

Calibration 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.

As Found / As Left – An instrument record can indicate the as found and as left calibration measurement data. This is beneficial for highlighting where remediation is required, provides concrete documentation on current condition and provides valuable information for further analysis.

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.

Calibration Failure Flags – A visual indication in a list of assets to highlight calibration failures.

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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.

Failure Escalation – A failed calibration or a problem occurring during maintenance can trigger a notification to the appropriate users to alert them to the instrument's status. This can be customized to fit your business processes.

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.

Flags – Flags are visual representations that alert users to various conditions, including past due events, calibration failure of an instrument, and out of tolerance conditions. Flags highlight particular information and make it easy to take the appropriate action.

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.

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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.

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.

Labor Planning – Labor requirements, either by individual or by craft, can be forecasted within the application. These forecasts are projected, either by week or by month, based on the number of hours or number of jobs scheduled.

Labor Tracking – The software allows you to keep track of labor information, including time utilized and associated cost.

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.

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.

Loop Calibrations – Perform a calibration on an entire loop or on individual components. This makes it easy to analyze the history and data for an instrument that is part of one or multiple loops over time.

Loop Records – The loop record contains information about the loop and its elements, including all work performed on the loop. Activity is tied-in with the loop record. Like all records, it is configurable to collect the information required.

Measurement Data Set Points Calculated from Percent of Operating Range – In a measurement data template, the set points can be specified as percent of operating range. When the measurement data template is used for calibration work, the operating range of the asset is then used to calculate the actual set points.

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Measurement Data Templates – For recurring activity, the measurement collection details can be pre-configured using measurement data templates. Templates can be created from a calibration record or from scratch, for individual instruments or groups of instruments. This saves time by eliminating the need for repetitive entry of the same set points and acceptable tolerances for each calibration and offers control over the approval process. Measurement Data Templates can be assigned during work planning or on demand for new calibrations.

Measurement Uncertainty – Measurement uncertainty for a standard can be tracked and referenced when it is used in an instrument's calibration.

Multiple Reading Data Entry – The measurement data collection table simplifies the collection of multiple readings per set point to improve productivity. The standard deviation and mean for each set point are calculated automatically with the ability to designate a tolerance level any reading can be from the mean before a warning is given.

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.

Out of Calibration and Failed Calibration Automatic Flagging – You can now choose to have the out of calibration and failed calibration fields automatically set based on as found and as left measurement data respectively based on calibration, adjustment or process tolerances. Based on the configuration, the user may then have the option to override the status assignments before they are saved.

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.

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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.

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.

Reverse Traceability – Quickly and easily view instruments impacted by a specific standard during a period of time. Configurable Reverse Traceability reports can be run directly within any standard record.

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 requires 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.

Set Point Calculation – For cases where the standard and instrument units are different, to save time, a series of set points can automatically be calculated based on range type and number of readings.

Standards Classification – Enhance productivity by filtering standards on a classification that you define to narrow the list of standards for an asset's calibration.

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Standards Management – When an asset record is designated as a standard, it becomes available to be used in an instrument's calibration. These standards have their own calibration schedule with the ability to provide a warning or even lock down standards that are out of calibration, overdue for calibration, or do not have sufficient accuracy to calibrate a specific instrument.

Standards Test Accuracy Ratio (TAR) Specifications – As a standard is referenced for an asset's calibration, the standard's TAR is immediately calculated. If the TAR is outside the asset's limits, the information is highlighted to ensure the standard applied has sufficient accuracy to calibrate that instrument.

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.

Tolerance Limits – Establish a process, adjustment, or calibration tolerance limit for each set point with flags and configurable notifications when a point falls outside the limit. This way a problem does not go unnoticed and can receive the appropriate response.

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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Work Order System – This system encompasses all the information required to do the work as defined by your processes. It includes the work request, the status of the work order and any specific work associated with it. Users can easily access the appropriate information to perform a particular activity.

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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