

Drug discovery is perhaps one of the most data sensitive processes in the world. From finding the drug target, to identifying potential drugs, sample validation, concept testing and ultimately launch, data has to be repeatedly logged, revised, checked and analysed in the laboratory. Advances in biotech and genomic technology mean this flow of information is no longer linear; instead, stages of this process are occurring simultaneously, creating a massive data mountain.

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Out on a LIM: How Data Loss Protection Technology Could Breathe New Life into Legacy LIMS

Laboratory Information Management Systems (LIMS) help automate the pooling and reporting of this data, providing manufacturers and distributors with access to critical scientific data, product information and trial records helping to streamline and accelerate development. LIMS are invaluable in automating, classifying and securing the increasing amounts of data generated by high throughput laboratories during lab trials into one primary database. They can also be instrumental in improving workflow, alerting staff to the resources required for stability studies and stipulating when these need to be executed; ensuring data quality by rejecting substandard samples; and, providing analysis and reports to inform future working parties, for instance. Yet LIMS tend to be laboratory specific (typically pharmaceutical) requiring adaptation for other labs, and many of the LIMS in place today are fat client legacy systems making integration with other systems problematic.

WHY IS INTEGRATION AN ISSUE?

Over the past few years, each new generation of LIMS has become more sophisticated and their remit has extended beyond the laboratory. Used enterprise-wide, LIMS can create economies of scale and increase efficiency and productivity. Data generated by multiple teams that previously sat in segregated parts of the network can now be used to inform decisions on an enterprise-wide level. Laboratory, production and management can all access the same data sets for different purposes. Consequently, state-of-the-art LIMS, typically used for handling a myriad of workflows, are now often interfaced with ERP (Enterprise Resource Planning), ASM (Advanced Planning and Scheduling), MES (Manufacturing Execution System), PIMS (Process Information Management Systems) and SCM (Supply Chain Management) systems, to channel data resources into these areas of the business.

The problem is that many laboratories now face a dilemma. Integration is a no-brainer, bringing greater operational efficiencies by allowing the different stages of drug development to occur simultaneously. The question is whether to invest in a new LIMS in order to automatically populate these systems with this information or whether to stick with a legacy LIMS and use additional technology to gain these advantages?

Legacy LIMS is adept at data management within the confines of the laboratory but integration issues faced by legacy systems can see data siloed. This prevents decision makers from accessing data in a timely manner. One technology that may help to bridge the gap, avoiding the costly decision of whether to replace a legacy LIMS, is Data Loss Prevention (DLP).

DLP DEFINED

DLP technology identifies, monitors and protects data in use, in flight or at rest using deep content analysis and centralised management to enforce access and security policies. Frequently used in an enterprise context to ensure data is managed effectively to meet stringent compliance regulations, the technology is tried and tested and has been used across government, military, financial and utility sectors to name but a few.

DLP is an effective means to make data more readily available to authorised personnel and the technology has much in common with LIMS. Sample data, specification targets and limits, dates and other analytical criteria all need to be shared in a manner that protects the integrity of the information and ensures it cannot be viewed, altered, copied or printed without authorisation; all of which can be carried out equally well by DLP. The technology provides



audit trails detailing user access and transmits and stores data securely but it also has the ability to grant access privileges enterprise-wide according to a variety of different rulesets.

Data can be classified for public, private or classified use on a file, folder, content, transaction or application basis and by user or user group. Subsets can then be created, specifying whether each user has the right to copy, print or export information. This can even be applied to key paragraphs or cells in a document, which can be labeled as restricted while the rest of the file is made accessible. Moreover, it is also possible to control which applications can be open at the same time, so users may decide a laboratory technician cannot access Excel or email at the same time, for instance.

DLP can be deployed at the endpoint, be it a desktop, laptop or smartphone, allowing the system to directly monitor the user's activity and respond far more quickly than a network-based solution. Prompts asking the user if they are sure they wish to save data in an unusual location, for instance, can be used to protect data and improve operational efficiency. Should a user behave suspiciously, an alert can be generated and sent to the system administrator who is then able to view screenshots, showing the actions or changes made by the flagged member of staff.

