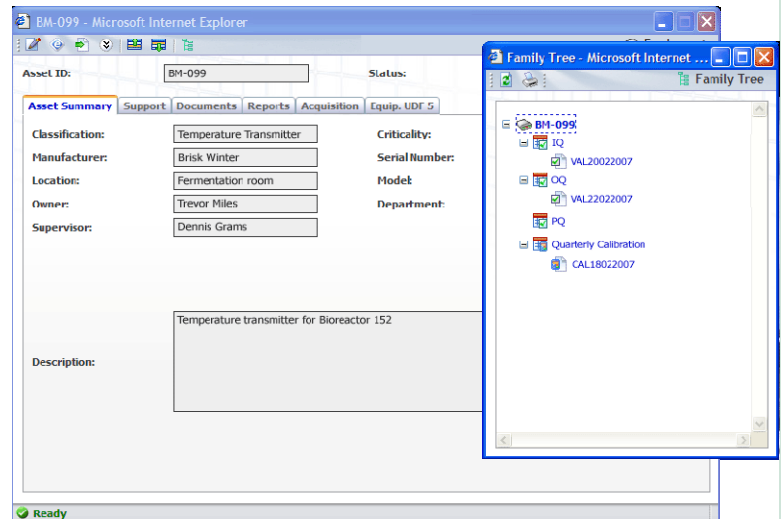




At the core of Blue Mountain Regulatory Asset Manager are its integral features to manage the validated state of assets. The software brings together the information and personnel required to maintain and oversee all assets and processes within a single platform. This centralization streamlines the flow of information and approvals throughout an asset's lifecycle. Events and changes that require additional activity to keep or quickly return an asset to the validated state are not overlooked.

## COMMISSIONING

When bringing a new asset online, design, install, operational and performance qualification can be planned in advance as necessary with all the required information available in the work records. In an asset's master record, a family tree of all events and work for the asset can be displayed. This way, progress on the commissioning of the asset can be easily reviewed and moving forward. Validation professionals can initiate work directly from the asset record or manage all qualifications for which they are responsible. Once the asset is in active use, this family tree is a quick way for users to get a summary of all activity, including calibration and maintenance, performed on an asset.



*An Asset's Family Tree*

## DOCUMENTS

Validation documents stored within an external document management system (DMS) or network file server can be accessed directly from within an asset or work record. User-definable fields available on records can be designated as document fields, providing a link directly to the required file. If you click on the file name, it brings up the document record. Validation protocols and user manuals can be available from within an asset or validation record. Likewise, when the validation is complete, summary documentation can be linked to as part of the validation history. Adding to the document library is as easy as browsing through the files in your DMS.

## MANAGING THE VALIDATED STATE

Once the asset is in active use, Blue Mountain Regulatory Asset Manager facilitates the collaboration of everyone responsible for the assets in order to ensure proper compliance and minimize downtime. For example, when maintenance work generates a need for calibration or revalidation, a notification can be sent automatically to the calibration and validation planners. When revalidations of assets occur, whether they are scheduled or as a result of other activity, they are documented in the software as well. Who gets notified and under what conditions is configurable to match existing business process rules. This collaboration can be an important key to efficiently managing the validated state for equipment and processes.



## QUALITY OVERSIGHT

All records within Blue Mountain Regulatory Asset Manager proceed through what we call “workflows”. Business process rules determine the different states a record passes or flows through. For example, regular validation workflow may be as simple as Open, Complete and Closed. In many cases, a more sophisticated workflow may apply, to make sure that the appropriate individuals, including quality assurance professionals, have a chance to review the activity.

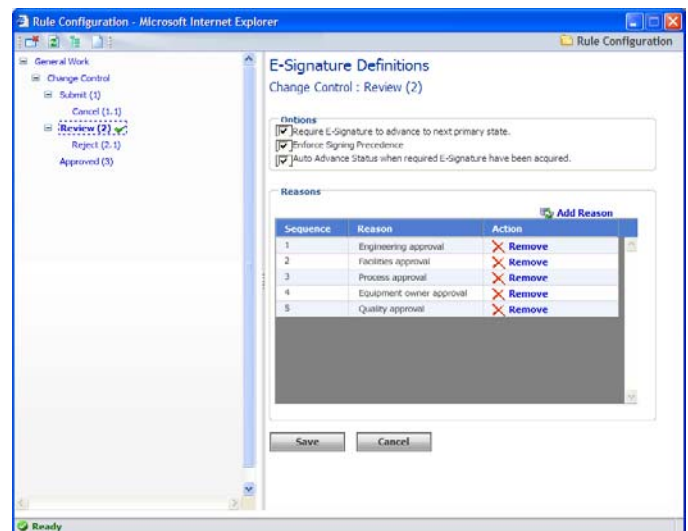
A practically unlimited number of business process rules can be defined to handle a broad range of circumstances. For example, maintenance work on a non-GMP asset would likely have a different workflow than emergency work on critical GMP assets, which would require additional quality oversight and review. At each state in a business process rule, different fields can be enabled and disabled and electronic signature requirements before the record can progress to the next state can be specified for a record. Precedence on signatures can be enforced and the state can be configured to automatically advance once all required signatures have been applied. Otherwise, it would be left to a person to make the final judgment as to whether the record is ready for the next state.

Integrated at all levels of the software, the advanced electronic signature and routing functionality, part of the workflow system, significantly expedites the approval process while satisfying all 21 CFR Part 11 requirements. By having all responsible individuals collaborate in a single application, faster communication reduces time spent in the approval process.

## CHANGE CONTROL

Just as there are differences on how companies manage change control, there are a number of different ways to handle it within Blue Mountain Regulatory Asset Manager. One way would be to set up a business process rule for change control activity. This rule might be used when a spare part is being discontinued and a replacement needs to be considered or when a new technology is considered for an existing process. Simply configure the sequence of states that the change control record passes through, including both primary states – for example, submit, review and approved – and alternate states – cancel and reject.

Change control can also be required as a result of other work, for example emergency maintenance work that calls for replacement parts. A separate business process rule may be created to meet those needs, diverting the work for its typical workflow into a change control sequence that would cycle the change through the change control before the work could be closed and the asset returned to regular use.



*Change Control Workflow*