Considerations for Software Expansions and Upgrades

Before you decide to rock the boat, several key decision-making steps can help to ensure a smooth and successful upgrade

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The last thing an organization may want to do is start a project to change a working enterprise application environment. A lot of energy has been spent to make it finally work in the way your organization works and so that your users like it! So, why rock the boat?

Industry reports show that the main reasons for introducing change are to

- implement new IT infrastructure
- apply new regulations
- consolidate applications after mergers and acquisitions
- reduce overall operational costs

The upside of upgrading the IT infrastructure will give many organizations the ability to eliminate barriers to enable cross-functional collaboration between research, development, quality assurance and manufacturing. Standardizing workflows and operating procedures and applying best industry practices throughout operations also are key drivers. Quick advantage occurs when the implementation is fast and when it results in strategic value. This article will highlight key decision-making steps to be considered when upgrading your software.

PAIN POINTS

The vendor, or one of his partners, discontinues support of the product. Although some vendors offer attractive unlimited support, this could lead into higher short-term customizations. Database, security and device technologies are changing rapidly. There will be a moment of truth.

Another key reason is no out-of-the-box support for new modern portable devices such as iPad, iPhone, Android, Flash technology, browser independency or service-oriented-architecture (SOA) support. Also, new regulations from the U.S. Food and Drug Administration (FDA) and International Conference on Harmonization (ICH) of Technical Requirements

for Registration of Pharmaceuticals for Human Use may become mandatory in your research or production facilities. Examples include electronic signatures and e-stability.

Legacy systems often result in higher operational costs and inflexible application license structure.

- Lack of SaaS or alternative license structures to support new customers may limit the utilization of the current infrastructure.
- Maintaining a legacy dinosaur is often expensive.
- Social media and focused discussion groups, like those found on LinkedIn, are uniting users and reducing the value of first-line support from a conventional vendor helpdesk. These forums also are a great way of gathering data points for your decision-making process.

PERCEPTION IS REALITY

The industry is using several terms for moving to a newer version of application software. This may sound trivial. However, in order to plan your test and validation protocols, it is critical to have a common understanding of what these terms mean, especially if your upgrade project includes multiple applications.

The benefits of software as a service (SaaS) and cloud computing address many upgrade inconveniences. However, in many deployments, this option may not yet be applicable. Although, for planning purposes, it is recommended that you include these new capabilities and services in order to be prepared for the new paradigm.

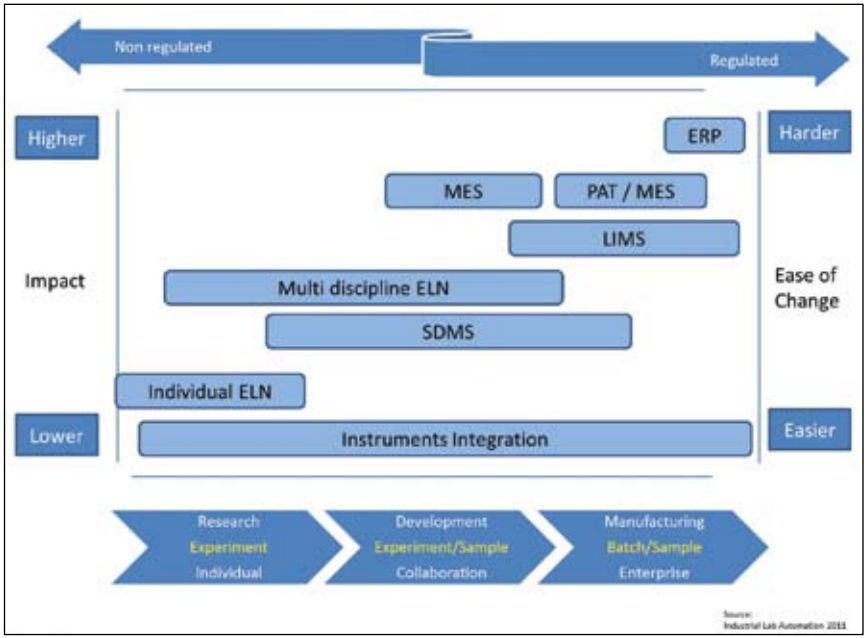
Application software changes in non-regulated laboratory operations or for specific individual users have, in general, a lower impact for the organization. However, different hardware platforms and network requirements may require individual attention. Also, upgrading applications from different vendors increases complexity (Table 1).

TABLE 1

Type	Technical description	Checklist
Update Patch	Fix or minor extension for a well-defined problem. Core application will not be updated. Patches are well-tested by vendor and may be made available generally or on individual basis.	**Does it fix the problem?** • What level of testing is conducted by vendor (IQ,OQ,PQ) • Will change be included in next official release? • Any other validation considerations • Training issues?
Upgrade	Major new software release. Compatible with previous release. New capabilities and technologies may be introduced. Parts of the kernel application may be rewritten, but overall behavior will not be changed. Database schema unchanged	**What is main purpose?** • Will existing customizations work? • Browser and platform independent? • Upgrade IT Infrastructure needed? • Any archive and restore issues? • Level IQ, OQ, PQ testing required • Paperless lab initiative
Migration	Change to a different software platform. Different application behavior. Existing data may be converted to new platform. New database schema	**Assure functionality is met** • Redesign customizations? • Service-oriented architecture (SOA)? • Upgrade IT Infrastructure needed? • Lower cost of ownership projected? • Validation process • Training issues
Consolidation	Replacement of legacy application with alternative.	**Legacy replacement** • Revisit existing software portfolio and research how your primary processes are supported • Corporate QbD initiatives • Protect legacy data (corporate asset)

