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QUALITY RESOURCES



When to Upgrade: Balancing Benefits of New Systems with Costs to Upgrade

Introduction

The decision on when to upgrade computer systems, such as calibration and maintenance management systems, is uniquely challenging in the life science industries. For most companies outside of life sciences the decision comes down to the cost of the new software, new hardware requirements, training, and interfacing with other legacy systems and users of older versions. All of these concerns are certainly involved in the decision for life science companies as well, but they are often dwarfed by the regulatory concerns, particularly direct and indirect costs and risks of validation.

The validation costs and risks themselves tend to leave most life science companies making rather conservative decisions on upgrading. However, with increased financial pressure today, life science companies are looking for new ways to reduce costs through improved productivity. The new computer systems offer clear and quick improvements on productivity, once the software is installed and the staff is trained on the changes to the procedures. Every day that passes using the current system means lost productivity and therefore increased cost.

The Changing Regulatory Landscape

The FDA and other national regulatory organizations have realized the part they have played in creating technologically conservative life science industries. They have also realized the potential for new technologies to improve the quality of products produced and have made adjustments to their techniques and regulations. Some key initiatives put forward by the FDA include:

- Title 21 Code of Federal Regulations Part 11 (21 CFR Part 11) provided details on electronic records and electronic signatures in March 1997
- The August 1999 release of the Guide to Inspections of Quality Systems established more clearly their expectations for systems for managing quality in life science industries and laid the groundwork for the Quality System Inspection Technique (QSIT)
- "Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach", launched on August 21, 2002 has as one of its primary stated objectives: "To encourage the early adoption of new technological advances"[1]
- The Process Analytical Technology (PAT) Subcommittee of the FDA's Advisory Committee for Pharmaceutical Science (ACPS) encourages greater innovation in the use of technology to improve quality and productivity
- Retooling of its field inspection program instills its inspectorate with a new appreciation and understanding for the value of quality systems.

Additionally, Sarbanes-Oxley is now placing greater demands on organizations to have specific information about operations, particularly exceptions and problems, available immediately to the top executives. The challenge is not only making sure that such information is made available to management, but also that the information is being collected, stored, and analyzed in real time to avoid the problems in the first place. This means that companies will need best-in-class software applications on the production floor in addition to a means to communicate that information throughout the organization, often through integration to other programs.

Current Trends and Latest Technologies

New developments in software, technology and automation deliver improved productivity and quality, reduction of costs and increased compliance features. These trends in development combined with the changing regulatory issues described above offer compelling reasons to counter the conservative argument delaying upgrading.

[1] FDA, Pharmaceutical cGMPs for the 21st Century – A Risk-Based Approach: Second progress Report and Implementation Plan, www.fda.gov/cder/gmp/2ndProgressReport_Plan.htm.

Going Paperless

While not a new concept, the electronic records and electronic signature features in software systems continue to evolve with many companies being able to drastically reduce the use of paper in their systems. The current best-in-class software applications, many now in their fourth or fifth generation with electronic signature capabilities, have robust and validated electronic signature systems that are completely 21 CFR Part 11 compliant, adding recently new routing, collaboration, and notification features.

Even where the work that needs to be done is not near a networked computer, the paperless ideal can be maintained (even with Part 11 compliance). It is now possible to use remote portable computers to collect data. These portable computers can download the appropriate records for the day or afternoon while connected to the network, disconnect, go out into the field and collect data, and then "sync" back up with the main database. For some applications, where the user needs to view and enter only small bit of data per job, this portable computer can be a simple handheld PDA device. For other applications, like calibration management where the user has to have quick and easy access to a broader set of data, new laptops and tablet PCs are portable and rugged enough to use in any environment.

Connecting Departments and Sites to Lower Costs and Improve Productivity

New technologies, additional features enhancing existing software packages, and new architectures and platforms have opened new opportunities for productivity and savings gains by pooling together the needs of multiple departments and sites.

The move to standardize has been developing much new momentum recently. As most applications developed today are designed for more robust database platforms and can therefore be implemented across a network, different departments at a single site can not only standardize on a single application, but they can even share the same implementation, as long as the application permits some way to handle variations in setup (often referred to as datasets) within the same implementation.

