

3 Paths to Proactive Quality

Your digital journey begins here

WHITEPAPER



Honeywell

 **Sparta
Systems**

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Destination: Proactive Quality

You already have a high-performing quality management system (QMS). But if one step could make it even more effective in ...

- Safeguarding patient safety
- Improving product quality and ensuring product efficacy
- Maintaining continuous product supply
- Reducing costs
- Meeting compliance demands

... would you take it?

Businesses that achieve proactive quality recognize it as a competitive differentiator to deliver business growth and customer value. A culture of quality enables:

- Agile, integrated, scalable quality systems across the organization
- End-to-end integration that drives rapid launch capabilities
- Preparation for and adherence to regulatory and industry trends
- Patient-centric product designs and solution delivery
- Predictive analytics to power strategic decision-making and reduce risk and recalls
- Minimal quality events and optimal responsiveness
- Streamlined process and operations to optimize total cost of quality

Imagine a 90% reduction in the time required to release a new product to market.¹

Risk of Inertia

Quality management has one overriding goal:

Drive better outcomes—for patients, for consumers, for your partners and for your business.

A rapidly changing landscape and pace of innovation create constant tension and demand continuous quality improvement as you work to—

- Meet a growing demand for precision medicine and real-time access to information
- Enable rapid innovation and delivery of novel products
- Increase yield while meeting the needs of a constantly shifting industry
- Manage change controls across an increasingly complex ecosystem of products, processes and supply chain partners

- Triage thousands of complaints and mitigate recurring quality events
- Modernize quality systems to maintain infrastructure integrations and protect your investment

With this approach, you can achieve—

- Real-time analysis of data from your operations systems (LIMS, MES, ERP, CRM)
- Proactive resolution of process and product deviations and nonconformances
- Signal detection to identify trends for effective root cause analysis

It's easy to see why, for life sciences manufacturers, the journey toward digital quality management has become a mass migration. Those who stay put risk being left behind.





But according to KPMG estimates, about 40 percent of quality resources are devoted to “reactive activities” such as corrective actions and complaint handling². A proactive quality approach, powered by a digital QMS engine, helps to break this cycle.