NEW DEVELOPMENTS AND TRENDS

- **Intelligent instruments:** Balance and titrator vendors are increasing the value of their instruments by implementing approved and pre-validated methods in their firmware. This may sound like a small step, but it may have a significant impact on validation efforts in the laboratory and in manufacturing operations, such as less points of failure during operation, less customization of software and better documentation.
- **Agile innovation in manufacturing:** Manufacturers are investing in agile manufacturing to increase their abilities to release products more rapidly, decrease engineering change cycle times, and increase asset and resource utilization.
  - Automating correlation of real-time manufacturing data to process and product specifications decreases cycle times.
  - Quality by design (QbD) will be increasingly deployed in pharmaceutical manufacturing processes.
  - Process analytical techniques (PAT) technology is expected to grow significantly in the next decade.
  - Over time, in-line, @line and on-line analysis will substitute off-line (batch oriented) manufacturing processes.
  - International regulatory authorities like ICH, FDA and the International Society for Pharmaceutical Engineering (ISPE) are evaluating these new processes intensively and developing new workflows. These processes will have a high impact how QA/QC laboratories will operate in the next decade. The QC functions are expected to decrease, while the laboratory will change into a knowledge center to support the new business processes.
  - Enterprise resource planning (ERP) and manufacturing execution system (MES) applications will integrate the QC laboratory more cost-effectively into the value chain, and electronic lab notebooks (ELN) will play a crucial role in supporting the knowledge management-extended lab functions.
- **Merging personal and business life:** According to Gartner, personal devices, such as tablets, smart phones and other new Internet devices, will be integrated into corporate IT strategies. Corporate security will expand to include social network protection, supporting the usage of these personal devices to perform work tasks. As a result, integrated application security policies will become mandatory in order to enable a secured and protected environment.
- **Go for growth:** The best systems include capabilities that give your organization new ways to become more competitive. SOA is an approach to develop enterprise software applications in such a way that software processes are broken down into granular "services," which are then made available and discoverable on the corporate network. SOA provides business with the ability to extend services to new customers (information consumers), streamline business processes (modular and interchangeable components) and work more efficiently with partners and suppliers, while unlocking information to other systems that need it.



Laboratory data management backbone landscape: cross-functional integration to achieve a single point of truth

MES, ERP, scientific data management systems (SDMS), laboratory information management systems (LIMS), and ELNs provide logical building blocks for assembling such a

hub. According to Gartner, Web services will drive a 30 percent increase in efficiency of IT development projects. User acceptance is higher using the new "app" approach, rather than the old "windows compliant behavior" paradigm.

- **Vendor's considerations:** Software vendors are under increased pressure to maintain their maintenance, support and license revenues. Community collaboration and social networking are changing the value of traditional vendor helpdesks. It is worth it to revisit the value you have received during the last one to three years. Make a judgment call on whether or not the return was worth the investment.
  - How often have new versions of the software been installed?
  - Investigate why so much software consultancy was invested for what the industry is calling a commercial-off-the-shelf (COTS) system.
  - Investigate how straight-forward it is to maintain the same software functionality to the newer version.

COTS solutions should have a minimal effort to be upgraded.

Acronyms

COTS Commercial-off-the-shelf ■ **ECM** Enterprise Content Management System ■ **ELN** Electronic Laboratory Notebook ■ **ERP** Enterprise Resource Planning ■ **FDA** U.S. Food and Drug Administration ■ **ICH** International Conference on Harmonization ■ **IQ** Installation Qualification ■ **ISPE** International Society for Pharmaceutical Engineering ■ **LIMS** Laboratory Information Management System ■ **MES** Manufacturing Execution System ■ **OQ** Operational Qualification ■ **PQ** Performance Qualification ■ **QbD** Quality by Design ■ **SaaS** Software as a Service ■ **SDMS** Scientific Data Management System ■ **SOA** Service Oriented Architecture

  - Investigate whether certain functions can be implemented in a simpler way, or can be transferred to other existing systems, or just be removed because nobody is using them anymore.
  - Watchdog whether legacy migration is performed simply because "we always have done it this way."
- **Migrate from hierarchy to network structures:** A LIMS' core function is to manage predictable and repeatable planned sample, test and study data flows. ELNs are new tools to capture and share complex scientific experiments and place the scientist in the center. Scientific data and content management systems, such as enterprise content management (ECM) and SDMS, are used to manage these large volumes of data seamlessly.

Vertical laboratory applications are built upon one of these backbones. When planning major upgrades or migrations, it is recommended that you revisit your backbone data information structure. To facilitate the cross-functional process between research, development, quality assurance and manufacturing, these backbones need to be integrated.

CONCLUSION

No two businesses are alike. A good implementation approach removes uncertainty, ensures a more effective transition, and delivers a faster learning curve and a shorter time to return on investment. Setting the right expectations and effective communication are key success factors for a smooth and successful upgrade. At the end, it is all a people's business

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