comply with regulatory requirements. Title II of HIPAA, which has the IT focus, requires the establishment of national standards for 'electronic health care transactions'. Protected health information (PHI) which is Individually Identifiable Health Information (IIHI) is to be

(I) Transmitted by electronic media hand

(II) Maintained in electronic media.

The requirement within HIPAA aims at aiding hospitals and their patients dealing with the extreme paper usage that may be caused by insurance forms, HIPAA privacy policies, etc. Hospitals now have the technology and the regulatory guidelines available to them to help save money and conserve paper/forms and be compliant with federal requirements without compromising on patient security, confidentiality and privacy.

- Business transformation objectives: Electronic submissions for faster review and approval of dossiers.

As per various market analysis reports, the business drivers for moving to paperless lab have increased. However, there are certain pressures which are to be considered:

- Faster time to market with both R&D and manufacturing
- Need for cost reduction
- Efficiency and effectiveness of the analytical laboratory
- Speed of decision making.

This needs to be delivered by effective, efficient, data repositories, plus effective integration and data transfer between applications that constitute the paperless laboratory for an individual organization.

4.0 CAN A LAB BE FULLY PAPERLESS?

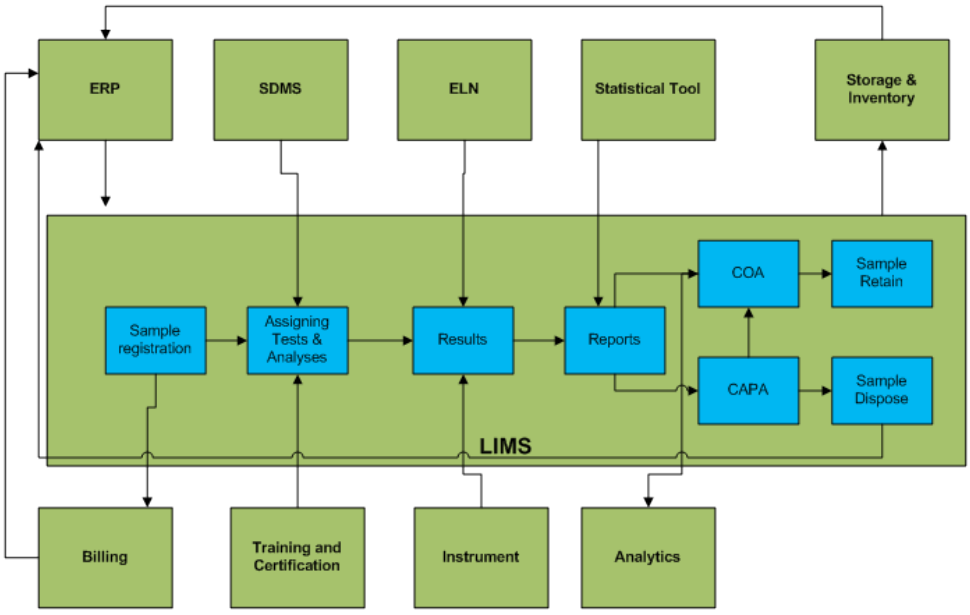
No. Until paper-based procedures are completely translated into electronic mode and a robust integration framework is available, a complete paperless laboratory cannot be achieved.

However, the good news is, transformation is enabling point solutions to help achieve close to 80% automation.

Now, the integration of systems is key to eliminating both manual procedures as well as paper with creation of a paperless laboratory that offers the following advantages:

- Data/ Information entered once is easily available across the organization.
- Data needs to be entered only in electronic mode and not manually.
- Data is instantaneously available to enable faster decisions and time-to-market.

To explain this further, let us take example of integrating LtIMS with ELN. These two systems are completely different with respect to data structures and functionalities. While ELN is more close to the research environment, LIMS is very powerful in quality control activities. Let us take an example of sample lifecycle management. Samples are logged in LIMS and received there too. These samples can also be logged in automatically after receiving information from ERP (Inspection Lot Info). Once logged in, an electronic acknowledgement must be sent to ERP. After sample login, it will be received in LIMS system and also allocated to technicians. Next, sample/ test level information needs to go to ELN and instruments must automatically send result to ELN using seamless ELN-Instrument connectivity. While conducting testing in ELN, analyst certification and material/reagent inventory level information must flow in from LIMS. While Standard Operating Procedure (SOP) is maintained in Document Management System, it should be available in ELN during testing. During testing, if results are found to be not as per specification, immediately flag-off information must flow to ERP via LIMS.