WEB-BASED LIMS

However, the problem of how to help legacy LIMS to communicate with data acquisition, ERP, MES and SCM systems, for instance, remains. LIMS can be migrated to a web-based architecture to help address integration issues. An n-tier architecture, for example, can provide a platform on which to house these disparate systems, avoiding the need for a homogenous physical platform. All of the systems are able to communicate in a virtual context over a common XML-based platform, reducing cost of ownership and cost of development in one fell swoop. The way that an n-tier architecture is built sees information on the LIMS retrieved from a dedicated database layer via SQL prompts.

An alternative approach is to adopt a SOA (Service Oriented Architecture) that uses a search engine mechanism to

interrogate data in place of the database management layer. This can speed up access, making it possible to rapidly access, analyse and use data to inform workflow going forward. But it also makes it a much simpler process to share data across the organisation via web services such as Microsoft BizTalk and SharePoint, for instance.

However, the move to a web-based enterprise-wide architecture is not without its risks. IP is one of the most hacked protocols in the world and laboratory data is some of the most valuable so there is a real need to ensure that the data being accessed cannot fall into the wrong hands. Access to the LIMS, particularly remotely, needs to be considered carefully to ensure data is secure. Internet protocol standards, such as SSL (Secure Socket Layer) for encryption of data in transit, along with digital signatures and certificates are tried and tested means of protecting data and authenticating users. But to provide a belt and braces approach, data needs to be encrypted end-to-end.

DLP can again help here with virtual vault applications that can instantly encrypt data at the point of creation on the desktop. This ensures information is stored or sent to colleagues securely. Look for vaults that offer robust encryption based on the AES (Advanced Encryption Standard) 256-bit algorithm and that comply with standards such as FIPS 140-2, an information technology security

accreditation which enables the vault to be used within government departments or by regulated industries which need to collect, store, transfer, share or disseminate SBU (sensitive but unclassified) information.

WEB-BASED DLP

DLP can also offer secure web-based data access via terminal services such as Citrix and Windows Terminal Server (Remote Desktop Connection) both of which can be highly effective in creating confidential domains within domains. Users can be logged in to terminal services transparently, simply by clicking on an icon on the desktop, enabling them to access critical information but with restricted Internet and email access, effectively limiting the potential for data leakage.

Within a terminal services session, DLP can apply 'total lock down' policies tightly restricting which applications are available and the functions within those applications specific to the user. Cut, copy, paste, print, save as, export; all can be disabled.

Similarly, technology is now available to restrict the availability of high-level administrator actions to secure locations. Through the integration of physical and logical (IT) security controls with endpoint security, location becomes an enforceable context. So it becomes possible to restrict access

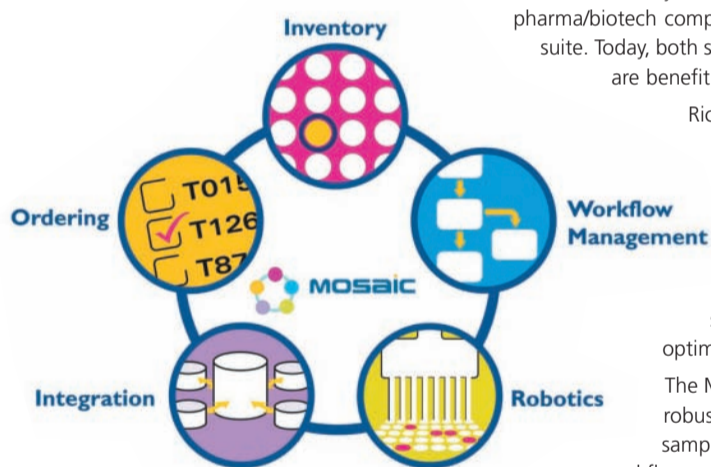
and data manipulation according to time or place preventing system administrators from abusing their access. Physical access control systems combined with CCTV can limit certain administrator actions to the console of the server within the data centre, for example, and provide irrefutable evidence of not just the user account but the actual human being that carried out a particular task, or equally ascertain if a particular individual was absent at the time. In effect this creates a visual and IT-based audit trail of who altered a document, when, where and how.

