IBM asset management solutions
White paper

Tivoli software

Managing corrective and preventive action (CAPA) in a life sciences environment.

March 2007

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Executive summary

In the life sciences industry, the process of managing non-conformities or defects from manufacturing, engineering, quality or other quality data sources, such as product complaints leading to corrective or preventive actions, is a formal and controlled one used to identify, correct and prevent problems that occur.

Today, the industry is facing strong pressure from regulatory bodies—government as well as from the industry itself—to focus on quality and, at the same time, the need to increase asset utilization and efficiencies, and lower cost as much as possible. A corrective and preventive action (CAPA) program is one tool to achieve these objectives.

A key part of a CAPA program is root cause analysis, which is utilized to ascertain the source of a problem, non-conformity or defect so that corrective or preventive action can be taken to address the issue.

CAPA programs have achieved some notable successes, first with the nuclear industry and subsequently in many other asset-intensive industries such as utilities, chemicals, pharmaceuticals and life sciences. As with any program, there are wide variances in program governance, structure, funding and effectiveness. As early as 1999, the Federal Drug Administration (FDA), began providing CAPA guidelines[1] and started to actively enforce CAPA requirements as part of its Quality System Inspection Technique (QSIT) initiative. According to research conducted in 2005 by Axendia—a specialized business consulting firm focusing on the life sciences industry, 50 percent of the top 10 FDA inspectional observation items (each commonly known as a "483") were CAPA related.[2] Since the publication of the "Guide to Inspections of Quality Systems," and with FDA's shift to QSIT and risk-based compliance orientation, CAPA will continue to be a key focus during FDA inspections.

Many CAPA programs have been implemented with few tangible enterprise-wide benefits. Probably the most common reason for disappointing results is the failure to connect and fully integrate CAPA programs with work management strategies and solutions, and other supporting corporate-wide information systems.

This white paper focuses on the asset-intensive companies that needs to reposition their assets from operational necessities to strategic imperatives, which allows the enterprise to consistently make decisions that result in higher quality and more reliable and risk-averse operations. Actively managing asset-related CAPA is important for these companies as this can create an obvious link between the quality management system and the enterprise asset management (EAM) or computerized maintenance management system (CMMS).

This document will also explore the role of handling non-conformities or defects, managing their occurrence or incidents, and the CAPA process that drives operational excellence, helps companies monitor and manage their regulatory compliance efforts, supports their goal of zero defects and enhances each company's ability to document the whole process of occurrence and prevention.

Furthermore, this white paper will provide an overview of IBM Maximo® Asset Management and its capabilities to support corporate initiatives such as complaint and incident management and CAPA, as well as to provide a framework for all stages of the CAPA process. This process includes identification, determination, implementation and the permanent embedding of CAPA as part of a continuous improvement process in regulatory environments like life sciences and healthcare.

Highlights

A new risk management agenda is placing new demands on life sciences businesses.

Setting the stage

Today, risk management is referred to as enterprise risk management. There has been a shift away from traditional compliance and insurance motivated risk management, to management that is more closely linked to business performance and long-term society commitments. A new risk agenda is emerging in the life sciences industry resulting in new demands on business and new ways to manage business.

- *The FDA provides guidance for a risk-based approach because risk management has become a more important tool to minimize safety-related risk.*
- *The FDA is actively providing guidelines on risk management. As with any program, there are wide variances in program governance, structure, funding and effectiveness.*
- *As mentioned earlier, the FDA has been actively enforcing CAPA requirements and reported that 50 percent of the top 10 FDA 483s are CAPA related. Based on feedback from the industry and an industry study, it appears that in operational environments 50 percent to 80 percent of all CAPA's have asset-related impact.*
- *The FDA initiative on Process Analytical Technologies (PAT) outlines a system perspective and facilitates the introduction of new technologies to the design, development and manufacturing of drug products. PAT focuses on integration of data (output from process control systems) into quality management systems and other related information management systems.*
- *The industry trend to benefit from Lean/Six Sigma initiatives will clearly impact the reliability and quality of critical assets to increase efficiency of production processes in the life sciences industry.*

Companies are focused on ascertaining the root cause of problems or events and taking action to prevent their recurrence. This enables the company to conduct largely error-free operations over a long period of time and to more consistently make decisions that result in higher quality and more reliable operations.

