

# Establish a complete life sciences asset management solution.



## Highlights

Help establish preparedness for governmental audits by leveraging a solution tailored for life sciences organizations

Employ a single-vendor solution that offers a risk-based approach for asset management to address Food and Drug Administration (FDA) regulations, including Good Manufacturing Practices (GMP) and FDA 21 CFR Part 11: Electronic Records; Electronic Signatures

Support full integration of instrument calibration and validation requirements

Leverage open standards-based technology to ease integration with third-party applications

Increasingly stringent regulatory requirements for life sciences organizations set by the FDA, the International Organization for Standardization (ISO) and other regulatory bodies have vastly increased pressure to meet the demands of managing assets across the business. Frequent governmental audits, advances in technology, changes in regulations, heightened competition and increased focus on cost have all made efficient asset management more essential than ever before.

Adding to these increased demands is the changing landscape for life sciences organizations. Today, maintenance and engineering departments often function as business units, with direct responsibility for availability and on-time delivery of services to both internal and external customers.

Because of this, asset managers are tasked with providing key information on all life sciences assets, to help:

- Meet regulatory requirements.
- Extend asset life cycles.
- Increase uptime.
- Control labor costs.
- Improve quality.

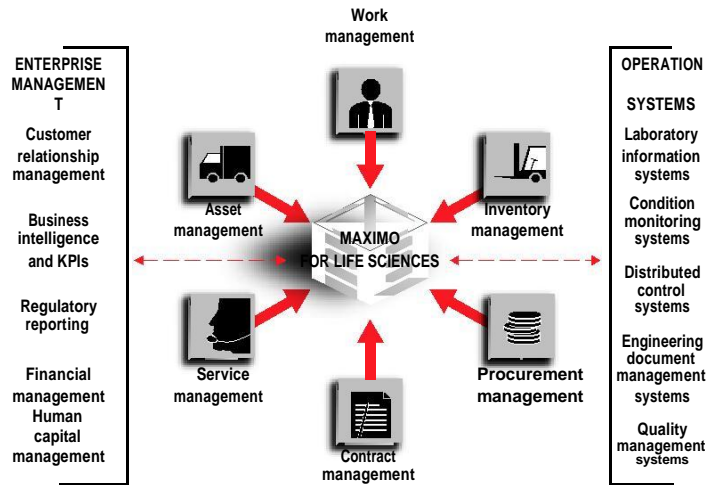
Unquestionably, maintenance and repair of strategic assets is central to meeting both compliance and legislation requirements and managing major risk elements for health and safety. For these reasons, managers of production, asset maintenance and services require a solution that addresses the multiple asset types spread across your organization — from equipment and tools to instrumentation and IT.

**Leverage a solution tailored for life sciences organizations**

IBM Maximo® for Life Sciences is a complete set of asset management solutions tailored for life sciences organizations that enables your operational, service and maintenance managers to track and manage all assets critical to the performance of the business and to maintain required service levels. The sheer breadth of assets that must be managed makes meeting regulatory requirements particularly daunting. Maximo for Life Sciences helps manage all your assets — from equipment, tools

and laboratory instruments to maintenance and engineering facilities to IT equipment, such as mobile devices, IP-driven assets and servers.

Asset managers within life sciences organizations need a comprehensive way to centrally manage critical assets throughout the various divisions in which the assets are located — from maintenance, engineering, and research and development to facilities, logistics and IT. Maximo for Life Sciences helps



Consisting of six key management systems, Maximo for Life Sciences integrates easily with your existing business systems, allowing you to work the way you want to work

address the numerous considerations to face when selecting a comprehensive asset management solution:

- *User access.* Knowing how and where users are accessing information is critical.
- *Auditability.* Regulatory requirements make it mandatory for asset management to be both auditable and traceable.
- *Ease of use.* An asset management solution must help speed — rather than impede — business processes and information extraction.
- *Maintenance.* Software standardization must not constrain maintenance processes.

- *Flexibility.* As business processes evolve, your solutions must adapt as well.
- *Information capture.* To extend the life of assets, you must also have a way to capture additional required information.

