

UNLOCKING VALUE WITH A DIGITAL QUALITY MANAGEMENT SOLUTION



Honeywell

**Sparta
Systems**

salesforce global strategic partner

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THE QUALITY IMPERATIVE

Companies in industries such as pharmaceutical, chemical, personal care, and medical device continue to feel growing pressure around the issues of quality and compliance. When attempting to sort through these complexities, it is imperative that organizations understand two key fundamentals.

“Get it right.” This means leveraging an in-depth understanding of the complex regulations that govern quality and compliance (21 CFR Part 11 is a typical example), and finding a way to be absolutely certain that the company’s best practices and record-keeping can stand up to an audit.

“Get it done.” This requires the deployment and maintenance of systems that are efficient and cost-effective. And can deliver the greatest overall value. This refers to the critical need to tap into brand new efficiencies and avoid the pitfalls of disparate or unnecessarily complex systems.

Together, these issues are at the heart of the conundrum for many players in the industry. This eBook will address these pressing concerns, and discuss how a cloud-based solution that leverages best practice processes can solve them.



COMMON INDUSTRY CHALLENGES



IMPLEMENTATION OF BEST PRACTICES

Industry best practices are typically well established, and following them not only ensures quality – it also helps with regulatory compliance.



SCALABILITY

Companies of all sizes seek to grow, and quality systems should be able to grow with them, not hold them back.



SYSTEM FRAGMENTATION

Avoidance of quality silos is one of the most important keys to efficiency and rapid response to quality events.



COST OF OWNERSHIP

Most IT organizations are already resource-constrained. Minimal dependence on these resources will mean faster implementation and – in the case of web-based solutions – guarantee on-time maintenance and upgrades.



CONSIDERING COMPANY DEMOGRAPHICS

Along with these common challenges, companies of different sizes and levels of maturity have specific needs. The ideal quality management solution needs to be able to address these varying requirements.

MATURING START-UPS

Developments in the change to manufacturing have given rise to a new generation of start-ups run and staffed by individuals who have strong scientific backgrounds, but little experience with the nuts and bolts of doing business in a highly regulated environment.

Dealing with quality and compliance at the production level is beyond their area of expertise. Frequently, business executives or those with previous similar experience are engaged, but such individuals are both hard to find and expensive.

MID-SIZED COMPANIES

It is not unusual for mid-sized companies that have grown over time to have a “team of one” to handle all issues related to quality and compliance.

Typically, that individual (or perhaps a small team) will be managing multiple, disparate systems – e.g. complaints may be handled with one dedicated software package, documents with another and CAPA with Excel spreadsheets. Some functions may even be paper-based.

This situation results in too much work for too few people, particularly given the fact that regulations are constantly changing and evolving, as are the definitions of what constitutes a best practice.

GLOBAL ENTERPRISES

Obviously, large international companies are no strangers to quality management and regulatory compliance. That said, the legacy technology in place in many large companies, once state-of-the-art, may not always be well-suited to today’s needs.

One example is the need for mobility. Another is the cost of maintaining manual, paper-based and/or outdated legacy systems when less costly web based options may be more robust, scalable to suite their growing needs.

OUTSOURCING AND OFFSHORING TRENDS

One challenge that companies of all sizes face is the outsourcing of business activities that were once performed in-house, often to foreign suppliers.

Today's supply chains are global, which means companies that have struggled with one set of laws and regulations must now understand and comply with several. Raw materials often come from countries where practices are lax in comparison to the U.S. and Europe, a fact that cannot be ignored.

Also, there are practical barriers to efficiency with modern supply chains, such as language issues and problems created by different time zones.



SOLUTION REQUIREMENTS

Today's manufacturers are striving to implement solutions that are based on best practices, support growth, provide unified data visibility, and are efficient and cost-effective to manage.

When selecting a quality management solution, companies should consider the following:



INTEGRATED BEST PRACTICES



A UNIFIED SYSTEM



SCALABILITY



FOCUS ON INNOVATION



MINIMAL IT IMPACT

“ORGANIZATIONS ARE STARTING TO RECOGNIZE THAT THERE IS A SOLUTION THAT CAN DELIVER IT ALL.”



INTEGRATED BEST PRACTICES

The regulations related to best practices are often ambiguous, and the only way to know what is truly acceptable in the real world is through experience. Companies should not have to reinvent the wheel when it comes to accepted best practices and validation criteria, particularly when expert support is available.

For example, best practices are integrated into every module of Sparta's cloud-based quality management system, TrackWise Digital. This not only helps accelerate time to value through rapid deployment, but also helps simplify and standardize GxP compliance. Industry-proven workflows and business rules help quality teams automate the capture, routing, notification, delivery, escalation and approval of quality events, while supporting the reporting needs to ensure visibility across the organization.