In parsing any CAPA definition, there are subtle but key differences between corrective action and preventive action. Corrective action is defined as an action undertaken to eliminate the cause of an *existing* non-conformity, defect or other undesirable situation to prevent *recurrence*. Preventive action is defined as an action undertaken to eliminate the cause of a *potential* non-conformity, defect or other undesirable situation to prevent an *occurrence*.

Four key words are different in the two definitions: *existing* and *potential*, and *recurrence* and *occurrence*. Corrective action relates to the root cause of an incident, whereas preventive action relates to the occurrence of an incident.

When is CAPA relevant?

Currently, there are five different types of information sources that can trigger a CAPA.

- *Complaints from customers, either direct or indirect users (or consumers)*
- *Process deviations as a result of a manufacturing inconsistency or production failure, or an engineering non-conformity, which causes the defect relative to the production deviation, non-conformance or out-of-specification that may occur*
- *Laboratory investigation or analyses*
- *Internal audits or audits from regulatory bodies such as the FDA that identify differences or deviations from given standards in the business or production processes or non-compliance to production validation guidelines*
- *Grassroots efforts by employees, e.g., an engineer who notices an oil spill and organizes a corrective action*

Highlights

The FDA published a set of regulations that require a formal complaint-handling process, which include the following.

- *FDA's Quality System Regulation requires medical device manufacturers to establish and maintain procedures for receiving, evaluating and investigating complaints by a formally designated unit.[3] "This [complaint-handling system] should be the beginning point of every inspection to determine whether the firm has received complaints of possible or potentially defective devices," according to the regulation.*
- *FDA's Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals require establishment of a procedure for reviewing and evaluating complaints about drug products.[4]*
- *FDA's CGMP requirements for blood and blood components require maintenance of records of complaints of adverse reactions, a thorough investigation of each adverse reaction and a written report of the investigation.[5]*

Companies need a streamlined strategy for managing different types of non-conformities.

How to manage CAPA

A company should develop a strategy for complaint handling as part of its overall quality system. The challenge is to turn the different types of non-conformities into opportunities to improve quality. Here are some of the requirements for such a complaint management solution.

- *FDA-regulated companies must be able to determine which non-conformities or complaints need to be reported to the agency as adverse events. Typically, customer complaints are handled by the FDA Office of Regulatory Affairs. Based on its investigation of a customer complaint, a company may launch a CAPA.*
- *Medical device manufacturers must have a process in place that includes skilled people who are able to make a well-informed decision as to the severity and significance of a complaint and whether it requires investigation.*
- *For FDA-regulated companies, a thorough documentation of complaints, various defects, non-conformities and adverse events, and the resulting investigation is a requirement. Records must include customer information, origin and details of the defect or complaint, product information, details of investigation (root cause, etc.), and the CAPA taken.*

Highlights

Paper-based or partially electronic complaint-handling processes can bog down the non-conformity or defect resolution life cycle. Tracking non-conformities or defects manually from unconnected sources can be time-consuming. It's very difficult to monitor the different non-conformities or defects that could potentially result in a CAPA in a manual system.

A system that handles defects or non-conformities with regard to asset-related activities is needed to streamline the process and increase efficiencies and effectiveness. Complaints, defects or non-conformity CAPA's can be monitored and assessed on their severity or priority and their compliance with FDA regulations.

Incident management

Any incident that may occur that can be described as a deviation from the standard operation procedure linked to an asset, tool, equipment or instrument, or service needs to be reported and managed, while maintaining compliance with FDA regulations. The objective is to restore the asset or the service to "normal" or to the defined standard as quickly as possible.

Definitions of severity, in terms of urgency, impact, affected services, etc., need to be clear and should be utilized to manage prioritization, which is mostly covered by service level agreements for either internal use (other departments within the organization) or external use. In this situation, third parties (external partners) are being involved to execute the work based on the agreed service levels.

