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QUALITY RESOURCES



Justifying an EAM in the Life Sciences Industries

INTRODUCTION

People who live and breathe maintenance every day are instinctively aware of the benefits of maintenance improvement: lowering costs and increasing output while still remaining compliant. The intent of this paper is to provide a framework for building the formal justification for investing in a CMMS (Computerized Maintenance Management System) or EAM (Enterprise Asset Management) system as part of a maintenance management improvement initiative.

In the past it was easier to justify a system critical to compliance like a CMMS or EAM system, as a cost of doing business. In the regulated life science industries this situation began to change early in the 21st century. With greater pressure on costs by the prospect of healthcare reform and the rise of generics, the demand for cost reductions, previously focused on R&D centers, began to spread into operations. With this new mandate to cut costs came the challenge of balancing productivity goals and compliance requirements, answered in the last few years by new software designed for both.

More recently, the current economic landscape raises the bar further still for the amount and nature of justification that must be satisfied before the purchase can proceed. While most companies in the life sciences have seen little to no slowdown in sales as a result of the world economic slowdown, they are impacted by the shrinking availability of capital investment and continuing trends in off shoring and other pressures in the life sciences that leave an air of uncertainty that leads many executives to require shorter and shorter payback periods for productivity-improving technology.

Perhaps one of the greatest challenges in justifying an EAM system is that there is not one overwhelming point of savings but instead a lot of different ways that contribute to one big payback. Nor is there a simple formula for determining the cost savings. It's difficult, for example, to say that implementing an EAM system will result in a 30% increase in productivity of maintenance personnel because it depends on what you're doing now as a benchmark and how you implement the software.

In this paper we'll explore how benefits and savings from Preventive Maintenance, Reliability Centered Maintenance and Workflow Improvement make the case for investment in an EAM system.

PREVENTIVE MAINTENANCE

The EAM system is a vital component to a Preventive Maintenance program. The principle of preventive maintenance is to "fix" the asset before it breaks, not after it breaks. Subject matter experts for each asset and a study of the historical frequency of failure (called the Mean Time Between Failures – MTBF) can help determine the optimal interval for preventative maintenance and what tasks need to be performed.

Preventive maintenance is not only scheduled but is also possible to plan out in advance, unlike corrective maintenance. An engineer going out to perform preventive maintenance knows what he or she is going to be doing, what parts will be necessary and roughly how long it is going to take. Planning executed within an EAM system puts all the information needed to perform the work at his or her fingertips within the electronic work order. There's no lost time hunting for the latest version of the SOP or going back for additional parts. Keeping an electronic record of this activity also means that the engineer can see when the work was performed in the past and what the results of that work were. The EAM system additionally helps ensure that the defined planning

process is followed and the proper documentation on decisions is provided and all appropriate review and sign off is executed with little to no administration or oversight of the process.

Once the preventive maintenance has been planned and scheduled, there is a wealth of information available to make better staffing and inventory decisions. It is possible within the EAM system, for example, to view the number of jobs or hours of work assigned to each person or craft to help balance workloads or make hiring decisions. The same sort of projections can be made for parts requirements into the future, valuable information to have when trying to determine optimal inventory levels and avoid tying up excessive capital in spare parts.

Benefits from Preventive Maintenance

- More productive use of engineer's time lowers labor costs
- Better forecasting for parts lowers inventory costs
- Decreased unscheduled downtime increases production output
- Reduce scrap from interrupted batches product increases production output
- Reduce capital expenditures with longer asset lifetimes

The fundamental principle of preventive maintenance is to perform maintenance during scheduled downtime and therefore reduce interruptions to production. Therefore when calculating the benefits from a Preventive Maintenance program the often significant benefits to operations and production should be included. Particularly as companies scale up production, being able to produce more with existing assets and resources can be very valuable. In addition to supplemental throughput, the value of any product that may currently need to be scrapped if a batch is interrupted should be considered as well. In this type of ROI calculations, in order to make the point more profoundly, the market value of the additional throughput and reduced scrap should be used.

The final, and perhaps most difficult, component of an ROI calculation for using an EAM system to facilitate preventive maintenance is the extended life of assets. Asset failures can dramatically shorten the lifetime of an asset. By performing preventive maintenance at the right time to avoid these failures can mean delaying the need to replace an asset. There is a financial benefit to delaying the outlay of cash for new equipment. In simplest terms think of the interest earned on that money for that time. Alternatively, consider how many fewer times the asset will need to be replaced in, for example, a 10-year or 20-year period.

RELIABILITY CENTERED MAINTENANCE

Reliability Centered Maintenance (RCM) takes the principle of Preventive Maintenance to the next level. While in Preventive Maintenance the goal is to understand the frequency of failures and intercede in a timely fashion, the objective in Reliability Centered Maintenance is to understand the root causes of failure and intercede to eliminate or control those failures at their source. Clearly the subject matter experts play a key role in this endeavor, but also of crucial importance is historical failure information (problem, cause and remedy coding) available from the EAM system.

The key to RCM is identifying and understanding the operational performance factors and risks of failures associated with specific assets. A useful tool to achieve this understanding is the Failure Mode(s) and Effects Analysis (FMEA). The FMEA explores:

- What the asset is supposed to do (function)
- How it fails to meet that function (functional failures)
- The causes of the failure (failure modes)

- The consequences of failure (to arrive at risk and criticality)
- How to eliminate causes of functional failures
- How to prevent failures whose causes cannot be eliminated

Obviously this is just a basic introduction to Reliability Centered Maintenance and FMEA (sometimes expanded as Failure Modes, Effects and Criticality Analysis – FMECA), on which there are extensive books and online resources. Our interest here is in the benefits from such a program, regardless of the degree to which it is taken. The value and benefits of a Reliability Centered Maintenance program come from better decision making, using a risk-based and well-informed approach. Understanding the sources of failure often leads to better engineering processes and better purchase decisions on assets that leads to lower total cost of ownership for assets, including lower maintenance costs. The criticality assessments, step four listed above, themselves are valuable in prioritizing work to get the greatest return from engineer's time.