[1] Point Solution is a single solution to connect two different systems like LIMS connected to ELN, LIMS connected to SDMS etc.

Testing results from instruments must be stored in SDMS as raw data, while processed data will be stored in ELN. After testing, analyst and supervisor approval will happen in LIMS, hence testing results will have to move from ELN to LIMS. Certificate of Analysis (COA) will be printed by either LIMS or ERP, therefore, appropriate information must be available any time through the interface.

Each of the above systems is an independent entity, but through appropriate integration, they should appear like one single unit, eliminating manual processes and paper.

Now the question is, whether this type of integration is available or not. Despite of the effort made over 10 years, there is no single framework available to achieve this integration.

Further to this, converting paper-driven procedures to electronic media is a challenging job.

5.0 FINDING A SUITABLE WAY TO ACHIEVE A PAPERLESS LAB?

In a drive to achieve a paperless lab, we are observing an honest effort from both end users as well IT industries to:

- Change paper-driven procedures to paperless procedures
- Consolidate requirements towards paperless workflow
- Optimize laboratory application portfolio to reduce the number of applications

While laboratories are involved in making the above changes, product vendors and IT service industries are thinking of the following:

a) Addition of cross product functions

b) Modification of product architecture to achieve the following:
   - Design of an application where the logic is organized into loosely coupled modules (services)
   - Services that use an agreed message standard
   - Usage of XML for data and SOAP (Simple Object Access Protocol) for messaging
   - Pull out and/or plug-in configurability

c) Enabling of existing middleware to connect multiple systems in laboratory space; this is little older concept with its own limitations

d) Development of new middleware using advanced integration protocol like AniML, HL7-V03 etc.

e) A standard way of integrating applications using XML (eXtensible Markup Language) data

f) Enablement of multiple applications from different sources to communicate without custom coding
   - Flexible, eliminates “one off” interfaces
   - Can “wrap” around a legacy application API

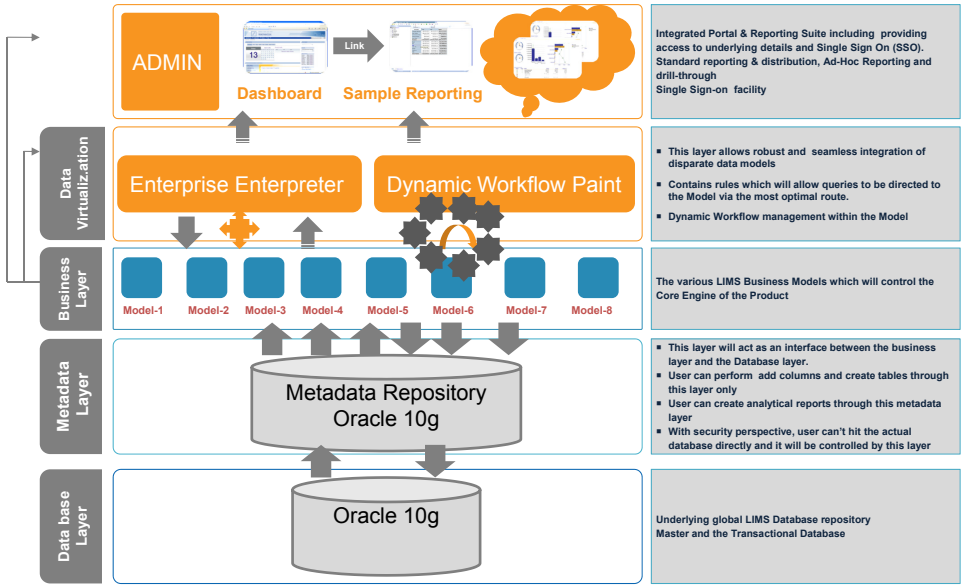
g) Facilitation to achieve a single view of multiple applications

   a. On-demand data access

   b. Predictive tools

6.0 HOW HCL'S LabIMS™ CAN HELP ACHIEVE A PAPERLESS LAB?

As we have seen in section 3.0 and 4.0, for any laboratory to become paperless, it needs to select an information system, which offers a flexible workflow and true integration engine. LabIMS™ from HCL offers a flexible workflow and a state-of-the-art integration engine.

