



- ❖ Ten Tips for Avoiding CCMS and EAM Failure in the Life Sciences Industries



Introduction

Computerized Maintenance Management Systems (CMMS) and Enterprise Asset Management (EAM) systems have been longtime fixtures in other industries, embraced to improve control over asset maintenance costs and improve asset performance. The marketplace for these systems has evolved to include a dizzying array of choices with a wide range of functionality, complicating both selection and implementation. In fact, a recent study conducted by Reliabilityweb.com, CMMScity.com and Maintenancebenchmarking.com demonstrated that even unregulated industries struggle with this selection and implementation, with 57% of the respondents indicating that their CMMS or EAM implementation failed to meet their ROI expectations.

It's one thing for an application to fail to meet expectations in an unregulated industry, but in the regulated life sciences industry failure to meet expectations can not only bring down reprimands from senior management, who themselves are often complicit in the failure, but also can evoke the "attention" of the FDA or other international regulatory agencies. The conservative approach often encouraged in life sciences would suggest sticking with current systems, usually paper-based. However this is becoming less and less of a viable option with increasing pricing pressures demanding greater cost controls in production and regulatory requirements placing more emphasis on control of processes.

Fortunately there are 10 simple tips to follow for a successful CMMS or EAM system implementation:

Tip 1: Set reasonable Goals and Targets

The first tip is a bit obvious in theory, but can be quite difficult in practice. You might start out with modest and reasonable goals and targets but as the costs of implementation exceed original expectations more grandiose targets are needed to justify the expense. It's an easy trap to fall into, as a savvy CMMS salesperson will happily lead the way on high-minded goals to close the deal.

The main goal areas to consider include:

- Reduce production downtime, particularly for unscheduled maintenance
- Enhance quality and reduce scrapped product
- Achieve increased compliance, at a lower cost and with less disruption
- Offer a safer and less stressful working environment
- Provide expedient and reliable information for smoother performance tracking, audits, etc.
- Lower maintenance management costs with improved decision making on asset purchases and preventive maintenance schedules

The amount of savings to be expected in any of these areas would naturally depend on comparison to current business practices. If the goal is to implement a preventive maintenance program from the ground up, then the resulting ROI might be higher compared to goals centered on the improvement of an existing maintenance process. When the pressure rises to expand targets beyond mutually comfortable levels, consider other ways the software can provide ROI to avoid having to resort to goal inflation.

One way to expand the scope of justification is to take advantage of the significant convergence of software applications focused on using one platform for multiple business practices. For example, it may be possible to use the CMMS for calibration management, IT asset management or as an asset-centric quality management system. While this can dramatically reduce the pressure on any one department to justify the whole cost of implementation, it is critical that each department feel comfortable that they will not have to make any significant compromises to their productivity and compliance to work in a single application. If properly implemented, the collaboration and information sharing across multiple departments can provide additional justification for the expense.

Tip 2: Choose the Right Software Package

This second tip ties in directly with the first tip. The best approach is to choose a CMMS that meets current goals and objectives without requiring the implementation or cost justification for functionality that you will not use. As



mentioned previously, there is a broad selection of CMMS applications on the market today ranging from simple applications providing basic functionality at a low cost, to massive applications with nearly all the maintenance functionality any industry would want at a much higher cost. CMMS systems designed to meet some of the more unique compliance issues of life science companies typically lie somewhere in between these two extremes. It may be wise to appoint a well-disciplined individual to the selection team just to ensure that features and functionality being sold are legitimate and tie back to a real and realistic goal.

Understand too the software vendor's philosophy when it comes to future product development. How well does their vision and driving forces to development match with your expected growth plans and projected needs in the future? What internal resources within the vendor's organization are truly knowledgeable about the target business practices driving the software functionality?

Tip 3: Involve Users in Selection Process

In addition to ensuring the chosen CMMS matches up well with established goals, it is critical to include end users of the software in the selection process. This tip may be stubbornly resisted by some, but including a representative from end users will increase buy-in and improve usage after implementation. They will also be able to add valuable tactical advice on how to achieve the strategic objectives and how well each particular software package would facilitate those efforts. All the latest functionality for highlighting trends and reporting costs are worthless if the foundational data is not available. Examples would include the software's difficulty to use on a daily basis, or forcing engineers to dramatically change how they do and manage their maintenance tasks. Although some individuals are insuppressibly resistant to the point of fighting any proposed system, the user perspective is invaluable.

Tip 4: Understand Your Organization and the Software Before Beginning

Once you've chosen your software package, take another close look at your organization, its strengths and weaknesses, needs and wants in light of the software features, functionality and benefits. An assessment of the relevant departments by either the software vendor or a consultant familiar with the software is generally a good idea in creating a viable plan for the implementation, in addition to many of the decisions about the configuration and implementation. An expert in the software, surveying your experts on your organization and processes, will bring industry best practices in the software and ideas on how your organization can best utilize the software.

As part of this phase of implementation, those involved in decision-making and planning should have a solid introduction to the capabilities of the software and the hosting business processes. "Core team training" designed to meet these needs will provide important background to the team as they make decisions. The assessment in combination with the core team training, usually around five days of effort, pays big dividends in the project with not only better utilization of and therefore greater ROI from the software, but also in a more accurate estimate on the total cost of implementation with fewer surprises during the course of the implementation.



Tip 5: Map Your Processes into the Software

Although the introduction of the computer system will offer an opportunity to improve some processes, the flexibility of many of the applications available today makes it possible to map or translate existing and proven business processes directly into the CMMS or EAM. Nailing down and formalizing processes, whether they are changing as part of this implementation or not, is a critical step. What approvals are required before a work request is released and work begins? What information is required at each stage of work? What signatures and signoffs are required at each stage? Who needs to be notified when the work progresses to a different stage? What sort of review is required after the work is completed? There will naturally be different answers to these questions based on the type of asset and type of work being done. For example, emergency work on a GMP-critical asset would have a different business process than regular maintenance of a non-GMP critical asset.

