BLUEmountain
QUALITY RESOURCES



Blue Mountain RAM Maintenance Application Note

Maintenance personnel are under constant pressure to control costs and improve productivity while maintaining product quality and satisfying regulatory requirements. To achieve this balance, work must be organized and prioritized to ensure that critical maintenance is performed on schedule to minimize the frequency and consequences of failures. Built specifically to satisfy the rigorous life science productivity and compliance concerns, Blue Mountain Regulatory Asset Manager has complete and robust maintenance management features to maintain control over costs and satisfy regulatory requirements.

Planning Work

Recurring work can be planned out in advance within Blue Mountain Regulatory Asset Manager. If the work is, for example, preventive maintenance that occurs on a specific schedule, this schedule can be designated uniquely for each asset that the work is being performed on. For assets whose use is more sporadic, work can also be generated based on actual usage as indicated by meter readings. In either case, maintenance professionals are advised when work is coming due so that critical maintenance is not missed.

Whether it is scheduled or as needed, all the necessary information to perform the work can be made available in the work order: SOPs, PM task lists, labor, parts, etc. Documents, residing either on the network file server or within a document management system, can be linked to directly from within the work record. The task list for the work indicates the order in which tasks should be completed and the labor craft that is needed to complete each step. As each task is completed, it can be checked off, recording the date and who completed it. If additional tasks are performed, this information can be added to the list where appropriate.

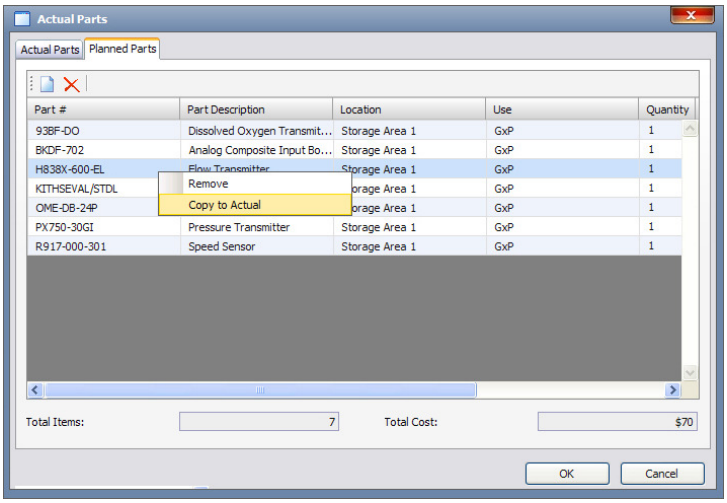
Actual labor applied to the job can be recorded, with total labor costs calculated automatically. If someone in the specified craft code is unavailable and a more senior-level person performs the work instead, the actual labor costs can be updated to reflect that change. Forecasting future labor requirements, by individual or by craft, within the software helps supervisors make better scheduling as well as hiring and contracting decisions.

Parts Planning and Inventory

The parts inventory in Blue Mountain Regulatory Asset Manager provides a complete parts list, including unit costs and reorder point.

Parts to be used for work can be planned in advance. Users can even designate and sign for qualified “like-for-like” substitute parts as well. Parts actually used are then easily noted when the work is done, with the quantity on hand automatically updated. Information about parts referenced on work orders is then traceable and available for where-used analysis.

Similar to labor, future parts requirements can be forecasted and part costs are rolled up for the job available for later analysis to discover the maintenance costs over time and identify areas for cost savings.

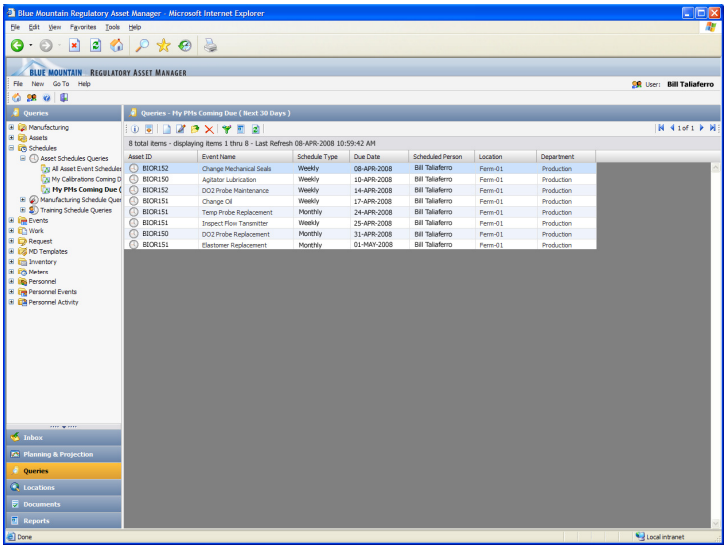


Parts Planning

Work Orders and Work Flow

Blue Mountain Regulatory Asset Manager provides a complete work request system. An unlimited number of requester licenses is included with all implementations so anyone in your organization can submit observations or work requests.

Once submitted, the path the request takes is determined by your business process rules. Depending on multiple factors, including the criticality of the asset or process under review, the work request may pass through a different review process, with varying signature requirements. If the request is approved, multiple work orders can be associated with the request in order to satisfy the need. For example, a work request on a critical system may require a follow-up calibration or requalification.



My Work Coming Due

The individual work orders pass through a series of states that match your business process rules to include appropriate quality review and change control as needed. Who has rights to edit the record, which fields are enabled and what signatures are required at each state is configured by your business process rules. Maintenance professionals can then manage their workload directly from a list of work coming due that day, week or month. The status of maintenance work in process can be displayed, highlighting what jobs are on hold or part of the backlog.

Working Smarter

The software's key performance indicator (KPI) reports analyze maintenance efficiency by highlighting trends and opportunities for improved productivity. For example, a report can highlight equipment with a high incidence of failure. Likewise, analysis of mean time between failure information for specific equipment can provide data for determining a more efficient preventive maintenance interval. These reports can be tailored as needed and new reports for analyzing any information within the database can be generated.

To speed an asset's return to production and minimize downtime, Blue Mountain Regulatory Asset Manager facilitates the collaboration between calibration, maintenance and quality personnel. For example, a notification can be sent automatically to the calibration planner when maintenance work generates a need for calibration. This collaboration can be an important key to efficiently managing the validated state for equipment and processes.

The software's advanced electronic signature and routing functionality, part of the work flow system, significantly expedites the approval process while satisfying all 21 CFR Part 11 requirements. Integrated at all levels of the software, different approval paths can be configured for different instrument and event types where needed. By having all responsible individuals collaborate in a single application, faster communication reduces time spent in the approval process.