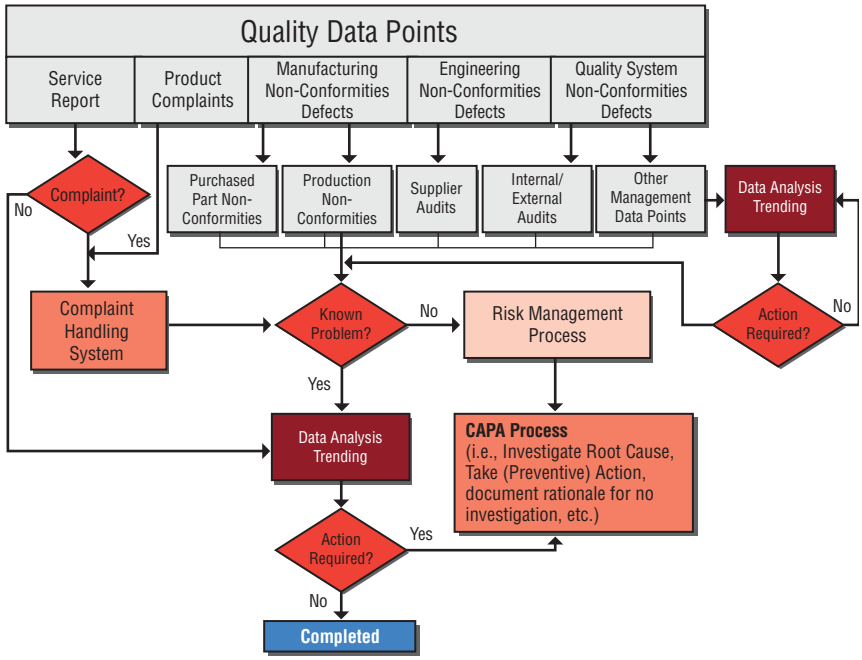
Any incident that deviates from standard procedure should be properly defined, analyzed, corrected and documented.

For any process deviation, there needs to be an analysis of how the deviation occurred, the impact of the deviation and severity, and what actions have to be taken to correct the situation to the standard-accepted situation. All these steps need to be registered and documented. Any action to restore process or prevent an incident that may occur will be stored in the CAPA system. When a process is not defined properly, a non-conformity can result.

CAPA process

To achieve the appropriate CAPA activity, it is important to track, manage and assess all different quality data points within the organization, and to manage key performance indicators throughout the process, as shown in Figure 1.

Figure 1: CAPA Process Flow



Highlights

FDA guidance is helping organizations focus on key elements of a quality system, including CAPA.

Background

Pharmaceutical and life sciences companies have to comply with regulations as directed by the FDA. The FDA drafted guidance (August 1999) on an inspectional process—the Quality System Inspection Technique—that may be used to assess a medical device manufacturer's compliance with the FDA Quality System Regulation and related regulations.[6] This guidance will help organizations focus on key elements of a quality system.

Within the total Quality System, there are several subsystems, along with related "satellite" programs. Four major subsystems are Management Control, Design Controls, Production and Process Controls, and CAPA.

In the Quality System, there is also a major emphasis on tracking and tracing of all medical devices and movements of the entire instrumentation within the organization. Tracking and control of facilities/locations is also essential and must be considered by organizations.

As mentioned earlier, more and more the life sciences industry is differentiating "deviations" from "non-conformities." Deviations are planned. There is knowledge of the deviation and documentation is provided up-front to justify how the deviation maintains CGMP protocol. In this case, the planned event will include the reason for the deviation, the details of the deviation and the rationale or explanation of how compliance is maintained.

A non-conformity is unplanned and is an event where protocol is not followed or an unexpected failure of equipment or systems has potentially impacted the product. A non-conformity will always require an investigation and almost always requires the CAPA process to be initiated.

Once a CAPA is initiated, the program follows its assigned workflow process. For instance, the first step may be to initiate an investigation to properly identify the root cause of the non-conformity. Once the root cause has been identified, CAPA items can be created and routed for approval. And as soon as corrective actions have been approved, appropriate changes are implemented and the CAPA is closed out.

