



**Tivoli** software

## Asset management for the life sciences industry.



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### Executive summary

In the heavily regulated life sciences industry, a dynamic regulatory and business climate and increasing global competition drive companies to optimize capital asset performance and seek to minimize operational risk. Asset management solutions directly address these critical concerns by enabling executives to better manage the assets that directly impact business performance, such as manufacturing equipment, precision instruments, warehouse machinery, and computing equipment.

A unified, enterprise-wide asset management platform can serve to help reduce compliance cost and risk, maximize asset utilization and performance, boost product quality and reduce overall IT complexity. Key features required for life sciences implementations include support for electronic signatures mandated by U.S. Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (CFR) Part 11, support for preventive maintenance and instrument calibration activities, and software validation compliance support. Also essential are the ability to integrate asset management processes with existing business systems, and a standards-based, adaptable architecture to address evolving IT requirements for interoperability and manageability.

This paper outlines important strategic considerations for implementing asset management in life sciences organizations. It also describes the IBM Maximo® asset management solution for the life sciences industry.

### **The business value of asset management**

Life sciences companies face stiff challenges to their long-term profitability in the form of mounting regulatory pressures, increasing price controls, rising quality expectations, and a global competitive landscape transformed by consolidation. Looking at pressures of drug patent exclusivity, stronger generic competition and rising research and development costs, it is more important than ever to deliver sustainable competitive advantage through improved capital asset utilization and performance as well as reduced operational risk.

An asset management solution supports these objectives by giving senior management the ability to achieve visibility of all assets critical to the performance of the business, enterprise-wide, in close to real-time. Assets can range from stand-alone instruments and manufacturing equipment to the facilities that house them, as well as vehicles, warehouse machinery, and IT assets like servers, desktops, laptops and mobile devices. Asset management also facilitates management of service providers to drive higher service levels.

By managing critical assets more closely, life sciences companies can:

- Improve the uptime of critical, revenue-generating assets through more efficient and timely maintenance.
- Reduce the costs of procuring, deploying, managing, tracking, maintaining and retiring assets through increased business process efficiency.
- Reduce asset-related compliance risk by timely instigating preventive maintenance and instrument calibration activities and documenting results.
- Reduce IT complexity through business process integration, while leveraging the value of current IT investments such as Enterprise Resource Planning (ERP) systems.
- Improve product quality and reduce time to market by enhancing overall manufacturing productivity and efficiency.

## Highlights

Automating compliance-related activities can help companies reduce the risks and costs associated with non-compliance.

By supporting a more efficient flow of information within and among critical business processes, asset management solutions can enable life sciences companies to better address key areas of focus directly related to profitability, including:

- Reducing compliance-related costs and risks.
- Optimizing asset performance.
- Maximizing product quality.
- Reducing IT complexity.

### **Reducing compliance-related costs and risks**

Reducing the costs and risks of non-compliance is a focal point for improving quality, performance and profitability in life sciences companies today. Many seek to achieve these reductions by adopting a more strategic, risk-based approach to managing compliance. The goal is to “build compliance in” by automating compliance-related activities.

Assets in a life sciences working environment do relate directly to compliance risk in several important ways. For example, assets that are maintained or cleaned improperly can contribute to increased risk of non-conformities, or to quality issues in production batches. An asset management solution can help mitigate these risks by helping to ensure that assets are maintained in accordance with specifications, regulations, and the needs of the business. The solution can also support closer compliance with regulations that relate to IT systems.

### Highlights

Deploying a single application that can manage all of a company's critical assets across the entire life cycle can help reduce the cost of compliance.

The way assets are managed can also impact compliance. In any regulated environment, a lack of standardization of applications can significantly impact the cost of compliance by increasing the complexity of data collection associated with documenting compliance efforts, as well as by multiplying software validation costs. Thus, deploying a single application that can manage all of a company's critical assets across the entire life cycle can help reduce the cost of compliance. As an example: more and more companies in life sciences and healthcare are adopting a risk-based orientation to managing manufacturing and quality processes, as advocated by the U.S. FDA in their report *Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach*.<sup>1</sup> The FDA's new risk-based approach to its regulatory role impacts asset life-cycle management in areas such as change control and auditing, underscoring the value of a single, authoritative source for asset change control data.