With 25 years of experience in the field of quality management, more than 800 installations and 850,000 users in 30 countries worldwide, Sparta is ideally suited to provide the expertise needed to integrate best practices into its systems. In fact, more than 600 companies leverage Sparta Systems solutions today.



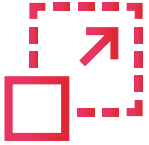
A UNIFIED SYSTEM

Given the numerous challenges facing companies today, many have taken an expedient approach to quality via point solutions, e.g. handling complaints through a dedicated system and using Excel for CAPA. While such an approach can obviously be made to work, it can create problems when a rapid response is required with input from these multiple systems. In addition, data can remain siloed.

Using an end-to-end digital system for all quality-related processes offers closed-loop tracking and reporting throughout the workflow process.

For example, a Change Control record in TrackWise Digital can be linked with an associated SOP document in TrackWise Digital Document Management, which can automatically notify relevant production and quality staff to be trained on the updated SOPs in TrackWise Digital Training Management.





SCALABILITY

The combination of new products and expanding markets in manufacturing is sure to drive growth for many companies. Growth, in turn, means more data and more complexity to be managed.

For example, when an American company starts doing business in Europe, it must deal with a new set of regulations. Companies must take care to invest in a quality management system they won't outgrow at a critical moment in their development.

Fortunately, cloud-based systems such as Sparta's TrackWise Digital are designed to handle growth easily (and transparently to end users), thus eliminating the need to add physical infrastructure, or worse, deploy a whole new system.





FOCUS ON INNOVATION

Part of the digital quality journey is embracing the close ties that quality has always had to innovation and new technologies. The evolution of QMS software is speeding up as organizations find new ways to apply artificial intelligence (AI), machine learning (ML), natural language processing (NLP) and deep learning to complex manufacturing and distribution processes. Therefore, it's important to invest in a QMS solution that can leverage these innovative leaps in quality management.

TrackWise Digital is the industry's first QMS solution to leverage AI for enhancing quality-related decision-making capabilities, providing a shift from reactive to proactive quality. By applying machine learning and natural language processing, TrackWise Digital can auto-categorize the intake of complaints and quality events, unlocking the value of the unstructured text data within quality event records.

TrackWise Digital's AI capabilities help uncover the meaning of that data based on relevant historical information, enabling improved productivity and intelligent decision making across the organization.





MINIMAL IT IMPACT

Migrating to a sophisticated quality management system imposes one more set of demands on IT departments that are typically already working overtime to keep their systems up and running while meeting service level agreements (SLAs). The ideal quality management system is one that makes a minimal impact on IT.

Cloud-based systems accomplish this goal. The database and operating system are always optimized. The provider's servers are always ready to maintain and manage the system. The quality team always benefits from the latest functionality upgrades and security updates, rather than having to wait for IT to find the time to install them.

The IT team, relieved of this burden, can focus on supporting the system users, establishing new data connections, optimizing processes, configuring new levels of reporting and performing other value-added activities.



A TOTAL SOLUTION FROM SPARTA SYSTEMS



QUALITY MANAGEMENT



COMPLAINT MANAGEMENT



DOCUMENT MANAGEMENT



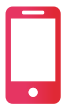
TRAINING MANAGEMENT



SUPPLIER QUALITY MANAGEMENT



QUALITY PROCESS ACCELERATORS



QUALITY ON THE GO



LEVERAGING AI FOR PROACTIVE QUALITY





QUALITY MANAGEMENT

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 **WATCH DEMO**





COMPLAINT MANAGEMENT

The Complaint Management solution enables companies to handle the entire customer complaint cycle in accordance with global regulations, including intake, further investigation, root cause analysis and reporting to regulatory agencies. It comes with pre-built and pre-validated data entry forms to ensure compliance.

Also, like all Sparta TrackWise Digital modules, it is built on the Salesforce platform. This means it can easily integrate with other data stored in Salesforce formats such as accounts, contacts and products, all of which are integral to the complaint handling process.





DOCUMENT MANAGEMENT

The Document Management solution maintains quality records according to regulatory requirements. It helps employees with all documents related to planned or unplanned deviations, risk assessment, root cause analysis and CAPA initiation. It automatically provides employees with regulatory-compliant templates based on the document type.

Documents move smoothly from the working document stage to review to final approval via configurable workflows, resulting in an “effective” document that is viewable by all employees. With this module, the details of paperwork never get in the way of more central, value-creating processes.



WATCH DEMO



TRAINING MANAGEMENT

The Training Management solution manages every aspect of training in accordance with global and ISO regulations, whether training is internal or external.

Managers can track their own and their team's training requirements at a glance. Administrators can easily set up group lists and assignments. Instructors can manage enrollment and sign off on training completion. Individual employees always know where they stand and what they need to do.



WATCH DEMO





SUPPLIER QUALITY MANAGEMENT

The Supplier Quality Management solution allows quality teams to effectively manage and collaborate with suppliers and contract manufactures across the supply chain. It helps you to segment your supplier base, identify your key suppliers, plan and manage to ensure that the capabilities of your suppliers are optimized.