The purpose of CAPA is to collect and analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. But, the ultimate goal is continuous improvement focused on quality.

Verifying and validating CAPA's, communicating CAPA activities to responsible people, providing relevant information for management reviews and documenting these activities are essential to dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures. CAPA support will also align quality requirements to the capabilities of an EAM system.

Corrective actions can also be seen in relation to the FDA publication on the guidance of PAT, as well as the risk-based approach for manufacturing processing. Therefore, full support of these CAPA processes will not only increase the quality and compliance of the products produced, but the business processes followed.

Benefits

According to industry analyst research, the core functionalities resident in a CAPA system should include:

- *Change management, audit trail and tracking.*
- *Visualization, reporting and quality performance analytics.*
- *Configurable workflows and standard template-based best practice workflows.*
- *Roles-based information view.*
- *Trigger and event management.*
- *Integration to back-end systems.*

Highlights

CAPA software solutions are becoming an integrated part of overall asset management information systems.

A software solution can be very helpful in managing and tracking a CAPA process. The adoption of CAPA information systems as part of a holistic asset and service management solution will become widespread because of their enabling role in mitigating significant business risks and driving quality as an integrated part of the manufacturing process. As a result, companies are no longer forced to buy a stand-alone CAPA system; the CAPA solution can be an integrated part of a quality and compliance monitoring and management solution and part of an overall asset management information system. A very important benefit is the ability to keep track of all investigations and CAPA's throughout the system and close them in a timely manner.

CAPA also forms the core of various quality management disciplines such as Lean Manufacturing and Six Sigma DMAIC (Define, Measure, Analyze, Improve and Control), or ISO 9000.

Understanding the problem

To identify the root cause of an incident, a complaint or a CAPA problem, the company must first specify what the problem is, when it occurs and how often, and how big the impact of the problem is.

The company also has to test different possible causes against the facts of occurrence. This process often shows some painful points, including lack of communication between different departments. However, companies can increase customer satisfaction and retention through improved responsiveness. Rigorous management of complaints or incidents also drives continuous improvement and compliance benefits, helping companies to:

- *Lower cost of regulatory compliance with streamlined and consistent complaints handling.*
- *Accelerate complaints recording, investigation, reporting and closure cycle as cases are automatically routed from one stage to the next.*
- *Gain enterprise-wide visibility into the complaints data, leverage a solution library or knowledge base, and track the process with performance metrics.*
- *Improve communication and teamwork on complaints or incidents across departments and functional areas.*
- *Drive continuous improvement by tying corrective actions with complaints for a closed loop quality process.*

IBM Maximo Asset Management as a framework to support CAPA processes

Failure to connect the CAPA process with overall work management strategies/solutions is often the primary reason for an ineffective program.

The four major components of CAPA are:

- *Identification (the problem)*
- *Determination (evaluate impact and risk assessment)*
- *Implementation (i.e., investigation, remedy and responsibility assignment)*
- *Verification/Validation (check and test the CAPA and document it)*

Ideally, there should be an interconnection between CAPA activities and the work management component as part of an EAM system. Within Maximo Asset Management, part of the IBM Tivoli® software portfolio, the key activities/components are:

- *Plan*
- *Do*
- *Check*
- *Adjust*

The results of these activities are linked and feed back the information to the CAPA process to close the CAPA. The EAM system is the central place to execute the required actions such as investigating the root cause; managing the preventive action; documenting all related actions per asset, tool or measurement; and testing the equipment. Again, in this respect, Maximo Asset Management functionality clearly ties quality assurance/quality control requirements into the capabilities and functionality of the EAM system.

If a CAPA program is not integrated with a corporate work management/EAM system, the result is disconnected databases that often lead to:

- *Slower resolution time across the entire life cycle (capture, action and analysis).*
- *Duplicate records that increase the risk of inconsistent data.*
- *An inefficiency to find the right information.*
- *Risk in losing an audit trail.*
- *Difficulty in making correlations between CAPA and work (work orders or preventive maintenance (PM) orders).*

Highlights

Companies need a closed-loop integration between CAPA and work management processes. Maximo Asset Management takes the power, performance and possibilities of work asset and services management and the process of CAPA to an entirely new level.

