



- Blue Mountain RAM
Validation Application Note



At the core of Blue Mountain Regulatory Asset Manager are its integral features to manage the validated state of assets and processes. 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.

Equipment Qualification

When bringing a new asset online, the qualification can be planned out in advance. For example, qualification of analytical instruments should include the 4Qs of design, install, operational and performance qualification as detailed in the United States Pharmacopeial Convention's USP <1058>. With Blue Mountain Regulatory Asset Manager all the required information to perform each of these validations is preplanned for each event. Any document can be made available within an asset or validation record, including User Requirement Specification (URS), purchase order, validation protocol, SOP, user manual and validation summary documentation. User-definable fields available on records can be designated as document fields, so 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. Additional details about the document, which might include the author, file type and last updated date, can also be viewed from within the record. 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 kept moving forward. Validation professionals can initiate work directly from the asset record and manage all qualifications they are responsible for from a single list of active validations assigned to them.

Managing the Validated State

Just as assets require periodic maintenance and calibration, so too do many assets require periodic revalidation after the initial qualifications. This activity can be scheduled on a recurring basis and documented within the software to ensure that it is not missed. Other types of validations can also be managed through Blue Mountain Regulatory Asset Manager, including cleaning validations, process validations and software validations.

Blue Mountain Regulatory Asset Manager facilitates the collaboration of everyone with responsibilities for the assets in order to ensure proper compliance and minimize downtime. For example, when an asset requires maintenance work that will require additional calibration or validation effort to follow, all three can be scheduled in sequence and associated with a single work request if appropriate. The system can also be configured to automatically send out a notification to calibration and validation planners when relevant maintenance or calibration work is completed. 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.