#### ***Compliance with FDA 21 CFR Part 11***

For life sciences organizations it is essential that asset management software comply with applicable regulations governing software and electronic records. In particular, as more and more life sciences organizations move to reduce the volume of paper records in line with the trend to "go paperless," FDA 21 CFR Part 11, which provides requirements for the use of electronic records and signatures, becomes increasingly relevant.

21 CFR Part 11 also provides guidelines for specific audit controls required to comply with document security regulations, which asset management software must also support. These include controls and warnings for user logins, the need to re-log in when a session is not continuous, and tracking the full change history for significant documents. At the same time, an electronic verification system should help streamline the audit process for all parties involved.

### ***Software validation support***

Another compliance issue that directly affects information systems is computer system and software validation. This process confirms that a specific system meets the intended use, operates as designed and has the built-in features necessary to ensure that data entered into and stored by the system is sufficiently protected from unauthorized access or alteration. Its primary goal is to support a high standard of product quality. The FDA's *General Principles of Software Validation: Final Guidance for Industry and FDA Staff* defines software validation as:

A confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.<sup>2</sup>

In other words, validation involves performing a series of tests that verify that the software or hardware is operating according to the customer's User Requirements Specification (URS) and meets applicable regulations, such as 21 CFR Part 11, or as recommended in The Good Automated Manufacturing Practice Guide for Validation of Automated Systems in Pharmaceutical Manufacture (GAMP4).<sup>3</sup> Any IT system that processes or stores data about product safety, efficacy, purity, etc., as well as any system that interacts with such a system, must be validated. This includes software that is itself a medical device, and software that supports and/or manages drug production or assets employed in drug production.

Critical data that may be stored in asset management applications includes maintenance, repair, inspection, and calibration data. The application should provide a robust level of security and configurability to allow organizations to track and protect relevant records. In addition, the application should ideally support the validation process itself, such as through support for Quality Assurance testing, documentation, and development of policies and procedures related to its implementation and use.

***Support for Process Analytical Technology***

Process Analytical Technology (PAT) is an initiative of the U.S. FDA to encourage life sciences companies to design, analyze, and control manufacturing processes through real-time measurement of critical quality and performance attributes of raw and in-process materials.<sup>4</sup> The goal of the initiative is to help optimize final product quality.

Adoption of the PAT framework not only helps ensure continuous compliance with FDA regulations, but offers bottom-line business benefits to manufacturers who can thereby leverage greater process understanding. Process problems and failures can be minimized by using analytical technology to reduce variability of critical process parameters to identify and address potential deviations before they occur.

PAT specifically encourages the analysis of process data to identify “critical to quality” parameters. This approach is very much in keeping with the trend in many manufacturing environments to augment traditional “plan and execute” business processes with “sense and respond” capabilities, in turn driving increased use of “sensored” systems throughout production and distribution processes.

In this context, it is valuable and synergistic if an asset management solution can manage these advanced devices and systems in addition to more conventional technology.

## Highlights

An asset management solution can enable maintenance best practices, increase labor efficiency and integrate asset history functions.

### **Optimizing asset performance and asset utilization**

Non-optimal asset performance and utilization of assets reduces operational efficiency, which can slow time to market, increase lost batches and reduce throughput. Reduced asset performance may also reflect inadequacies in maintenance, repair, inspection, calibration and other processes that directly affect product quality and employee safety. By improving asset performance, life sciences companies can reduce line outages and other forms of production downtime; drive down costs associated with defects, waste, over-fill, etc.; optimize material yield; and improve distribution efficiency.

An asset management solution can improve asset performance across a wide spectrum of processes, including maintenance, inventory and monitoring.

### ***Adopting maintenance best practices***

An asset management solution enables life sciences companies to adopt maintenance best practices, thus maximizing asset performance and production reliability while minimizing the cost of keeping assets in operation. Among the ways that a comprehensive asset management solution can support maintenance best practices include:

- Scheduling preventive maintenance activities during planned downtime to help maximize asset utilization and improve return on assets.
- Maintaining historical and performance data for high-value assets.
- Monitoring critical levels, readings and event-based conditions.
- Automatically generating compliance documentation.