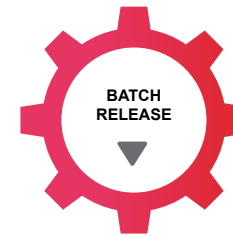
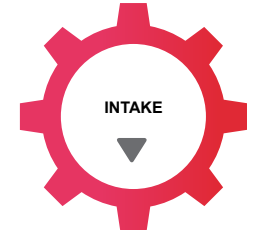
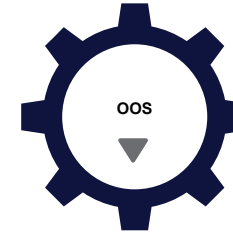
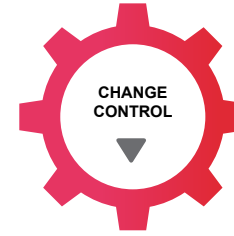
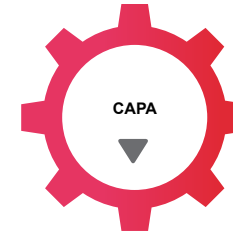
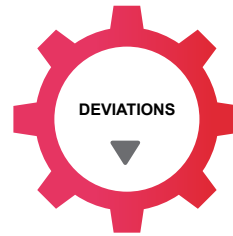
Quality teams can have increased visibility and accountability with suppliers, reducing unintended exposure. The solutions supports collaboration and communication, streamlining quality event activities and supplier data. With robust reporting capabilities and dashboards, your organization has insights into supplier performance and assessments.

 **WATCH DEMO**



QUALITY PROCESS ACCELERATORS

Sparta's Quality Process Accelerators (QPAs) for TrackWise Digital enable companies to meet or exceed regulatory requirements, while supporting rapid deployment. Built on industry best practices and expertise, QPAs help organizations simplify and standardize GxP compliance with pre-defined workflows, forms fields, configurations, and business rules. Modular and adaptable to meet your organization's specific needs, QPAs help reduce risk and accelerate time to value with your TrackWise Digital investment.





QUALITY ON THE GO

TrackWise Digital supports the Salesforce mobile app, allowing users to capture and approve quality events anytime, anywhere.



Reduce cycle time by enabling record approvals on mobile devices



Speed up Audit Assessments/ Checklists execution directly on shop floor using tablets

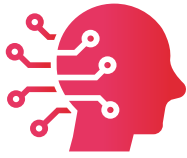


Encourage “see something, say something” culture



WATCH DEMO





LEVERAGING AI FOR PROACTIVE QUALITY

TrackWise Digital is the industry's first enterprise QMS with embedded AI-augmented decision-making capabilities.

AUTO-CATEGORIZATION

By applying machine learning and natural language processing, TrackWise Digital can auto-categorize the intake of complaints and quality events, ensuring critical issues are prioritized swiftly and appropriately. It provides classification suggestions and probabilities so that quality teams can quickly triage the quality record, driving improved productivity and intelligent decision making.

AUTO-CORRELATION

TrackWise Digital also leverages AI capabilities to derive insights across quality data. TrackWise Digital identifies and correlates similar quality events to assist with next best actions.



WATCH DEMO

DEDICATED TO YOUR SUCCESS

Sparta's Services & Support team can help you achieve your quality management goals and support you throughout your quality journey.

IMPLEMENTATION & MIGRATION

The team at Sparta has unmatched experience implementing enterprise quality & compliance management solutions, as well as supporting system consolidation and migration.

RAPID VALIDATION

Our team effectively streamlines the validation process, shortening the time to launch.

EDUCATION

Sparta offers a variety of courses on our quality management solutions to ensure that your team has the experience and knowledge needed to maintain and enhance your Sparta QMS solution.

TEAM & TALENT

Our Support teams are uniquely positioned to help our customers on their path to transform quality management.

SPARTA SYSTEMS YOUR TRUSTED PARTNER

For over twenty-five years, Sparta has worked side by side with companies in life sciences, consumer products, discrete manufacturing and more across the globe. That partnership not only supported the implementation of quality best practices, but helped define those best practices. The combination of best practice integration, cloud-based delivery and the digital quality approach makes Sparta's TrackWise Digital solution the ideal system for companies seeking the ultimate in modern quality management.

Companies have found a huge benefit in leveraging TrackWise Digital for a cost effective and fully scalable quality management solution. These companies have seen cost savings and overall efficiencies across the board. They have also been able to deploy the system and train employees in record time.

The industry has spoken and many companies have decided their legacy QMS solution or manual processes are not equipped to meet today's complexity and regulatory challenges. Competitive companies are seeking solutions that can keep up with emerging rigors while ensuring product safety and supporting a culture of quality across the supply chain. Hundreds of companies are using TrackWise Digital to be ready for what's next.



Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.

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