Being able to map business processes into the software will provide two significant advantages to the success of the program. First, it helps to ensure that these processes are followed. These processes are in place to ensure quality and compliance and make up part of a systems approach to quality that regulatory agencies are increasingly expecting. Secondly, because the software reminds users if key information is missing before moving on, engineers get to focus on the actual work against an asset, improving efficiency and job satisfaction. With automatic notification based on criteria, information flows more readily, reducing those stresses and improving proper oversight.

Tip 6: Make Risk-Based Decisions about Legacy Data

There are two aspects to decisions about migrating legacy data into a new system. First there is bringing foundational information such as asset information and schedules. If there is confidence in legacy data, finding a vendor willing to migrate this data can save significant time and expense in the implementation. In contrast, if the data in the legacy system is inconsistent or inaccurate, it may be worth making the investment to enter the data manually to make a clean break with a concerted effort to standardize and sanitize the records.

The other component to consider in data migration is the question of legacy records of work performed, including electronic signatures and audit trail, signifying the risk-based approach. In a regulated environment, access to this legacy information will have to be secured one way or another. One option would be to maintain the legacy system intact to access legacy information as needed. This can be somewhat awkward from an IT standpoint, all the while making composite views of legacy and new system data difficult for the end user.

On the other extreme, and the most appropriate for those who are risk averse, is to migrate historical data into the new application to be viewed akin to the new system's native historical records. Not all vendors will facilitate this sort of migration and it can be costly, but it does provide the most seamless data store. A middle-ground alternative would be to migrate the data from the legacy database to the new database, maintaining the existing structure and reports. This approach provides great confidence in the integrity of the data, reduces IT maintenance costs, but is not 100% seamless in that reports will need to be modified to span across the two table structures.



Tip 7: Decide What to do with Internal Resources, What to Leave the Experts

One common approach to lower costs of an implementation is to rely on internal resources to handle a larger portion of the implementation and validation. While this approach will lower the apparent costs of an implementation, it can easily be taken too far. With lean operations, it's rare to find internal staff that aren't already booked solid with projects that provide significant value to the organization, leaving little slack for a CMMS implementation or validation effort. Additionally, assuming the software vendor has experience in life sciences and given their experience with their software, they will generally be far better equipped to handle implementation and validation tasks. They will be able to complete the tasks at a much more reliable pace and with much more consistent results. In this way, outsourcing implementation and validation could prove the deciding factor in a project's success at meeting expectations and staying on planned budget, but confidence in your partner is key. If they don't bring a unique expertise to the undertaking keep looking.

Tip 8: Train Users for how They'll be Using the Software

Even with goals to proceed with a straight CMMS without bringing in other departmental functionality, roll based training is the recommended approach to preparing different users to use the software. A training regime designed specifically for your users will provide each type of user – in the simplest scenario, regular users versus administrators – with the right amount of training to do their job efficiently without burdening them with a lot of extra information. Roll based training naturally becomes increasingly important as additional departments using the software differently and for different purposes are brought in.

Tip 9: Document Software SOP's

Particularly in a regulated industry, comprehensive SOPs should be developed for the use of the CMMS or EAM as part of your overall Quality System in place to ensure control of the production environment. These SOPs should be quite detailed including such descriptions as how, when and where equipment information is entered into the database, specific instructions on how to navigate the software for the purpose at hand, scheduling, user rights, and key performance indication and notifications. To promote a comprehensive approach and mindset, the SOP should also explain how each process in the software implementation relates to the larger business processes. Additional SOPs should be developed to include administrative procedures on how rights and access are assigned. Clearly documenting the SOPs will provide a clear authority on how the software is to be used, a valuable reference not only for employees but also something viewed quite favorably by regulatory agencies.



Tip 10: Leverage the Success

Once you've gone to the effort to ensure a successful CMMS or EAM implementation, replicating that success at other sites is generally a smaller incremental cost even if there are process differences across multiple sites. This standardization allows you to further leverage the investment in the implementation at the first site and provides a strong answer to regulatory "recommendations" that similar operations at different sites have similar processes, even across different business units. Most enterprise software packages will accommodate local differences, including language, cultural settings and even business process variations making sharing a single centralized implementation the most practical and cost effective approach.

With regulatory agencies increasingly looking for systems in place to ensure what you say needs to be done to maintain control over processes does get done, the significance of a successful implementation of a critical software system like a CMMS or EAM cannot be overstated. The key, as explained above, is having clear and properly prioritized goals and targets, sticking to those targets and working with partners that have a track record for reaching those goals in the life sciences.

About Blue Mountain Quality Resources

Blue Mountain Quality Resources has been developing technologically advanced software applications for asset management at FDA-regulated and ISO-compliant companies since 1989. The company's Blue Mountain Regulatory Asset Manager[®] was the first regulatory asset management system, designed specifically as a harmonization of calibration, maintenance and validations systems into a single comprehensive solution for life science companies.

The company's suite of implementation services was specifically designed to leverage their experience toward reducing costs and risks in implementing and validating these systems. Companies that outsource these activities to Blue Mountain Quality Resources are not only up and running with the software quicker, but they also achieve a higher return on investment by utilizing more of the functionality of the system.

For more on products and services available from Blue Mountain Quality Resources call us at 800-982-2388, email us at bluemountain@coolblue.com, or visit www.coolblue.com.