### ***Improving labor efficiency***

Sophisticated asset management systems provide all the information required to execute work orders more efficiently, helping to reduce search time and increase actual “wrench time.” For example, an integrated e-catalog and indirect procurement capabilities can help maintenance technicians identify needed repair parts and better ensure they are available when required.

An asset management solution ideally should also support mobile access to asset information pertaining to work orders, maintenance best practices, parts inventory, etc., to help increase productivity not only for maintenance technicians but also shipping and stockroom staff. Real-time data access can also enhance asset monitoring, scheduling, operational analysis and planning functions.

***Managing asset history***

A key component of an asset management system is to link essential asset historical data to purchasing, redeployment and asset retirement planning processes for asset life-cycle management purposes. Integration of these capabilities serves to enhance license compliance and to streamline the management of lease, warranty and service contracts. An improved ability to manage asset history also provides better decision support for asset provisioning, configuration, tracking and life-cycle activities.

***Maximizing product quality***

Every life sciences company seeks to deliver products of the highest possible quality where life, health and well-being are at stake. In line with the FDA's guidelines, as well as regulations like the 21 CFR Parts 820 and 210-211, many organizations have adopted quality inspection processes and other frameworks that support continuous improvement of product quality; e.g. the U.S. FDA's Quality System Inspection Technique (QSIT).<sup>5</sup>

***Support for instrument calibration***

Calibration of precision instruments and devices is essential to confidence in the accuracy and precision of measurements such as liquid volumes. If calibration is not performed in line with business goals, regulatory requirements, and manufacturers' specifications, processes involving the equipment in question cannot be deemed to be reliable due to the increased possibility of instrument error. Product quality may therefore be compromised and compliance risk increased.

## Highlights

Asset management solutions can enable more effective collaboration activities.

All companies operating in regulated environments must calibrate their precision instruments. 21 CFR Parts 210 and 211 require:

The calibration of instruments . . . at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy/precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments . . . not meeting established specifications shall not be used.

Asset management solutions can directly support management of calibration activities by incorporating features to integrate documentation, validation, applicable standards and tolerances, and traceability data for all calibrated assets. Specifically, it should help track calibration costs, support the integration of calibration data with other business systems such as Laboratory Information Management Systems (LIMS) or Manufacturing Execution Systems (MES), and allow the tracking of replacement instruments. More effective calibration activities can result in improved worker safety, product quality and compliance efforts, along with reduced equipment downtime.

If an asset management solution supports mobile access to asset data, the addition of mobile calibration capabilities can enable companies to automate calibration processes end-to-end. Using hand-held computers, technicians gain real-time access to all relevant calibration specifications, tolerances and related data during their calibration rounds. Mobile calibration likewise eliminates data entry delays and paperwork errors, streamlining compliance documentation production and supporting optimal asset reliability.

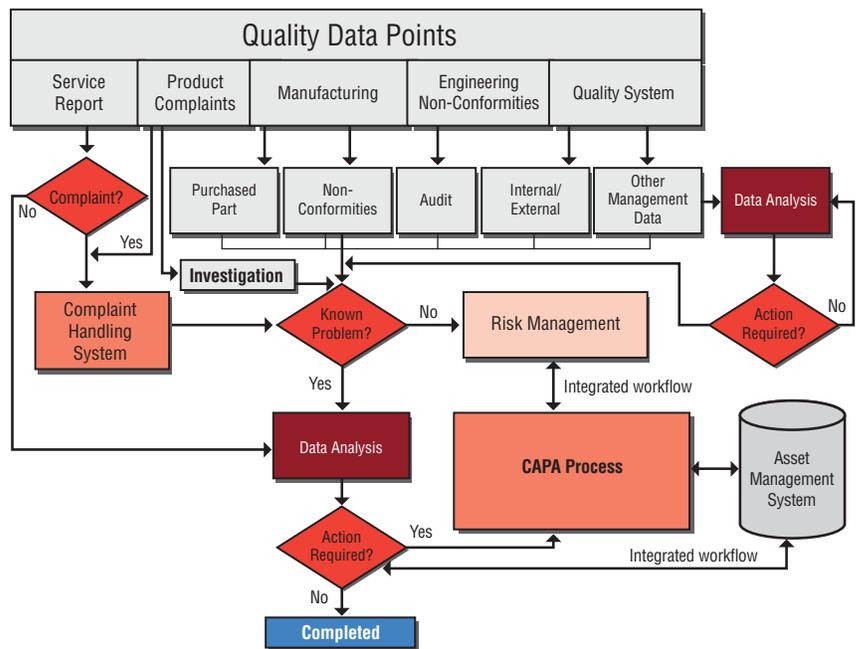
### ***Support for Corrective Action and Preventive Action***

