

Quality and Validation Features Guide



Add Similar – When adding a new record (for most record types), the user can create the new record based on an existing record. You can configure which fields to copy over from the original for each record type.

Administration – A designated administrator can set-up the software to appear and behave according to your business processes for each department and/or site. Settings include, but are not limited to, label configuration, user access, work processes and electronic signature usage.

Archive and Delete Records – Records throughout the application can be archived and deleted to eliminate from active use assets and related records that are no longer available or applicable. Rights to archive, delete, unarchive, undelete and view archived and deleted items are all controlled and can be provided to limited groups and individuals.

Asset Records – All data pertinent to an asset is recorded in the asset master record, including manufacturer, department, serial number, and contact person. Information on work performed is accessible from the master asset record. The asset record is completely configurable, including field labels, tabs, pick lists, and associated documents and reports in order to track information important to your facility.

Audit Trail – The audit trail provides a permanent record of all changes made to the data. Each time a record is saved and changed, the audit trail tracks the date, time, old value(s), new value(s), and the user who made the changes. Data from a specific point in time can then be easily retrieved and reviewed, with highlighting of the changed or signed fields. Audit reasons can be configured to be entered in a freeform textbox or from a pre-defined picklist. Different approaches and different picklists can be used for different record types.

Barcode search – Use the quick search field to pull up any record automatically from the input from a barcode reader.

Batch advance – Users with the appropriate rights can advance multiple records to the next state or even move them into an entirely different business process rule. Select records to advance from the query results. The user will be advised if any of the selected records have not met prerequisites to be advanced.

Batch assign – Through the Batch Update functionality, multiple work items can be assigned or reassigned to an individual.

Batch sign – In cases where the review process can be completed from the query results and where consistent with corporate policies, users can sign off on multiple records at once.

Batch update – Replace values on multiple fields across multiple records at once. The software will confirm that the user has the right and the current state permits the update of each field to be updated before proceeding, clearly indicating any cases where the update cannot be completed as requested.

Change Control – The software tracks Change Control for many different aspects of an asset's life cycle. This includes but is not limited to the current status of an asset, changes to the maintenance and calibration events for an asset, and like-for-like substitutions for an asset's replacement parts.

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Configurable Labels – You can rename most of the labels for fields and tabs within the software to match the specific terminology used at your facility. Different departments can have different labels, giving you the utmost flexibility to collect unique data for each group.

Data Export – Use the integrated reporting tools to export specific data from Blue Mountain Regulatory Asset Manager or export the data to a spreadsheet from most on-screen query results.

Datasets – Datasets allow sites to separate their asset records into functional groupings to account for variations in procedures and access rights. Datasets can be set-up by department, facility, or however your organization wants to best manage records. Users can be set-up with different rights per dataset.

Due Date Calculation – Blue Mountain Regulatory Asset Manager automatically calculates due dates for activity based on a pre-established interval. This scheduling feature can enhance productivity and improve compliance.

Dynamic Queries – Dynamic information taken from the active session used in a saved query. For example, there is a macro to include the active user's display name within a notification or as part of query. Other macros provide such information as the current day and time, business process rule and other user information.

Electronic Signature – The Electronic Signature functionality meets 21 CFR Part 11 requirements while offering extreme flexibility to fit your business processes. A user ID, password and reason must be specified when signing a record. Signatures can be required at various work states with precedence enforced. The order and number of signatures can be specified. Different signature rules can be created for different circumstances. All signatures are recorded in the audit trail and become a permanent part of the record.

Family Tree – The family tree window provides a quick view of all records associated with the active asset, including scheduled and past activity. The family tree not only provides a summary of activity, but also allows for easy navigation through the different records associated with an asset.

Field Counters – Counters automatically enter a number in a field whenever you add a record; for example, system IDs BMQ-001, BMQ-002, etc. This capability makes it easy to create an identification sequence based upon the order in which records are created.

Functions – Fields can be automatically populated with a username, date, time or counter. This feature reduces data entry. These functions are also available in the query builder, for example to request work coming due 7 days from today or are assigned to the active user.

Groups – Individual users can be members of one or multiple groups. A group can then be assigned specific rights and receive notifications. Any user definable fields within the software can be configured to select an individual within a certain group.

Hiding Fields – Fields that are not being used can be hidden for a simpler screen display and data entry experience.

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Impact Assessments – On a single screen, users can perform a complete impact assessment for a given time period to see where the asset was used in production of specific lots / batches, test runs and work on other assets (including Standards reverse trace), what log book entries were made and what work was performed on that asset.

Key Performance Indicators – Key Performance Indicators (KPI) are a beneficial tool for optimizing calibration and maintenance operations. The pre-configured KPI Reports in the software cover asset base, productivity and quality and can be expanded and configured according to specific needs.

Linked Fields – Administrator can configure linked fields, transferring any information from a wide variety of records (including events, equipment, system, loop, location, lot and process records) into the work record.

Localization – As a global solution, the software can be localized to meet the needs of different locations. Cultural settings can correspond to local date, time and number conventions. Information displayed in the application can be configured to a native language and all of that information is stored separately from the main data. The application uses the UTF-8 character set, which supports almost every language.

Log Book – Electronic asset logbook to store all information about an asset's lifecycle in a single location. Users with the rights to do so can make a log book entry for an asset. When it comes time to review the logbook entries, quality personnel can view all logbook activity on a single form, select individual entries to review, review all selected entries in a single window, choose which of the reviewed items to sign for immediately and sign for all selected items at once. A complete history of logbook entries, including a history of revisions to log book entries is maintained and available whenever the information is needed.