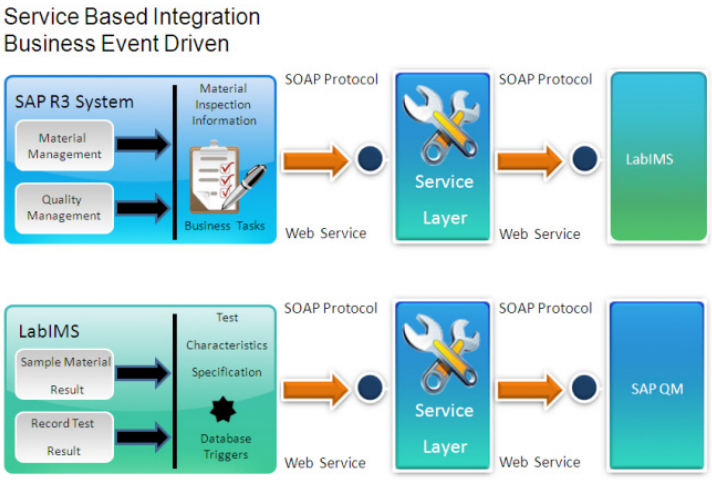


The core engine of the LabIMS™ contains all the basic LIMS features but the uniqueness of the IP lies in the fact that it is a low cost solution with a robust and flexible SaaS (Software as a service) based architecture, which enables repeatable and easy rollout and single sign-on. Functionality-wise, the uniqueness lies in modules like The Stability Study Management, Instrument Management, Analytical Workflow Management, CAPA Investigation Management and External Interface Management. So it is a one shop solution for complete laboratory automation and information management. The product features are as below:

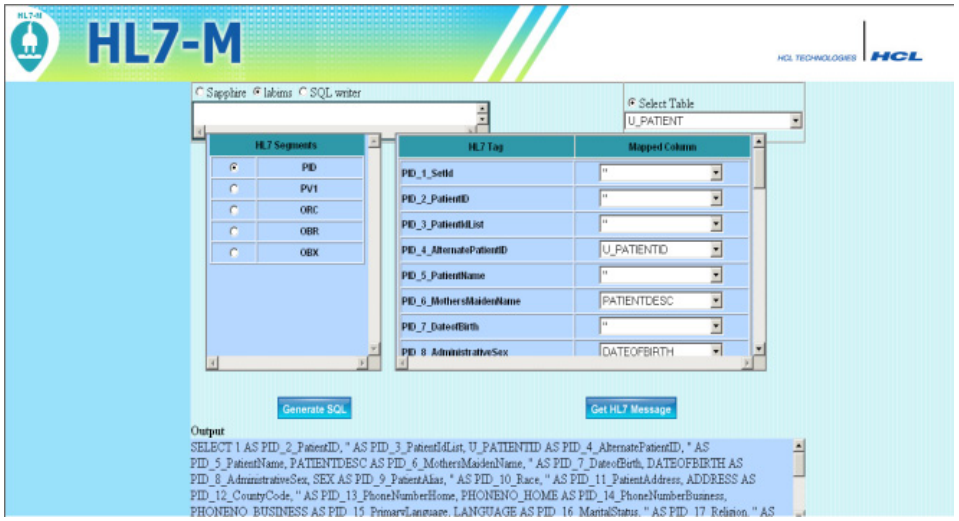
- One stop solution
- Single sign-on
- SAAS-based architecture
- Integration with other external applications like, SAP, other ERP through open web service interfaces (point-to-point integration)

- Instrument interfacing (depends on vendor tie ups)
- Seamless integration with Jasper reporting tool
- Easy alignment of the proposed architecture with any business intelligence architecture.
- Pre-configured modules including:
  - Sample Management
  - Analytical Workflow Management
  - Security and Administration
  - Master Data Management
  - Dashboard and Reporting
  - Schedule Management
  - Stability Study Management
  - Instrument Management
  - Multilanguage Support
  - Plate Management System
  - Inventory Management
  - Invoice Management
  - CAPA Investigation Management
  - External Interface System Management
  - Master Data Management
  - Storage Management and Logistics