A major component within QSIT is Corrective Action and Preventive Action (CAPA). The purpose of CAPA activities is to collect and analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to address the issues and prevent their recurrence.

CAPA is the logical starting point to begin inspecting for medical device reporting, corrections and removals, and medical device tracking programs, which relate to a company’s post-market activities. The implementation of CAPA systems has led to measurable reductions in requirements for corrective action across the medical products industry. Regulations require medical device manufacturers and importers to promptly notify the FDA and possibly other regulators of any correction or removal.

An asset management solution can directly support a wide range of asset-related CAPA processes across all critical asset types, such as measurement and test equipment and instruments, as well as all other production, facilities, transportation and IT assets, as shown in Figure 1. It can automate the capture of service complaints, problem investigations, manufacturing defects or non-conformities, and other CAPA-related data pertaining to assets.

**Figure 1: How asset management can support CAPA processes**



*This diagram shows the process of managing Corrective and Preventive Actions and how the CAPA process interacts with the enterprise asset management system.*

For example, a full-featured asset management solution enables life sciences companies to:

- Enter, track and manage data pertaining to CAPAs taken on assets, including problem reports, audit results and failure analyses.
- Integrate corrective action data with asset problem management.
- Provide configuration management data in support of root cause and analysis investigations.
- Automate incident notification relating to CAPAs.
- Support effectiveness analysis with ongoing asset performance data.

#### **Reducing IT complexity**

Life sciences companies have traditionally managed different categories of assets separately, using non-integrated and department-level applications. Consolidation and analysis of these diverse “islands” of asset data for decision support purposes has not been practical or cost-effective in many instances.

As a result, life sciences executives have suffered from a lack of control over critical assets, lack of visibility into asset status and performance, as well as lack of information about asset life. This has invariably led to poorly informed decisions that have negatively impacted metrics like return on investment, return on assets, and operational equipment efficiency. The lack of an executive-level view on assets has also increased the cost of regulatory compliance. When the process for obtaining asset-related compliance data requires access to multiple systems, it becomes inherently more time-consuming, labor-intensive and error-prone.

Life sciences enterprises can find significant value in rationalizing multiple systems with a unified asset management solution that can efficiently manage the operation and maintenance of all types of critical assets across their respective life cycles, to provide optimal levels of service and return on investment while streamlining validation processes.

### ***Managing IT assets***

For IT, the ability to optimize and manage all IT-related assets and processes is critical to cost-effective service delivery and alignment with business goals. Without a holistic IT service management (ITSM) solution with support for best practices, it can become difficult to simultaneously minimize costs, maximize return on assets and comply with service level agreements (SLAs). This is especially true in heavily regulated life sciences environments, where the integration of ITSM with asset management can facilitate the inclusion of IT assets and activities into the validation process.

The ability to manage IT assets alongside all other corporate assets using a common solution has the further significant benefit of simplifying the IT infrastructure and supporting consolidation of multiple, disparate asset management and ITSM systems – resulting in significant cost savings. Given the unrelenting pace of mergers and acquisitions in the life sciences industry, the ability to extend a unified asset management solution to manage newly acquired assets is all the more valuable.