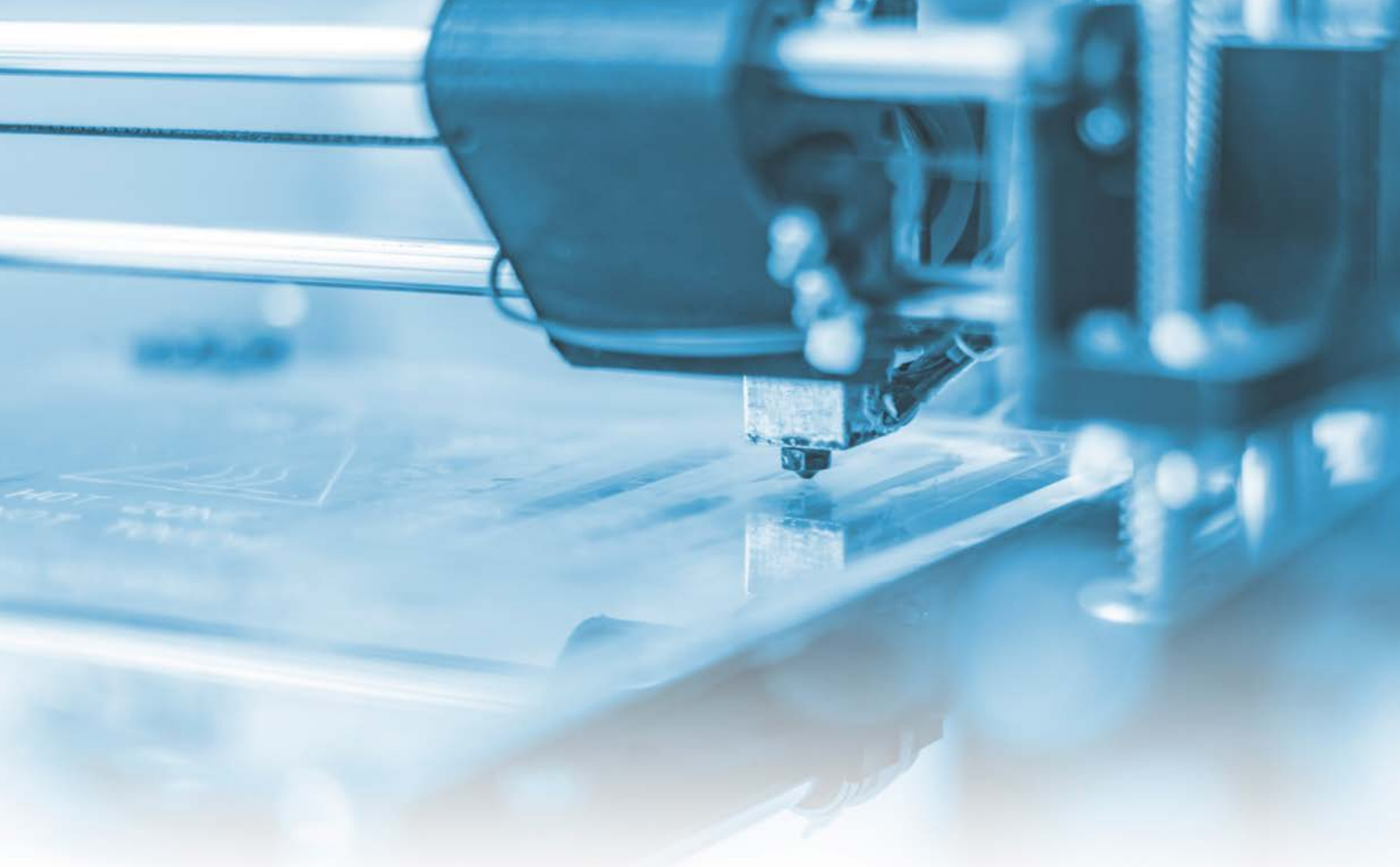
Quality as a Growth Engine

Whether in response to new product developments, evolving technology or global health crises, change in the life sciences space occurs quickly and often. Your quality infrastructure needs the flexibility and efficiency to keep up with your organization's evolving needs:

- Support new business models and revenue opportunities through collaboration and coordination across an expanding network of partners
- Connect quality data across manufacturing and enterprise systems for more actionable insights
- Reduce the total cost of quality by boosting operational stability, predictability and efficiency implementing incremental continuous improvement
- Future-proof both quality and operations by embracing innovative solutions that optimize available and emerging technology

Instead of constantly looking in the rear-view mirror, quality leaders need to shift gears to enable proactive quality.





Your Digitally Powered Vehicle

Advances in technology such as 3D printing and 3D sensors create new possibilities along with new data and insights to streamline processes and automate decisions. The ability to connect quality across physical, human and digital interactions to provide up to the minute, accurate information is key to enabling smarter workers and manufacturing lines.

An enterprise, cloud QMS enables an accelerated path to digital, proactive quality with:

- Improved usability and productivity
- Aggregation of data to leverage Artificial intelligence (AI) / Machine Learning capabilities
- 24/7/365 access to quality events and analytics
- Faster deployment, maintenance and upgrades
- Seamless scalability and integration to enterprise applications