CONCLUSION

It should be said that DLP certainly isn't a substitute for the comprehensive data management a LIMS solution can provide. However, for those still using legacy systems, a DLP can be an effective complementary technology which, when used in tandem with a web-based architecture, be it a SOA (service oriented architecture), n-tier architecture or terminal services, can effectively manage and secure data across all of the production systems and departments of the organisation.

Favoured Sample Management Software

Now in its 10th year, **Titian Software** has announced that 10 of the top 20 pharma/biotech companies have chosen its Mosaic sample management software suite. Today, both small biotech as well as large global pharmaceutical companies are benefiting from the Mosaic modular platform.



Richard Fry, Commercial Director of Titian, commented: "We are delighted that so many of the top Pharma companies are using the Mosaic software suite, and in particular that the growth of our installed base has been largely driven by repeat business with, and recommendations by, existing customers." He continued: "This success demonstrates not only the flexibility and robustness of the Mosaic software, but also increased awareness of the benefits that optimised sample management can bring to the laboratory."

The Mosaic software suite has been proven as a reliable, stable and robust system, with modules to control and monitor all aspects of sample storage and preparation. It incorporates inventory tracking, workflow management, sample ordering and the integration of robotic workstations from a variety of vendors. The result is higher throughput, faster

completion of orders, reduced labour costs and low error rates.

Titian's first system was deployed over nine years ago and in the time since no customer has ever retired a Mosaic system. Commenting on this, Richard Fry said: "We have a wonderful community of customers. Their investment, experience and suggestions for product improvement continue to move Mosaic forward and keep it relevant to current needs. I think that's why the systems are enjoying such long and happy deployed lives, and continuing to deliver strong return on investment."

Circle no. 155

Changing the Face of Computer Forensic Case Management

IntaForensics is pleased to announce the launch of new case management software that is set to change the way computer forensic cases are managed.

Available to both service providers and Police High Tech crime units, LIMA™ streamlines case and resource management and gives authorised personnel the ability to track a case's progress without the need to inundate users or the Forensic Investigator with update requests.

Designed by and with Forensic Practitioners in mind, LIMA™ offers a complete solution. Highlights of the new software include: contact resource management; sales management, quotation and proposals; resource management and scheduling; forensic case management; exhibit and asset tracking; quality assurance; reporting and statistics; knowledge base; and secure customer/Officer in Charge/Senior Investigating Officer portal access

Update requests, staff absences and incongruous shift patterns can be to the detriment of the speed of an investigation. LIMA™ offers a complete solution that ensures all authorised personnel are fully up-to-date on a case's status, thereby maximising the efficiency of the investigation.

Circle no. 156

Lab Training Management

Labtronics, Inc is pleased to announce the latest addition to Nexxis iLAB, the integrated laboratory solution where instruments, systems and people are able to automatically share and access information, as they need it.

Nexxis TM (Training Manager) is a web-based training management solution that introduces new levels of automation, control and integration to all aspects of employee training and training management.

Nexxis TM can automatically prevent analysts from executing tests and procedures if they aren't properly trained.

Nexxis Training Courses can be created on-line in minutes and can be automatically graded providing proof that training was completed and measuring how successful the trainee was. Results from Nexxis Training Courses are automatically stored in Nexxis TM where they can be easily accessed during reviews, inspections and audits.

On its own, Nexxis TM gives all organisations an easy-to-use, web-based, automated solution that efficiently manages employee training requirements and provides laboratory management with real proof that training took place and that the training goals were achieved.

As part of the Nexxis iLAB solution, Nexxis TM delivers a completely new level of training management where training requirements and training activities are fully integrated with everyday laboratory procedures.

Circle no. 157

*The Spotlight
could be on you!*

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