Technology framework

Using a single state-of-the-art technology platform, sophisticated asset and service management solutions such as Maximo Asset Management provide companies the most comprehensive view of all critical asset types—production, facilities, transportation and IT. This holistic perspective is part of the foundation of Maximo asset and service management solutions, and allows companies to see all of their assets, as well as to identify the untapped potential within them.

Maximo Asset Management provides companies a view of all their assets and closes the loop between CAPA and work management processes.

Using the Maximo Asset Management solution, companies can gain knowledge and the control they need to more closely align their goals with their missions on safety and security within the organization, as well as with applicable regulatory compliance requirements. Companies are then better able to reduce costs, minimize risk and increase service delivery responsiveness and revenue.

With Maximo Asset Management, companies can gain the power to get more performance and value out of every asset throughout the enterprise and support a more effective and compliant CAPA program in place to meet increased requirements for continuous improvement and risk management.

The foundation of Maximo Asset Management is a business process management platform that can be configured to support various industry standard workflow processes and can be used as a powerful engine to support IT Infrastructure Library® (ITIL®) methodology and standards. The same platform can also be used to secure a structured and logical step-by-step approach to manage all requirements for production non-conformities, defects or service complaints, as well as asset-related CAPA's. The platform can also mange all changes in the IT assets, which have to be added into the validation processes.

This approach can help reduce the recurrence of failures, improve service levels and customer satisfaction, and reduce fixed and variable costs.

For purposes of this document, a service request, defined as a CAPA, can simply be the identification of a need for a corrective or preventive action.

- *Incident management can be used to ensure that business-appropriate responses to incidents occur and that responses help to maintain the highest justifiable levels of service.*
- *Notifications are sent to relevant departments and personnel, and an escalation mechanism is triggered based on severity and priority.*
- *Problem management can be used to prevent or reduce the business impact of recurring incidents.*
- *Change management can be used to understand and control the impact of changes to the assets on the business.*
- *Release management can be used to manage the impact and disruption of a set of changes on the business and to help ensure proper and complete deployment.*

Additional specifics for incident, problem, change and release management are detailed in Figure 2.

Figure 2: CAPA Management

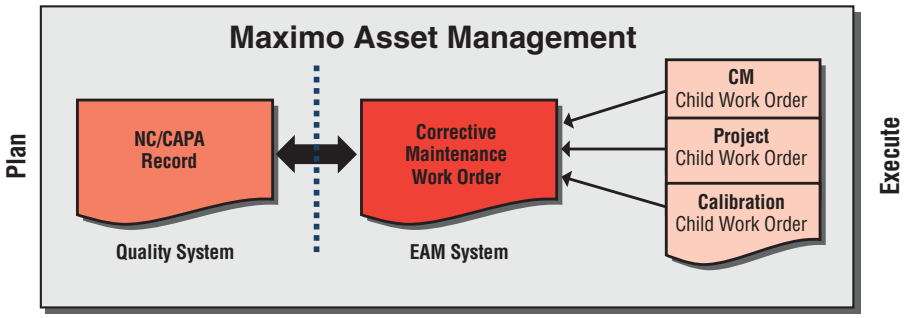
Incident	Problem	Change	Release
Definition: deviation from the standard operation of a service or asset–outage, stoppage, failure, etc.	**Definition:** unknown underlying cause of one or more incidents	**Definition:** an activity that results in a new configuration of a service or asset	**Definition:** activity which moves or deploys authorized configurations of assets into the production environment
Objective: restoration of service to "normal" as quickly as justifiably possible	**Objective:** preventing incidents from occurring again or reducing the impact of further incidents	**Objective:** design changes to increase capacity, availability, reliability, etc., or for regulatory compliance	**Objective:** changed asset needs to be deployed into the production environment