Logs – In addition to the audit trail which tracks changes to the data, the log files keep track of changes and activity in the system. Examples of such log records include changes to system configuration and failed login attempts.

Lot Records – Lot records store information about specific lots or batches. In many cases, these lots would reference the process used and "inherit" the assets specified for that process. At this time, the system will look through all planned assets and advise the user of any assets that are either passed due for work, have failed any past work or will have work coming due during the expected timeframe for the batch. Actual assets used can then be updated to reflect any variation from the planned assets.

Multiple Windows – Blue Mountain Regulatory Asset Manager lets you view multiple records at once by having several windows open at a time. This is an excellent way to multi-task and to compare and analyze data quickly.

Multi-site Ready – To reduce validation costs and improve consistency, Blue Mountain Regulatory Asset Manager can be implemented across multiple sites. The web-based architecture significantly simplifies implementation and validation across multiple sites and the ability to localize the software by site within a single implementation accommodates differences in uses and preferences across sites. When new sites are brought on board an existing implementation, downtime during the migration of the new site's data is minimized by staging out the data outside of the live database before the final import is executed.

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Notification System – A notification can be sent to a user's Blue Mountain Regulatory Asset Manager inbox or external email address triggered by an incident, such as the need to sign a record, a calibration or maintenance failure and a record status change. This functionality is configurable and facilitates collaboration between departments.

Personal Queries – Queries that are not marked as shared are only seen by the user who created it.

Personnel Fields – Any user-defined field can be designated as a personnel field. This provides the user a list of names from which to choose from. When used in combination with a notification condition, this field identifies the recipient of the notification message.

Personnel Records – Information about personnel are stored in personnel records, configured to collect all the information about direct personnel, contract personnel and contract companies. Training can be recorded for personnel to document an employee's qualifications.

Picklists – Most fields within the software can be designated as a picklist. Lists can be either appendable or offer a fixed list of choices. Picklists not only save time, but also guarantee the data is entered consistently.

Planned Work – Planned work includes work that is on a fixed frequency schedule or work that is planned but only occurs as needed. Planned work can be configured to meet your SOPs, business rules, and GxP requirements and stored as an event to be used as a template when the work is to be performed. Events can include, but are not limited to maintenance, calibration and validation.

Procedures – A procedure for an event can be referenced within a record. A link to an external document containing procedure details can be included in any record. The document can reside on the network or within a document management system. This puts information right at your fingertips in a controlled environment.

Process Records – Process records provide a single location for information pertaining to process lines used at a site, for example production and QC processes. The process records retain information about the process line and the assets that make up the line. Work, such as validation, performed on the process is also documented and managed within the application.

Query – Queries enable users to search the database for specific records. Most fields or combination of fields in the software can be used to locate records and specify the order in which they are sorted. Users can apply the quick find to search for a particular record(s). A list of most recently used queries is presented to users on the home screen for quick access to information used on a regular basis.

Quick search – Users simply start typing the record ID for any record type in the quick search box available from any area of the application and a list of matches is displayed. Once the result set is narrowed to a single item that will record opens automatically.

Reporting System – Out of the box, the software utilizes SQL Server Reporting Services. The software comes with standard reports, which can be tailored to your needs. New reports can also be created.

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Rules – Allows users to model their business processes within the application. Work rules define many things, including what “states” records go through as data is collected and reviewed, when electronic signatures are required and when notifications are sent. Different work rules can be created to model different kinds of work.

Security – The software offers two choices for setting up system security; integrating with ADSI (including NT security) or using the software’s built-in security system. Like NT security, the built-in security system allows administrators to specify minimum password lengths, password complexity, and password expiration.

System Records – Users can define systems with subcomponents. Subcomponents can include individual assets, loops and even other systems. Like all assets, work can be scheduled and performed against system records.

Task Lists – A task list includes a series of actions to be performed on an asset with a username and date recorded as each task is completed. These checklists help ensure proper procedures are being followed when an activity is carried out on an asset.

Technology – Blue Mountain Regulatory Asset Manager is a browser-based, zero-client application utilizing the most recent proven technologies including Microsoft.NET, XML, AJAX, and WebDAV. Built with Service Oriented Architecture in mind, integration with other systems, such as accounting systems or LIMS, becomes more practical.

Test Events and Test Records – Tests performed can be planned through test events and managed through test work records. These tests would generally be performed against a lot, either one manufactured internally or one brought in from another vendor. Assets used during a test can naturally be referenced within this record as well.

Training Records – Training events and training records apply to personnel, to plan, schedule and record training activity to keep a record of an employee’s qualifications.

Unplanned Work – Unplanned work includes activities that are not anticipated, such as emergency repairs and recalibrations. Unplanned work can be initiated via the work request system and carried out using on-demand work. Unplanned work can follow a unique approval route so appropriate procedures are being followed.

User Defined Fields – User definable fields throughout the application can be configured to track information specific to your needs. These fields can be configured by dataset and site. They can be designated as picklists, dates, personnel fields, document fields, report fields, etc. User defined fields are available for searching and printing.

User Sessions Management – The software will automatically log a user out of the system after a period of idleness as determined by your organization. This feature not only frees up licenses for other users, but meets the regulations of 21 CFR Part 11.

View documents stored within external Document Management Systems – Any record can link to documents stored in document management systems that are WebDav compatible. This allows for easy access for viewing controlled documents.

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Where Assets Used – On a single screen, users can bring up a complete history on an asset for a given time period to see where the asset was used in production of specific lots / batches, test runs and work on other assets (including Standards reverse trace).

Work Request System – With an unlimited number of requestor licenses, anyone can raise a concern in general or with a specific asset. Users simply fill out a form describing the issue. The form and follow-up activity is set-up by your organization based on your business processes.

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