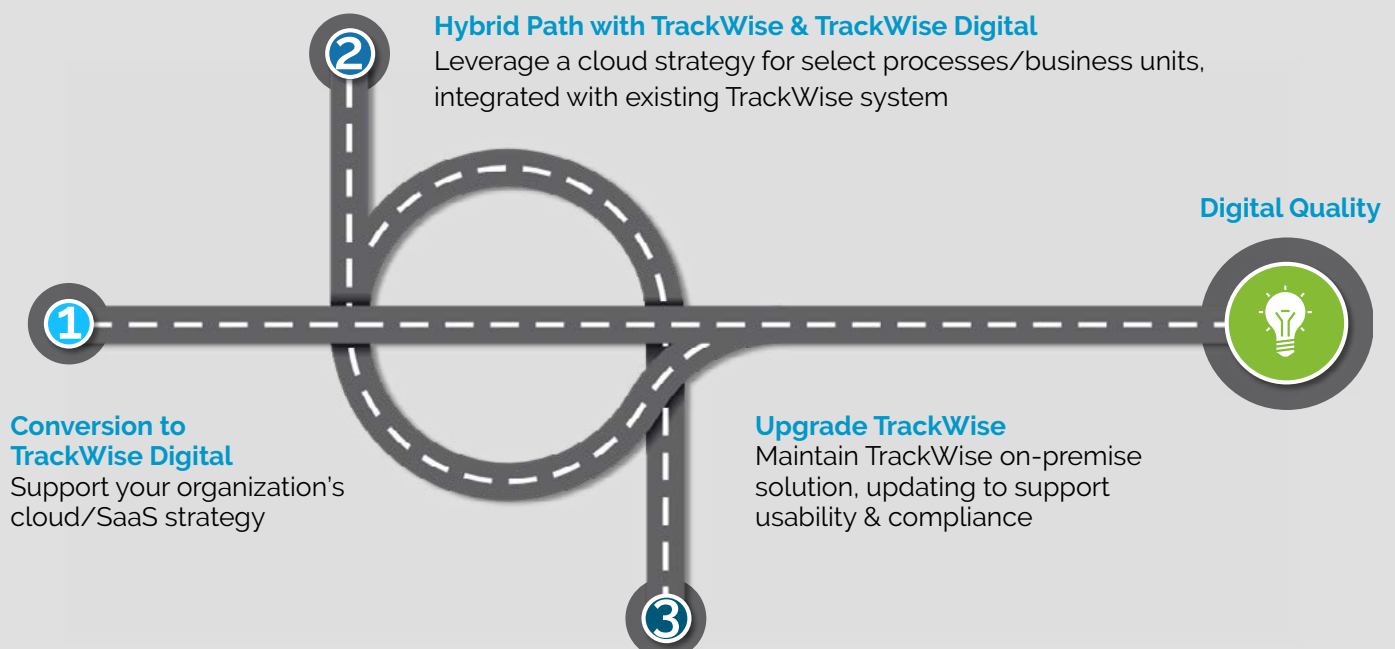
These capabilities mean even better insight into quality data for life sciences manufacturers. And that data powers the type of decision-making that leads to greater efficiency, speed and responsiveness.¹

Supporting the need for high-volume data, application performance, backup and integration can slow down IT and quality teams. It's easy to see why so many businesses are choosing a digitally mature SaaS solution to get the most out of these emerging technologies.

Start Your Journey

Embracing a fully digital approach offers the most benefits, but not every organization is ready to take that leap. Organizations need to go at their own pace, but even a small step forward can reap big rewards.

- 1. Take your bearings.** Assess the current environment to identify key challenges and opportunities. Are your processes harmonized globally? Are your operational systems already providing more data than your QMS can handle? Is your on-prem infrastructure due for an upgrade? Are you effectively managing supplier quality and audits?
- 2. Find your true north.** Determine where you want to be 3 – 5 years from now. What's your strategic vision for quality as a driver of business growth? What are key digital initiatives? Have you set goals to overcome specific quality or operational issues? Do you want to improve visibility and resiliency across your supply chain?
- 3. Map out the landscape.** No matter which path you take, finding the common intersection with other department objectives will help you gain greater buy-in for the initiative.
- 4. Gear up for change.** How is your quality organization structured? Does your current operating, data and governance model support where you want to go? How will you manage change and ensure successful implementation and adoption? Are metrics aligned to strategic goals?
- 5. Converge on a path forward.** Map out the journey that aligns your business ambitions and digital readiness. Users of Sparta Systems' on-premises TrackWise QMS, for example, have three potential paths:
 - Take advantage of a mature, enterprise cloud QMS by converting to TrackWise Digital, Sparta's fully digital, cloud-based QMS solution.
 - Extend quality to suppliers or expand processes with TrackWise Digital in a hybrid strategy.
 - Modernize infrastructure and gain new capabilities with an upgrade to TrackWise 10, available in Winter 2020.