Many life science companies are taking a close look at their different software needs to see where they may overlap, to further extend the use of a single application. For example, companies have realized that many of the needs for managing regulated assets (i.e. calibration, maintenance, and validation) are very similar. They are considering which of these functions have the most unique and demanding requirements, and weigh the regulatory and quality risks associated with each function. They then evaluate each software package with a broader set of criteria to see if there is a single application that can meet all their needs. In a recent survey of Calibration Manager customers, out of hundreds of respondents spanning all versions back to the original DOS version, 57% said they were using this calibration management application to manage maintenance events, using functionality that has been in the software for years now. When going down this path, it is critical not to compromise on important functionality in one department to implement the preferred solution for another department. For example, there have been many companies who had intended to implement maintenance packages to manage calibration events, only to find out that those packages don't meet the basic requirements of the calibration department.

For companies that cannot find an appropriate compromise on a single application, integration between multiple packages has also recently become a practical alternative. For example:

- Simple integrations between calibration management software and LIMS packages that pass instrument and calibration information to the LIMS on a regular basis
- Complete integration between high-end maintenance packages and best-in-class calibration management software, eliminating double entry and risk of errors

Recently great strides have also been made in technology that facilitates a single implementation for multiple sites. Multi-site implementations usually have lower total system lifetime ownership costs versus placing individual instances of the software at each site. Savings come from:

- Lower total software purchase costs versus buying the software multiple times

- IT infrastructure and costs (hardware and support) required at only one site
- System validation only needing to be performed once (usually the greatest savings)

When a software package is found that offers this flexibility and is built on an appropriate platform (web-based or browser-based platforms that do not require external applications such as Citrix Metaframe offer the best performance), it becomes possible for one site to upgrade to the latest technology at lower costs than would otherwise be possible just on their own.

Techniques for Reducing Risk and Cost

Having to validate a new system adds extra costs to the implementation and often means moving from a system that has been approved by the FDA to one that may conceivably fail validation. There are a couple of steps life science companies can take to reduce their risks in implementing and validating a new system. The first step is taken during the software selection process, making sure the software does what it needs to do and can successfully be integrated with procedures to complete required tasks. Feature checklists are an important tool for evaluating multiple software packages. They provide a quick and easy way to evaluate the advantages and trade-offs between different packages. Much more difficult to evaluate and compare, but just as important, is the ease-of-use, which determines likelihood of use and ease-of-compliance. There are several techniques that can be used to evaluate not only the features themselves, but also how they have been developed in the software. Traditionally, the most common way to evaluate ease-of-use was to install an evaluation version of the software. However, many companies have realized that to perform an accurate test of the software (that accurately simulates actual use conditions) will require more time than they can afford to invest. In contrast, contacting a vendor's reference sites will likely always be a useful tool, particularly if an actual daily user of the software can be contacted. Perhaps the simplest way to ensure that the features in software are developed with use (and not just the sale) in mind, is to perform a thorough vendor comparison, to understand each company's commitment to and leadership role in the industry. These are good predictors of how their software and features have been developed for the market and how they have been received. (See below for suggested vendor evaluation questions)

Vendor Evaluation Questions

1. Number of years the company has been in business
2. Number of years of experience selling and servicing life science companies
3. Total number of installations
4. Number of installations at sites in life science companies
5. Number of sites where the system has been successfully validated
6. History with industry audits
7. Demonstrated understanding of the challenges and issues faced by life science companies:
   - Active in industry associations?
   - Active contributor to industry knowledge and best practices?
   - Consulting offered?
   - Background of company management and employees
8. Reputation within the life science industries

Having a software package designed to be used and validated in a life science company will certainly reduce the risks of the upgrade. Another simple way to reduce the costs (and the risks) involved in implementing software is to outsource the implementation, keeping in mind that the costs of validation are not always direct costs. Dedicating resources to a validation that can take anywhere from weeks to months depending on the depth and

breadth of the system ties up these resources and keeps them from other activity. With internal resources already extended to their limits, asking these individuals to perform validation of a new system on top of their existing responsibilities can also drain energy from the organization and usually results in a slower validation.