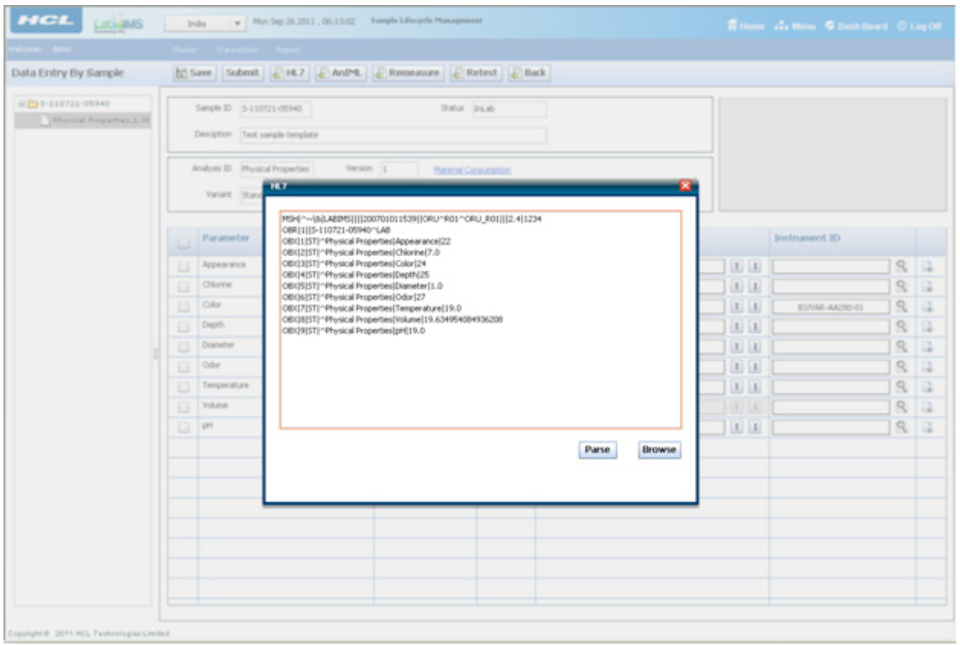
LabIMS™ is a flexible product, with LIMS as the core engine and the option to connect to various external applications like SAP, MES, Analytical Devices etc. LabIMS™ has a core integration engine (**SLC – SAP LIMS Connector**), which is generic enough to connect with SAP/MES.



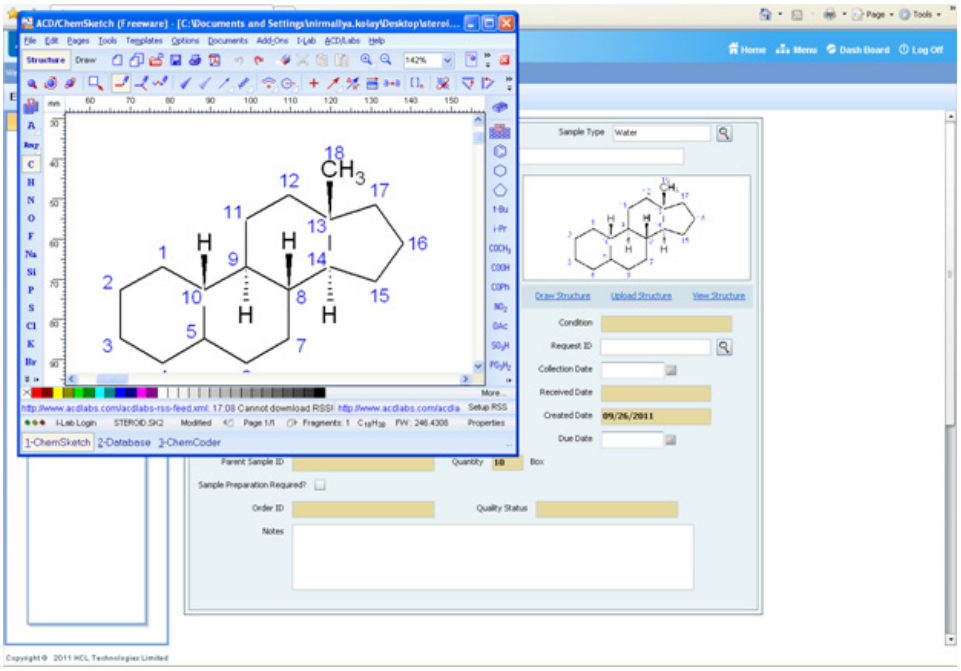
Similarly, it has HL7-Manager, another, integration engine, which is a configurable tool to connect any systems (which generates and accepts HL7 formatted message). Keeping the recent trend of HL7-driven interfacing in mind, HL7-Manager could be good option to connect to various healthcare systems like EHR, EMR, HIS and other medical devices.