Path 1: Accelerate Towards Digital

Organizations that are ready to accelerate to the benefits of proactive quality can adopt [TrackWise Digital®](#)

This path is a great choice for life sciences manufacturers who:

- Want to optimize quality data analytics
- Have a company-wide cloud-first strategy
- Have one or more digital transformation champions
- Have a Salesforce Center of Excellence or other enterprise applications on the Salesforce platform
- Want to stay ahead of the pack in the use of technology to drive quality
- Are planning Factory of the Future with smart sensors and equipment

Immediate Benefits

For TrackWise on-premises users, migrating to TrackWise Digital has several immediate benefits:

- Enables access to digital documents to support a mobile workforce and culture of quality
- Ease of use and configurability for greater efficiency
- Optimize workflows using pre-validated Quality Process Accelerators
- Leverages Salesforce cloud platform with built-in scalability, integration and development resources
- Provides advanced reporting and analytics to monitor quality events and metrics

Easier Transition to Digital

We won't lie: Data and process migrations requires planning and effort. But TrackWise customers who are ready to convert to TrackWise Digital have a shortcut: TrackWise Transfer. TrackWise TransferSM is an automated solution to migrate data and configuration from TrackWise to TrackWise Digital.

Time-Saving Preconfigurations

TrackWise Digital also provides enhanced, pre-validated configurations in the form of Quality Process Accelerators, which reduce the need for time-consuming modifications and validations. These pre-configurations accelerate implementation and time to value on the TrackWise Digital platform. With Sparta's Quality Process Accelerators, customers can—

- Standardize and modernize quality processes
- Leverage Sparta's 25 years of industry experience and customer council best practices
- Optimize workflows while keeping unique elements of existing business processes
- Ensure compliance with ICH, GMP and GLP regulation and guidance

TrackWise Transfer minimizes risk and reduces migration effort for existing TrackWise customers by as much as 80 percent.

AI Augmented Decisions and Insights

TrackWise Digital features AI-powered workflows to automatically classify, categorize and streamline complaints triage, quality event handling, and complaint intake. This automation enables you to manage larger volumes of complaints and redirect valuable quality resources to high-risk areas.

With AI Insights, TrackWise Digital and TrackWise customers can leverage historical quality data and identify correlations and patterns that were previously invisible. Users can review this data at a glance for more context, learning from existing data and identifying possible trends. With the power of machine learning and natural language processing, Insights can identify recurring or similar events to avoid investigating the same event twice. Systematic identification of related records removes redundancy and adds a higher degree of consistency and traceability to investigations.

The use of artificial intelligence and machine learning can enable Life Science organizations to harness data and turn it into intelligent and actionable insights that enable predictive quality.⁶

Path 2: Extend Digital Quality

No journey is the same. Organizations that want to benefit from digital expansion of their QMS but aren't ready to move fully into the cloud can implement a hybrid [TrackWise/TrackWise Digital solution](#).

This path meets the needs of organizations that:

- Outsource manufacturing or have a complex supply chain
- Have a high volume of complaints
- Have recently acquired a business or product line with independent processes

Immediate Benefits

A hybrid option provides tighter control over your quality data while still enabling you to explore some of the benefits of a digital quality approach. For example, you can continue using TrackWise

on-premises at your existing locations, while implementing TrackWise Digital:

- At new or acquired sites, for faster deployment and affordable scalability
- To qualify and extend processes to suppliers
- To gain insight into the supply chain without giving suppliers direct access to your TrackWise system
- To harmonize Complaints or Intake processes across sites
- To implement AI-based automation

A Unique Opportunity

Sparta Systems is the only provider in the market that offers a hybrid digital QMS solution. With it, you can combine the best of both your TrackWise investment and the TrackWise Digital experience. A hybrid deployment bridges the digital gap, so you can adopt a phased approach to digital quality.

Path 3: Modernize On-Prem

Organizations that want to maintain an on-premises-only QMS can help to protect their data and improve usability by [upgrading to TrackWise 10](#).