By outsourcing any combination of implementation, configuration and validation of a new system, the process should be completed in less time and with fewer difficulties. If the company chosen to perform the tasks has extensive experience in the industry, they should be able to foresee and avoid possible problems that would either seriously impact the timeline or put at risk the final validation of the system. They would also have access to best practices on how the system could be implemented to maximize the usefulness of the application. This is naturally particularly true if the tasks are outsourced to the software developer (who presumably knows the software and its uses better than anyone else), assuming they have an established and experienced services department. The ideal partner would not only have technical expertise, to address system and infrastructure issues, but should also have good depth and expertise in the industry.

One area where outsourcing these tasks provides the biggest payback is when timeframes are tight, particularly when trying to get a new site up and running in the shortest timeframe. In these cases it is valuable to select a partner with the resources to concentrate on a single project so that, when applicable, multiple steps of the process can be handled simultaneously. This fast track service, in addition to the benefits gained from their expertise, can get a system up and running in short order.

When to Upgrade

The above pages present new developments that change the landscape for the decision on when to upgrade. There are plenty of new technologies available today that improve quality, reduce risk, enhance productivity, and lower costs. Many of these new technologies have been successfully implemented and validated at hundreds of life science sites. These benefits and incentives need to be balanced against the costs. These costs include:

- Software costs
- Costs of new hardware (for server or users)
- New database licenses and/or IT resources
- Training on new system
- Implementation costs (in-house or outsourced)
- Integration costs (should be matched against additional benefits)

With the benefits of new software applications today, the payback on this investment can often be quick, providing a compelling ROI. As mentioned previously, the benefits generally fall into the categories of reduced risk, improved quality, enhanced productivity, and lower costs:

- Comply with FDA recommendations or citations (the decision is easy when the FDA explicitly says it must be done before operations can resume)
- Avoid a situation where the FDA has to dictate action, moving to a system implemented at many sites and would therefore already be familiar to FDA inspectors
- Reduce risk of catastrophic problem that could impact the health of the company's end customers through implementation of robust, tested, and reliable systems (an example: Process Analytical Technology, which promises to highlight issues before they become serious quality problems and affect large batches of product)
- Comply with good practices (GxP) with less effort
- Improve speed and accuracy by transferring to computers the tasks that are repetitive, onerous, or require large amounts of calculations or quick accessing of large amounts of information
- Reduce amount of costly risk management systems required for systems that are not automated
- Reduce costs of recalls and scrapped batches
- Lower personnel, infrastructure, and management costs

Usually the decision to upgrade is a strategic one. Is the company in a position where maintaining the status quo and the current position strategically appropriate? Does the company need to build up its capacity, to do more with the same resources? Or does it need to find ways to run leaner, doing the same with fewer resources? The company's current position and needs direct their decision on when to upgrade.

Ultimately, for many companies, the decision on whether or not to upgrade comes down to the extra value they can provide their customers. For most, their ability to provide a reasonable return to investors is a driving force as well. For publicly traded companies, there is clearly a responsibility for top management to make decisions that provide a positive return on investment. For other companies, they find value in establishing and maintaining a superior reputation, enhanced by implementing only best-in-class solutions, keeping up with leading edge tools to provide the absolutely best product at a reasonable cost.

Recent advancements are compelling and make now the time to consider upgrading. The financial, regulatory, and competitive pressures are mounting, pushing companies to find ways to reduce risks and costs in production. Meanwhile, much of the software available today has successfully kept up with the evolving needs of life science companies, developing new technology to offer those reductions and savings that ultimately result in better products with lower costs. The simple fact is that return on investment doesn't start accumulating until the investment is made. By partnering with software companies that are leaders in the industry, the risk is negligible and the rewards, both short-term and long-term, are considerable.

About Blue Mountain Quality Resources

Blue Mountain Quality Resources has 15 years of experience implementing calibration management systems for regulated life science manufacturing companies. The company's own calibration management system, Calibration Manager®, with many features designed specifically to meet the rigorous demands of life science companies, has been installed in over 1500 companies.

Their suite of implementation services, available individually or as part of complete solutions, was specifically designed to leverage their experience toward reducing costs and risks in implementing and validating these systems. Their consulting services, offered by individuals with years of experience directly in calibration at life science companies, provide these companies with a solution for getting a compliant and efficient calibration department up and running in the required timeframes.

For more help on deciding if now is the time to upgrade to software from Blue Mountain Quality Resources call us at 800-982-2388, email us at calman@coolblue.com, or visit www.coolblue.com.