### ***Improved corporate performance***

Asset management can help drive improved corporate performance within life sciences companies focused on increasing output and streamlining compliance efforts. Its ability to integrate key business processes across all types of assets, enterprise-wide, can help reduce costs and enhance overall productivity, leading to stronger profit margins. A unified asset management solution also provides greater executive control by allowing asset performance to be measured against clear expectations as specified in asset-related SLAs.

## Highlights

Maximo Asset Management allows life sciences companies to consolidate multiple asset systems.

### **A complete asset management solution for life sciences companies**

IBM Maximo Asset Management, part of the IBM Tivoli® software portfolio, is a comprehensive suite of asset management solutions that enables life sciences companies to streamline compliance activities, improve product quality, increase maintenance productivity, and reduce IT and operational costs.

Maximo Asset Management scales to manage asset classes across the enterprise – including test and monitoring equipment, precision instruments, IT assets from PCs to handhelds to network equipment to mobile phones, fleets of vehicles (including aircraft), and facilities like plants and offices. Likewise, Maximo software offers a full complement of features to optimize the performance of critical assets across their life cycle, from planning through procurement, deployment, tracking, maintenance and retirement. This breadth of capabilities allows a global life sciences enterprise to consolidate multiple asset systems onto one solution platform.

With Maximo Asset Management, all job plans, work histories, safety plans and CAPA reports, are accessible in real-time and in a paperless system. Built-in workflow capabilities allow organizations to automate asset-related business processes, including service complaints, corrective/preventive actions, manufacturing non-conformity reports, etc. to help eliminate paperwork and manual processes. Optional Maximo Mobile capabilities bring relevant data to the point of performance, improving service quality while reducing time spent on paperwork and data entry.

***Features for the life sciences industry***

IBM Maximo for Life Sciences, an extension of Maximo Asset Management, shortens time-to-value and reduces compliance costs with built-in asset management capabilities that directly address the specific needs of life sciences companies. These features include:

- Electronic signatures. Maximo e-Signature and e-Audit features fully support all 21 CFR Part 11 requirements, including audit trails and document security controls.
- Calibration support. Maximo Instrument Calibration provides processes for calibration activities, documentation of calibration history, calibration data validation, and standards/tolerances and traceability/reverse-traceability references for all calibrated assets, greatly simplifying the management of calibration activities. Built-in Maximo work management capabilities make it easy to define and enforce calibration intervals for each asset, including the automatic generation of work orders. Maximo Mobile Instrument Calibration enables end-to-end automation of calibration processes using hand-held computers.
- Software validation compliance support. Maximo software provides a high level of security, stability and configurability to ensure that companies can identify, track and protect records that concern Good Manufacturing Practices (GMP). The IBM Maximo Compliance Assistance Documentation consists of a set of quality assurance test cases, business process templates and accompanying documentation that life sciences customers can build upon to develop more compliant document policies and procedures related to the implementation and use of Maximo software in their organizations.

## Highlights

Maximo Asset Management is built on a standards-based service-oriented architecture, enabling business agility and IT flexibility.

### ***Integration with other applications***

IBM and the Maximo software development team are working in close concert with life sciences customers to ensure that Maximo software helps meet the needs of the industry. To support the flow of asset-related data to and from existing systems common in life sciences environments, Maximo Asset Management offers integration with a wide range of financial/ERP systems, MES, LIMS, and Supervisory Control And Data Acquisition (SCADA) systems, as well as most popular document management systems.

### ***The advanced Maximo architecture***

Advanced, component-based architectures based on open standards like Java™, XML, Web services, and Lightweight Directory Access Protocol (LDAP) are crucial to business agility and the alignment of IT with business goals. A standards-based, adaptable foundation also helps IT reduce costs by simplifying interoperability and manageability, while enabling improved performance. Standards-based solutions also reduce the risk of vendor lock-in, and they support a wider choice among products and vendors.