Remaining on TrackWise on-prem is an option for companies that:

- Have no digital or cloud initiatives but are interested in enhanced usability
- Are concerned with the risks of an outdated tech stack
- Have a high degree of custom configurations in their TrackWise solution
- Can tap into rich quality data history to use AI insights for faster and better decisions

Immediate Benefits

By upgrading to TrackWise version 10, you can—

- Take advantage of an upgraded tech stack for easier, wider integration with other infrastructure
- Use Intelligent Forms to limit focus to only key information to decrease cycle times
- Enable AI capabilities and Insights to identify recurring events and automate decisions
- Reduce risks associated with unsupported hardware and software

Powerful Automation

TrackWise 10 builds on the familiar structure that customers appreciate with added features to streamline the user experience. With Intelligent Forms, users are presented only the critical information required for each process. This helps new users by zeroing in on updating key information instead of sifting through hundreds of fields, minimizing the burden of a wide-reaching process.

With AI Insights available in TrackWise 10, customers can harness the power of machine learning and natural language processing to automatically recognize trends across similar records and record types based on rich historical quality data stored in the TrackWise system. By understanding related events, Insights can automatically suggest the next best action to significantly reduce time and effort spent on investigations.

Keep up to Speed

Sparta continues to invest in TrackWise with a robust roadmap for improvements and support. But modern quality solutions that meet [regulatory requirements](#) are here to stay — and in many cases, need to be evaluated by regulatory agencies.

Although a full cloud QMS might not be on the immediate horizon for you, a refresh of your TrackWise system should be. Sparta is dedicated to supporting our on-prem solution with updates that help to maintain data security and reduce the risks that accompany older tech stacks. And according to Gartner, an eventual transition to cloud will be easier for companies that maintain modern architectures:

Legacy systems are often seen as holding back the business initiatives that rely on them. When a tipping point is reached ... it's time to look to application modernization to help remove the obstacles.

Choose the Right Travel Partner

Solutions only get you so far. Achieving proactive quality and understanding what it takes to get through each turn requires a partner that knows the landscape inside and out.

With more than 25 years of deep quality management experience in the life science industry, Sparta provides the flexibility and expertise to guide you on your journey and help you reach your destination at your own pace. And Sparta's commitment to quality and innovation means you'll be ready for whatever comes next.

Make Your Move

Taking the first step in any journey can be a difficult decision. But when it comes to quality management, doing nothing is worse than standing still.

Life sciences manufacturers face a challenging landscape, full of competitive and cost pressures and technological disruptions. Increasing process and product complexity demands a QMS that can keep up. Gartner notes that failure to modernize is a competitive disadvantage:

CIOs who do not modernize their data and analytics approaches will limit their own ability to optimize existing processes or create new products with digital approaches.⁵

Life sciences manufacturers can leverage IT as a competitive advantage by taking the first step in their digital journey. Ready, set ... go!

¹Reh, Greg. "2020 Global Life Sciences Outlook." 2020. Deloitte Insights. <https://documents.deloitte.com/insights/2020globallifesciencesoutlook>.

²Handor, Camal; Kapadia, Anuj; van den Heuvel, Roger; van Zijl, Frobert. "Quality 2030: Quality Inside." 2019. KPMG International Cooperative. <https://assets.kpmg/content/dam/kpmg/xx/pdf/2019/09/quality-2030-quality-inside.pdf>.

³Handor, Camal; Kapadia, Anuj; van den Heuvel, Roger; van Zijl, Frobert. "Quality 2030: Quality Inside." 2019. KPMG International Cooperative. <https://assets.kpmg/content/dam/kpmg/xx/pdf/2019/09/quality-2030-quality-inside.pdf>.

⁴Moore, Susan. "7 Options to Modernize Legacy Systems." June 1, 2018. Gartner. <https://www.gartner.com/smarterwithgartner/7-options-to-modernize-legacy-systems/>.

⁵Gandhi, Animesh; Holmes, Brad; Shanler, Michael; Smith, Jeff. "Business Drivers of Technology Decisions for Life Science Organizations." January 22, 2020. Gartner. <https://www.gartner.com/en/documents/3979846/business-drivers-of-technology-decisions-for-life-scienc>.

⁶Matlis, Daniel; McMullin, Ellyn. "AI Drives Shift from Reactive to Predictive Quality." 2019. Axendia, Inc. <https://go.spartasystems.com/eBook-Axendia-AI-Predictive-Quality.html>

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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.

Sparta Systems | 2000 Water View Drive | Suite 300 | Hamilton, NJ 08691 | USA | www.spartasystems.com