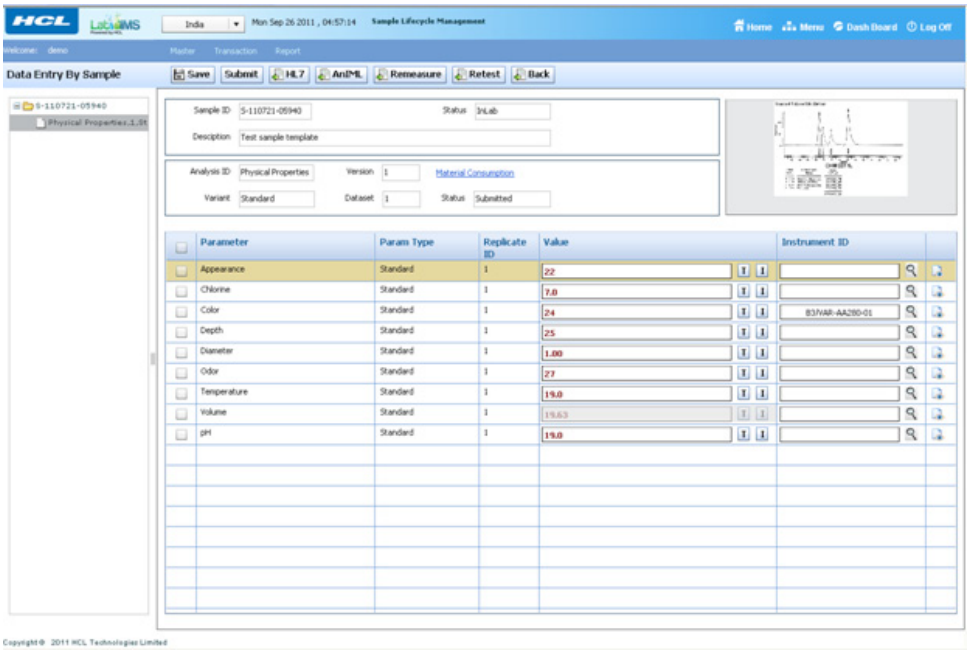
The above picture illustrates HL7-Manager Configurator engine, while the picture below illustrates how HL7 message are parsed within LabIMS™.



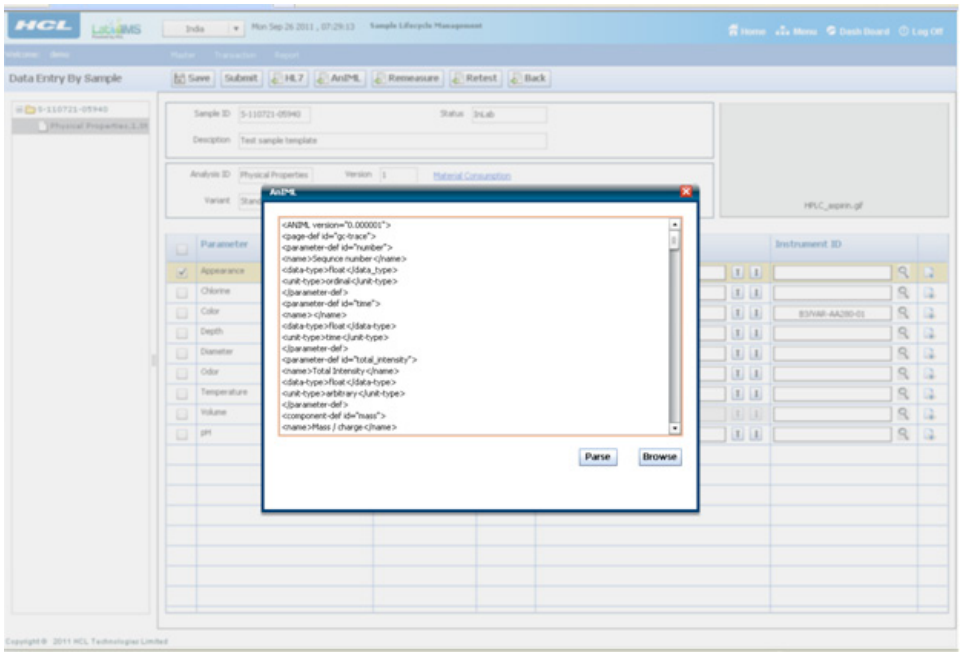
LabIMS™ is a LIMS solution with flexibility to store molecular structure, drawn with ChemDraw, MarvinSketch, ISIS/Draw-like standard structure drawing tools.