**Apply a single solution to facilitate efforts to comply with strict regulatory requirements**

The assets that must be managed are broad-ranging and spread across multiple divisions, operations and maintenance managers. As a result, field engineers and other asset managers

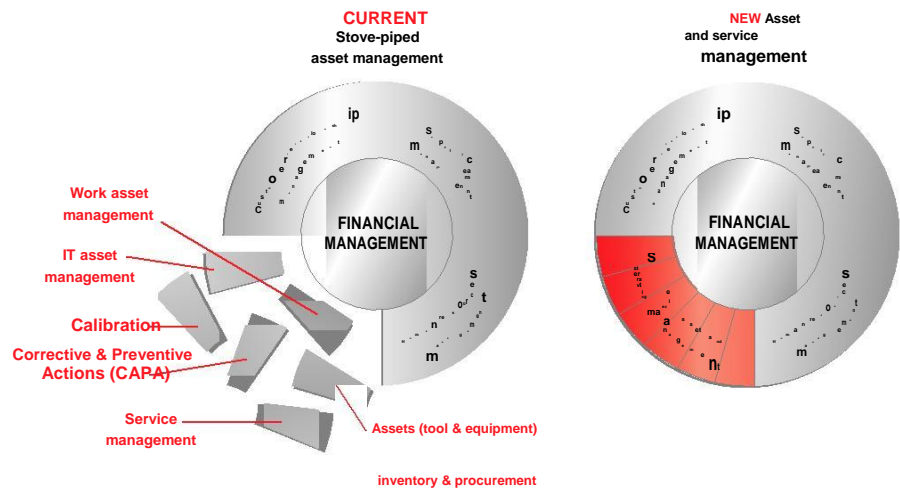
face significant challenges in tracking and managing equipment, tools and instrumentation. Maximo for Life Sciences helps you overcome these challenges to comply with numerous requirements and best practices, such as:

- GMP.
- FDA 21 CFR Part 11: Electronic Records; Electronic Signatures including e-Signatures, e-Records/e-Audit.
- Instrument calibration.
- Corrective and Preventive Action (CAPA).
- ISO guidelines.
- Reliability-centered maintenance.
- Lean manufacturing.
- Validation support with compliance assistance documentation.
- Best-practices maintenance improvement programs.

Maximo for Life Sciences also helps deliver better information through industry-specific reports and key performance indicators (KPIs).

**Empower operational and maintenance managers**

With a single repository for all asset-related information, Maximo for Life Sciences gives senior and operational management the ability to view and manage asset performance from a



Caption to be provided.

corporate perspective. In addition, by managing critical assets more closely, maintenance managers help improve the uptime of critical, revenue-generating assets; reduce the costs of acquiring, maintaining and even disposing of assets; and, ultimately, increase share-holder value. Use Maximo for Life Sciences to manage every aspect of the asset life cycle, including:

- Acquisition.
- Work orders.
- Preventive maintenance.
- Inventory control.
- Purchasing.
- Quality management.
- Regulatory compliance.
- Disposal.

**Support a service-centric business model**

Maximo for Life Sciences provides enhanced capabilities to allow users to implement a service-centric business model that takes advantage of the IBM Service Management approach to aligning IT with your business goals.

This business model encourages partnerships between the maintenance organization and internal customers. It fully supports third-party service providers by tracking all relevant activities and monitoring asset and service performance according to agreed service levels.

Maximo for Life Sciences is built on open standards-based technology

such as Java™ 2 Enterprise Edition (J2EE™), making it easy to adapt business processes, protect technology investments and improve overall agility. Integrate Maximo for Life Sciences with your existing applications for:

- Enterprise resource management (ERP).
- Finance.
- Human resources.
- Engineering document management.
- Information systems, including manufacturing execution systems (MES), supervisory control and data acquisition (SCADA), laboratory information management system (LIMS), mobile devices and engineering documents.

**For more information**

To learn more about how Maximo for Life Sciences can help your organization maximize your asset management capabilities, please contact your IBM representative or IBM Business Partner.