Built on a standards-based, services-oriented, Internet-ready architecture, the Maximo Asset Management suite of solutions offers strong, long-term value with uncommon flexibility and reconfigurability and freedom of choice. Maximo software is built from the ground up on the Java 2 Platform, Enterprise Edition (J2EE™). Leveraging the J2EE specification and the underlying J2EE framework, Maximo software's component-based application design enables reuse within the application, as well as integration with external applications. Deploying Maximo Asset Management on an open, standards-based, J2EE-compliant application server platform provides customers with a solution that protects their investment today and provides options for growth into the future.

## Highlights

More than 175 life sciences companies worldwide are using Maximo software today, including the thirteen largest life sciences enterprises.

Support for Web Services is provided within Maximo software via platform-level services definition and provisioning. This framework provides enterprise-level application services and business process coordination between Maximo Asset Management and other enterprise systems or solutions such as portals. Web Services are dynamically generated based on each specific configuration, for optimal service-oriented architecture (SOA) support and upward compatibility with future releases.

### ***A proven solution***

A proven and innovative solution, Maximo Asset Management is the leading asset management software in the life sciences industry. More than 175 life sciences companies worldwide are using Maximo software today, including the 13 largest life sciences enterprises.

Life sciences companies operate with a focus on quality because human life may ultimately be at stake. Maximo software has been developed with a similar focus on quality to meet the needs of its life sciences customers. This emphasis on quality is reflected in the long-standing practice of involving life sciences customers directly in Maximo product development.

- Life sciences customers have participated in the design and content of the Maximo for Life Sciences industry solution, to ensure that the product appropriately automates key business processes to improve efficiency and reduce compliance risk.
- An active Life Sciences Industry User Group, with the goal of sharing information, experience and maintenance best practices, creates solid customer relationships and leads to improvements in customer retention rate.

### Summary

Asset management solutions can help life sciences companies deliver sustainable competitive advantage through improved capital asset performance and reduced operational risk.

By improving executive decision making while supporting a more efficient flow of information within and among critical business processes, asset management solutions can enable life sciences companies to more effectively reduce compliance-related costs and risks, optimize asset performance, maximize product quality and reduce IT complexity.

Maximo Asset Management is a complete asset management solution for life sciences enterprises. Built on a standards-based, Internet-ready architecture, Maximo software can scale in size and to manage all enterprise asset classes, while integrating smoothly with existing investments. Built-in workflow capabilities allow Maximo software to automate a wide range of business processes in support of CAPA initiatives, paper records reduction, mobile applications and more.

Specific Maximo Asset Management features for the life sciences industry include:

- 21 CFR Part 11 compliant e-signatures, audit trails, and document security controls.
- Robust support for calibration activities, including mobile calibration data collection.
- Comprehensive support for software validation activities.

By acting as a unified, enterprise-wide repository for all asset-related information, Maximo Asset Management gives senior and operational management the ability to view and manage asset performance from a corporate perspective. By managing critical assets more closely, life sciences companies can improve the uptime of critical revenue-generating assets, reduce the costs of acquiring, maintaining and even disposing of assets, and, ultimately, increase shareholder value.

**For more information**

To learn more about IBM Maximo Asset Management, please contact your IBM representative or IBM Business Partner, or visit [ibm.com/tivoli](http://ibm.com/tivoli)

**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](http://www.tivoli-ug.org)



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Somers, NY 10589  
U.S.A.

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<sup>1</sup> Available online at: [www.fda.gov/Cder/gmp/gmp2004/CGMP%20report%20final04.pdf](http://www.fda.gov/Cder/gmp/gmp2004/CGMP%20report%20final04.pdf)

<sup>2</sup> Available online at: [www.fda.gov/cdrh/comp/guidance/938.html](http://www.fda.gov/cdrh/comp/guidance/938.html)

<sup>3</sup> Available online at: [www.ispe.org](http://www.ispe.org)

<sup>4</sup> For more information please see: [www.fda.gov/Cder/OPS/PAT.htm](http://www.fda.gov/Cder/OPS/PAT.htm)

<sup>5</sup> For more information see: [www.fda.gov/ora/Inspect\\_ref/igs/qsit/qsitguide.htm](http://www.fda.gov/ora/Inspect_ref/igs/qsit/qsitguide.htm)

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