



The Blue Mountain Difference:

Why Pharma Manufacturers, MedTech Companies, Cell & Gene Therapy Providers, Biotech Manufacturing, and CDMOs Trust Blue Mountain with their EAM and CMMS Needs

TRACK ASSETS, MANAGE ASSETS, MAINTAIN COMPLIANCE

In life sciences, the primary goal is to deliver lifesaving and life-changing medicines to patients safely, quickly, and efficiently. As a SaaS provider of the industry-standard EAM and CMMS, Blue Mountain takes this responsibility seriously. Equipment readiness, safety, and maintenance are mission-critical to getting production batches to the patients as planned. For over 35 years, we have been committed to innovating with our customers to drive efficiency and excellence.

Pharma manufacturers, medtech companies, cell & gene therapy providers, biotech manufacturers, and CDMOs work with Blue Mountain because of our platform's unique ability to combine compliance, efficiency, scalability, and seamless integration into one powerful solution. With Blue Mountain Regulatory Asset Manager (RAM), over 450 global life sciences companies confidently manage their assets, streamline maintenance activities, and maintain regulatory compliance, ensuring they are well-positioned to succeed in a competitive and highly regulated market.

OUR TECHNOLOGY

Comprehensive Compliance Management

As a platform that was designed and built exclusively for life sciences, our core strength lies in the ability to support regulatory compliance for life science manufacturing. Blue Mountain RAM ensures compliance with Good Manufacturing Practices (GMP) as required by the FDA and meets the stringent regulations of 21 CFR Part 11 and ISO 9000. RAM tracks data input, manages audit trails, and enforces electronic signatures, to ensure data integrity. These features make it easier for customers to remain compliant and audit-ready, reducing the risk of observations, findings and penalties.

Blue Mountain RAM supports asset management throughout the drug development and production processes. From early-stage R&D to full-scale production, our system adapts to meet expanding regulatory needs, enabling manufacturers to maintain control over their operations as they scale. By centralizing asset management data, companies can access historical records quickly, improving their ability to make informed decisions and ensuring compliance throughout the production cycle.

Understanding the importance of safety and precision, Blue Mountain RAM provides rigorous calibration and maintenance management functionality, helping organizations ensure that their equipment and devices are in full working order. By integrating asset management, calibration, and maintenance in a single platform, manufacturers can reduce human error, improve asset reliability, and maintain the highest standards for regulatory compliance.

GxP Ready, Fully Validated Solution

Blue Mountain RAM is delivered fully validated. By providing a commercial off-the-shelf (COTS) system that meets industry regulations, RAM reduces the time and cost associated with in-house or outsourced validation. In highly regulated sectors like life sciences, software systems must adhere to strict standards such as GxP and FDA 21 CFR Part 11. Every release of the solution is pre-validated, from initial deployment to every subsequent software enhancement. This reduces the validation burden for companies, ensuring faster deployment and minimizing compliance risks. RAM is also designed around industry best practices, reducing the need for customization and offering reliability, efficiency, and a strong foundation for managing sensitive data and processes.



Efficiency and Productivity Enhancements

Blue Mountain RAM helps life sciences companies streamline processes to improve overall productivity. Our platform's work management functionality enables automatic scheduling of routine calibration and maintenance tasks, helping to avoid unnecessary downtime. The result is an increase in operational uptime, fewer disruptions, and improved workflow across departments.

RAM's data management capabilities support business intelligence by offering robust reporting tools, enabling teams to monitor key performance indicators (KPIs), track assets, and manage work more efficiently. With more than 30 built-in standard reports and the option for custom reporting, data-driven decision making is made easy. RAM enables users to identify underperforming assets quickly, allowing proactive measures to be enforced before those assets impact productivity.

Scalable Solutions for Multi-Site Enterprises

Scalability is an important requirement for many life science companies, and Blue Mountain RAM is designed to meet this need. RAM can handle the complexities of multi-site enterprises, providing a centralized platform for managing calibration, maintenance, and asset data. Whether a company is operating in a single location or across multiple facilities worldwide, companies can utilize Blue Mountain RAM to harmonize work practices, ensuring consistency and accuracy across all sites.

Seamless Integration with Existing Systems

Blue Mountain RAM provides the flexibility needed to integrate with other industry-specific systems, making it ideal for companies that require tailored solutions for equipment calibration and maintenance management.

Many life science companies, particularly larger organizations, already rely on Enterprise Resource Planning (ERP) systems, such as SAP or Oracle. Blue Mountain RAM is designed to work alongside these systems, offering seamless integration that allows the exchange of asset management data, calibration schedules, and maintenance records without duplication of effort or data silos.

PROVEN RESULTS AND INDUSTRY EXPERTISE

With over 35 years of experience serving the life sciences industry and over 1,000 successful RAM implementations worldwide, our employees are the backbone of Blue Mountain. Collectively, we bring hundreds of years of life sciences industry experience to strengthen RAM's position in the market as the EAM and CMMS system of choice for life sciences. It is this in-house expertise, combined with industry-leading software that makes Blue Mountain customers remain loyal to our brand. It's the results you need that delivers the value you expect.

For more information contact sales at sales@coolblue.com