Benefits from Reliability Centered Maintenance

- Lower total costs of ownership, including lower maintenance costs, for assets
- Better prioritization of work makes engineers more productive and lowers labor costs
- Better use of scheduled downtime decreases total downtime
- Reduce capital expenditures with longer asset lifetimes

WORKFLOW IMPROVEMENT

For most organizations, there is incredible potential from improving workflow processes, helping people spend more time on value-adding work and less time on documentation, communication and preparing for work. Planning work out in advance, a process greatly streamlined by the EAM system as mentioned above, can itself provide significant advantages to workflow. It means less time spent by engineers preparing for work and, with a wireless device, the elimination of a reliance on paper. Additionally, making all the information available on the work order, including SOPs and task lists, means that operators can be enlisted for simple preventive maintenance tasks. Returns from planning increase over time as ability to estimate time requirements for each job improve. Comparisons between estimated and actual times for work are important in this continuous improvement effort.

Benefits from Workflow Improvement

- More "wrench" time and focus on assets dramatically lowers labor costs
- Enlist operators for basic maintenance lowers labors costs
- More complete information increases returns from Preventive Maintenance and RCM efforts

The EAM system streamlines work not only by making all information about the work available from the work order but also by keeping track of requirements at all stages of work. What fields are required, when is an electronic signature required, who needs to be informed when the work is complete or if a problem arises? All these issues are handled by the EAM so the engineer can focus on the asset. If he or she attempts to progress the record to the next state, the software provides a reminder on what is required before the work is completed. Engineers are also relieved of the responsibility of making appropriate notifications. If review is required the appropriate parties can be notified automatically and a failure can trigger a different set of notifications.

When it comes time to review work, all the information is together in one place, attached to the notification received that the work is ready to review. Unlike a paper record, multiple people can be reviewing the same

information simultaneously. And with the controls in place to ensure all requirements are met in the previous state, the likelihood of issues with a work record, hard to resolve after the fact, are dramatically reduced. This eliminates the back and forth required to confirm and fix problem records. Then when all reviewers have signed off on the record, it can progress automatically to the next state, typically closed or completed state, with notifications sent to the asset owner that the asset is ready to return to use in production. The ability to map these processes into an EAM system means that no one needs to manage progress through the process, walking the materials to review manually.

UNIQUE CONSIDERATIONS FOR LIFE SCIENCES

Most of the benefits mentioned above apply to most industries. There are however some unique considerations in the life science industries that influence choices on which EAM system to implement, how it is implemented and expand the benefits from such a system.

Firstly there are the unique documentation requirements for FDA-regulated companies. Since maintenance is a regulatory requirement (see CFRs 211.63, 820.60 and 58.63 for example) to keep assets in the validated state, the activity must be properly documented, including change control for any replacement parts. These documentation requirements can impose significant additional costs to a company. If the selected EAM system has the functionality for 21 CFR Part 11 compliance integral to the application it can meet these documentation requirements as part of a streamlined workflow reducing the additional time required and thus minimizing these costs of compliance. Simply put, an EAM system can ensure the appropriate documentation and signatures are complete before proceeding to the next state without requiring managers or keepers of this process.

An EAM system can also simplify and reduce the stress of an FDA audit. The FDA now follows a Quality System Inspection Technique (QSIT) during audits. This approach focuses the auditor's attention on systems and controls that ensure a quality product. In the context of maintenance and asset management, if maintenance needs to be performed to maintain the validated state, then a company must be able to produce documentation that the work was done in a way consistent with approved SOPs. If any changes were made these too must be properly documented through change control. The EAM system can dramatically simplify this type of inspection by providing quick and solid answers to these sorts of system questions. Within the system it is easy to show how work is managed to ensure it gets done on time and easy to demonstrate work that has been done according to approved processes and SOPs. Change control processes and such maintenance specific decision-making as like-for-like replacement parts can be documented and demonstrated during an audit. These confidence benefits in an audit certainly provide a strong psychological benefit to anyone involved in the audit, but can also dramatically reduce the amount of time and effort required for an audit.

CALCULATING SAVINGS

The below sample worksheet can be used for calculating your unique cost savings and capacity increases (remember to use market value of product). To put this number in perspective, the payback period can be a useful and easy to calculate figure. How long will it take to payback the investment in the EAM system? The average is around 2 years, with some significantly shorter. Of course, the system can pay for itself in as short as one day if the software ends up avoiding a citation from the FDA. In many cases this payback period can be

reduced further by expanding the use of the software to solve needs in other departments, including calibration and validation management.

Description	Currently	% Improve	$ Savings
Labor Costs	Current Cost		
Better use of engineer's time through scheduled activity instead of reactive and diagnostic activity			
Risk-based and criticality prioritization of work makes engineers more productive			
Less time on paperwork, preparing for work and greater focus on assets			
Operators handle basic preventive maintenance			
Additional labor cost reductions			
Inventory costs	Current Cost		
Better forecasting of parts requirements and automatic reorder notifications reduce inventory requirements			
Additional inventory cost reductions			
Capital Expenditures			
Reduce capital expenditures with longer asset lifetimes			
Additional capital expenditure reductions			
Increased capacity			
Decreased unscheduled downtime increases production output			
Reduce scrap from interrupted batches product increases production output			
Additional ways to increase capacity			

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.