In summary, Maximo Asset Management supports the CAPA processes related to all critical assets, tools and measurement, and test equipment or instrumentation, providing solutions to:

- *Enter, track, trend and manage all related CAPA data, including multiple complaints, audit results, failure analysis and other quality issues.*
- *Add multiple products or classifications to each CAPA record, as well as how the data can be used to track performance and quality.*
- *Facilitate better communication with quality assurance and other departments.*

CAPA's developed as a result of non-conformities often involve work on assets that require evaluation, review and approval of a planning process prior to the execution of physical work. Once approved in the Quality System, the CAPA plan can be executed via individual "child" work orders in the EAM system, as shown in Figure 3. Coordinating processes between a quality system and an EAM system allow departments to work in their native applications and avoid redundant approval cycles without losing traceability across systems. Another important function includes master data management and audit trail capability linked with integrated business process workflow capabilities.

Figure 3: CAPA Execution



Workflow component of Maximo Asset Management

Capturing business processes and implementing them in a consistent, comprehensive and auditable manner is critical to business success. It is equally important that business processes are applied consistently across the organization to help avoid issues with regulatory requirements and service level agreements.

Maximo workflow allows the capturing and automating of all asset management business processes, including service complaints, investigations and audits, manufacturing defects or non-conformities, and CAPAs.

This results in more efficient and productive information about the relevant business processes in terms of more consistent performance and quality improvements. Tracking and managing CAPA's throughout the whole process is challenging and can be solved by optimal use of the integrated workflow engine capabilities.

Maximo workflow is designed to manage change and business process optimization more efficiently and quickly. Because rules and logic are not hard-coded into Maximo Asset Management, optimization of business-critical processes to incrementally improve operational efficiency can be done continually. The end result of an effective use of Maximo workflow is a "leaner" process with shorter cycle time from which meaningful and robust reporting capabilities can be derived.

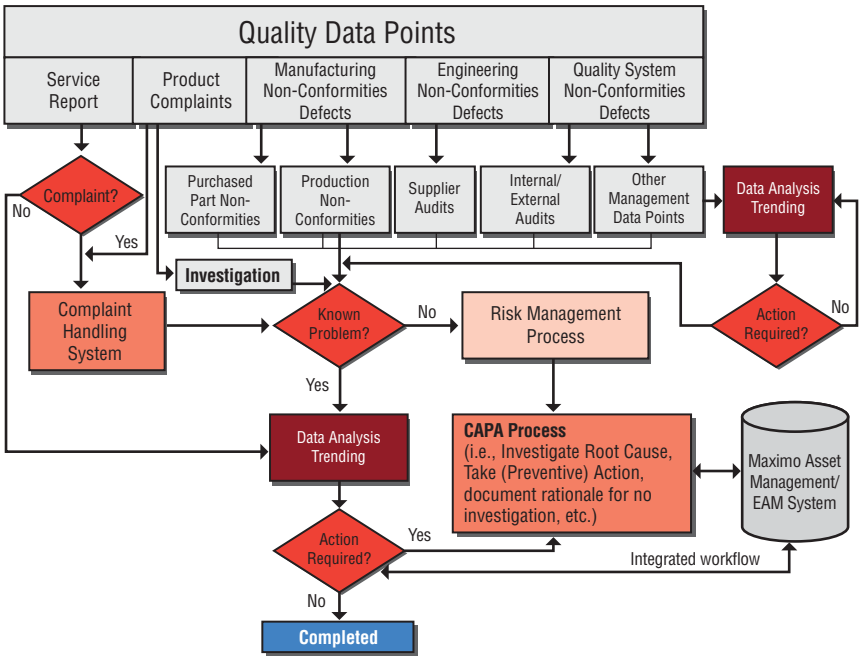
The integrated Maximo workflow capability also helps smooth the flow of information throughout the organization, provides a visual, easy-to-use tool for modeling business processes, and secures a complete audit trail of all actions or activities done, as well as reduces many manual processes and paperwork, therefore helping to increase efficiency and reduce costs significantly.

