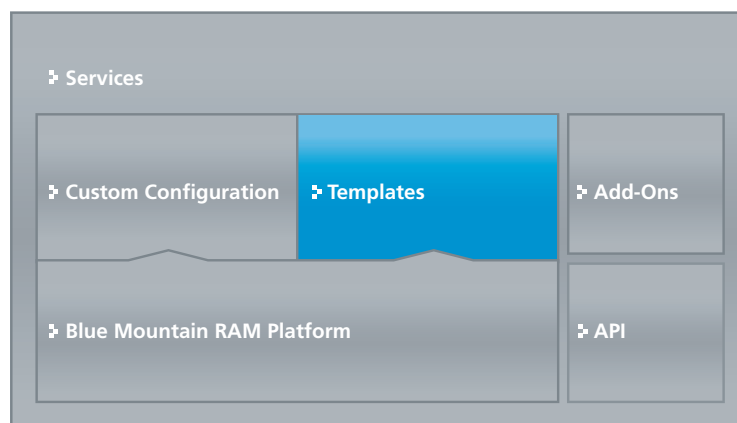# BLUEmountain
## REGULATORY ASSET MANAGER

## ⁜ Best Practices Template

### Get GMP-Compliant with Limited Resources

Just about all Life Sciences companies have the need, or perhaps even mandated requirement, of implementing a software solution to manage calibration and maintenance operations. Unfortunately, many struggle with limitations of time, budget or people. This often makes it challenging to justify a custom configured Blue Mountain RAM implementation.

The Blue Mountain RAM Best Practices Template is the perfect solution. As a pre-configured implementation of Blue Mountain RAM, it enables your company to put in place a world-class calibration and maintenance solution quickly, easily and economically. Best of all, it's built around GMP Best Practices, so maintaining compliance is first and foremost.



The Best Practices Template is a pre-configured implementation of Blue Mountain RAM.

## Speed Implementation and Reduce Costs

Our Template solutions are purpose-built to save you time and money, especially during the implementation process. They're built on the full Blue Mountain RAM platform and have pre-defined forms, fields, business rules, reports and queries. A pre-configured system means you can leverage a standardized configuration which reduces installation and training time and streamlines validation. Organizations typically see a significantly faster return on investment with this solution.

### Key Benefits

- **Complete calibration, maintenance and validation management framework.**
- **Reduced overall system implementation time.**
- **Streamlined validation.**
- **Robust CMMS/CCMS with a lower implementation cost.**
- **Quick alignment with GMP best practices.**

## Built Around Industry Best Practices

The Life Sciences industry has evolved to a broad set of Best Practices as demonstrated by NCSLI's Recommend Practices RP6 Guide and ISPE's GAMP guides to Calibration and Maintenance. Blue Mountain is a strong supporter of these guides and proud to have participated in the writing of NCSLI RP6. We combined that with our 20+ years of industry and implementation experience to give you a feature-rich, CMMS/CCMS template of Blue Mountain RAM for both GMP compliance and productivity.

With the Best Practices Template solution, you won't have to compromise functionality. Our team of industry experts designed this template to include a full set of features and functionality that includes:

- Complete Control of an Asset's Life Cycle from induction to retirement
- Management of All Work – Calibration, Corrective and Preventive Maintenance
- Paperless work flow and data capture for Maintenance and Calibration Events
- Management of Out of Tolerance limits, processes and notifications
- Enforcement of SOPs and Electronic Signatures with GMP Business Rules
- Management and Notification of calibration and maintenance incidences and/or failures
- Full Reporting, Querying and Audit Trails for turning data into actionable knowledge

Over time, as your business grows, so can your implementation because it is based on a full version of Blue Mountain RAM. Think of it as your starting point for gearing up your calibration and maintenance program or as a jumpstart for getting into compliance after an audit. Either way it allows you to maintain asset data in a single-point, cost-effective solution.

### What's Included

- **Pre-configured Best Practices Template which overlays the Blue Mountain RAM platform**
- **User documentation for getting started and ongoing use**
- **Work instructions (SOPs) that can be validated for use and administration**
- **Business process flow diagrams**

## Designed for Quick Implementation and Modest Budgets

The Blue Mountain RAM Best Practices Template is the solution for your organization if:

- You need to put a full GMP calibration and/or maintenance program in place immediately.
- You have a modest budget and can't afford a full custom implementation.
- You are constrained on people resources and can't dedicate the time required for a full custom configuration.

## Complete Validation Package

One of the biggest challenges in a custom configuration of a software package is the validation. Each validation is unique to its implementation. Depending on the depth of validation required, it can be a time-consuming process and tie-up internal resources.

The Best Practices Template solution can alleviate many of those issues. Since it's a tightly, pre-configured software implementation, a complete validation package is available and ready to go, speeding the validation process. With the template solution you can leverage Blue Mountain as the Subject Matter Expert (SME) in software design, testing and validation. You don't have to start from scratch and can take the GAMP 5 industry approach to validation.

The Validation Package Includes:

- Software Quality Assurance (SQA) documentation
- User and Functional Requirements
- Traceability Matrix
- Installation Qualification (IQ) and Performance Qualification (PQ) test scripts
- Digital copy of pre-executed Operational Qualification (OQ) tests performed by Blue Mountain

## Services to Speed Implementation

While the Best Practices Template is built for off the shelf use, Blue Mountain has designed simple cost effective services to get you up and running even faster. These include:

- Installation
- Training
- Validation Execution (IQ & PQ)

## Next Steps

Blue Mountain invites you to take the next step in evaluating this exciting new product:

- Sign up for a web demo – www.coolblue.com/demo
- Contact a Regional Sales Manager for more details – 800.982.2388

To learn the specifics of what's included in the Best Practices Template, ask the Regional Sales Manager for a copy of the User Requirement Specifications that were used to develop the template.

**BLUE**mountain
QUALITY RESOURCES

PO Box 830, State College, PA 16804-0830