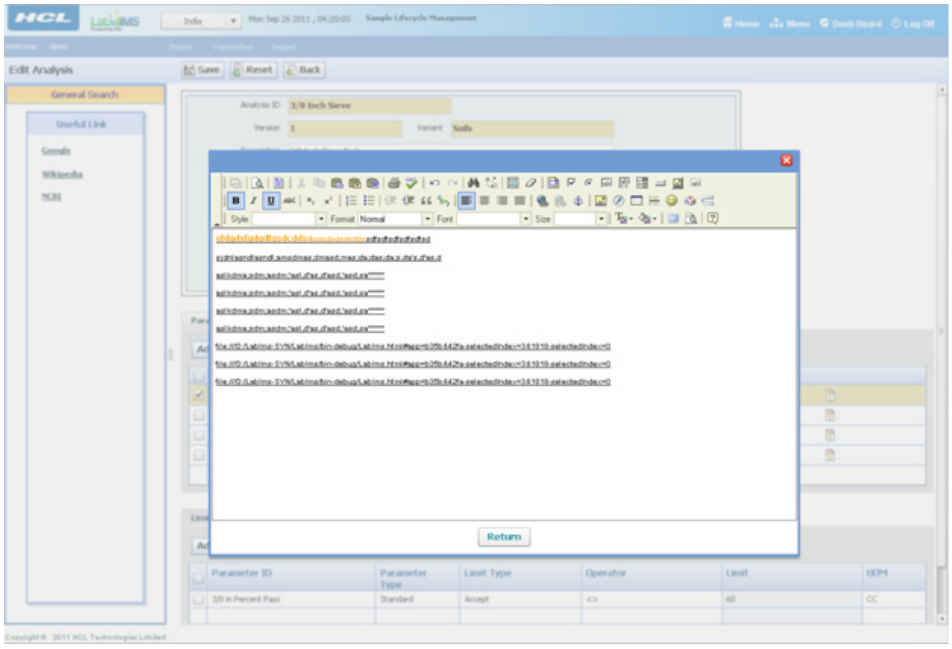
System even helps to store chromatogram data and image during result entry by directly capturing images from analytical devices. This feature is helping analysts to review the image as well data while taking pass/fail decisions.



LabIMS™ is a powerful tool to connect to any third-party system using AniML protocol. Currently, AniML is being used extensively to ensure data integrity.



LabIMS™ allows analysts to note down textual observations while recording analytical results or writing an SOP.



7.0 CONCLUSION

A paperless laboratory is the next step to transformation. It is now becoming inevitable. Industry Analysts as well Market Research cite the following reasons:

1. The healthcare and pharma industry has an urgent need. Leading healthcare and pharma companies must develop and commercialize new products more quickly, improve productivity throughout their operations and ensure compliance under more and more demanding regulations.

2. The FDA is committed to electronic filings and audits. 21 CFR Part 11 defines how electronic records can meet or exceed today's paper-based records. The FDA now mandates electronic submission.

3. More than fifteen years of automation and IT innovation have set the stage for the paperless laboratory.

4. The technology is available today and it is rapidly improving, quite economical and readily integrates with legacy systems.

As new technologies enable the transition from paper-based to paperless operations, two good things happen—data and documentation compliance increase while compliance costs decrease. Leveraging its LabIMS™, technology platforms and business process knowledge, HCL is equipped to help organizations realize their goals for a paperless lab.

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Please feel free to write to us at contact.lsh@hcl.com

ABOUT THE AUTHOR

Somnath Mukherjee

PMP Certified professional having more than 18 years of technical, strategy and compliance consulting experience in lab informatics specializing in services to the regulated life sciences and pharmaceutical industry. He has expertise in building Practice, Competency Centre, and in global informatics systems (LIMS, CDS, SDMS, ELN) in the regulated life sciences. Focus on leveraging expertise in lab informatics strategy, implementation, enterprise integration, validation, process improvement, delivery management and team facilitation. Possess experience to lead a team to achieve sustainable growth in Revenue.

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