Highlights

Life sciences organizations are striving to integrate CAPA solutions to improve compliance, reliability and quality.

See Figure 4 for more information on how Maximo Asset Management supports the whole information process.

Figure 4: CAPA Process Flow



Conclusion

Although most life sciences and healthcare organizations are on the road to a CAPA solution, many have not yet achieved a fully integrated and quality-focused system capable of managing service complaints, production defects or non-conformities, and CAPA's.

In view of FDA initiatives, such as "Pharmaceutical CGMPs for the 21st Century – a Risk-based Approach," Process Analytical Technology (PAT), and pressures from regulatory bodies on compliance and quality, many regulated companies are working hard to become high reliability organizations with a clear focus on continuous improvement on quality.

Highlights

Today, life sciences organizations must be able to:

- *Manufacture based on high standards with regard to quality and reliability.*
- *Manage risk.*
- *Make timely decisions utilizing all inputs.*
- *Make decisions that are transparent and focused on long-term sustainability within the context of connected assets.*
- *Get to the root causes of defects or non-conformities.*
- *Monitor, manage and document their efforts to comply with increased regulations.*

Timing, accuracy, integration and availability of data are paramount to meeting ever-increasing standards for quality and efficiency, and to manage risk. These aspects combined provide the common denominator and backdrop to help a company maintain equipment reliability; manage, monitor and document efforts to meet internal and regulatory health, safety, security and environmental requirements; increase organizational effectiveness; enhance human performance; and improve CAPA effectiveness.

Effective CAPA programs help organizations achieve their full potential.

Asset and services management solutions provide the platform to achieve quality, efficiency and reliability improvements. It is in those areas that discrete systems, lacking integration, can allow performance to drift or keep the organization from achieving its full potential.

Key requirements of an effective CAPA program include:

- *A way to identify, classify, analyze, and solve problems related to critical production assets (e.g., tools, measure and test equipment, instrumentation), people, processes and technology.*
- *A systematic approach to resolving problems.*
- *A strong commitment to activities to prevent problem recurrence.*
- *Close integration of CAPA activities to the work management component of the enterprise asset and services management system.*
- *Improvement of a company's ability to meet objectives for quality and risk management.*

Key management systems that effectively capture and analyze asset data are mandatory for successfully introducing a CAPA program that helps organizations manage, monitor and document their efforts to be fully regulatory compliant and to meet high standards for quality, efficiency and reliability.

Companies where assets are critical and strategic must realize that enterprise systems should include asset and service management capabilities. Specifically, the solution must contain critical and key functionality, such as recording and tracking of service complaints or production, defects or non-conformities, problem definition and analysis, change planning and management, configuration control, and release management capabilities. Individually and collectively, these components must be used to properly manage all deviations or non-conformities while helping the company to manage, monitor and document its efforts to comply with FDA regulations as well as international protocols, and to help solve the CAPA processes conundrum to maximize efficiencies and minimize costs while continuously increasing product quality.

For more information

To learn more about asset management solutions from IBM, including Maximo Asset Management, please contact your IBM representative or IBM Business Partner, or visit **ibm.com**/tivoli or maximo.com

About Tivoli software from IBM

Tivoli software provides a comprehensive set of offerings and capabilities in support of IBM Service Management, a scalable, modular approach used to deliver more efficient and effective services to your business. Meeting the needs of any size business, Tivoli software enables you to deliver service excellence in support of your business objectives through integration and automation of processes, workflows and tasks. The security-rich, open standards-based Tivoli service management platform is complemented by proactive operational management solutions that provide end-to-end visibility and control. It is also backed by world-class IBM Services, IBM Support and an active ecosystem of IBM Business Partners. Tivoli customers and partners can also leverage each other's best practices by participating in independently run IBM Tivoli User Groups around the world – visit www.tivoli-ug.org

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Produced in the United States of America
03-07

[1] FDA's Quality System Regulation CFR 820
[2] Refers to Non QSIT inspections
[3] 21 CFR Part 820.198
[4] 21 CFR Part 211.198
[5] 21 CFR Part 606.170
[6] 21 CFR, Part 820

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