
Sparta Systems
3 Steps to Quality in the Cloud
Transitioning to an All-Digital Quality Management System

Introduction

Many small and mid-sized – and even large/enterprise – companies are struggling with quality issues due to outdated or fragmented systems. These systems don't provide the efficiency and visibility needed to manage quality events, ensure industry and/or regulatory compliance and avoid financial risk.

Manufacturing organizations across many industries – from pharmaceutical and biosciences, to high tech electronics and food & beverage – are often passionate about the products they bring to market. However, they may be less so about the day-in, day-out demands of managing quality and compliance.

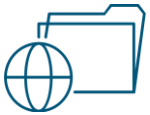
This may explain why so many companies that produce leading-edge products manage quality with systems that are out of date, overly complex, time-consuming to use, and potentially inadequate to their needs.

In spite of all the technology that's available, many quality managers seem reluctant to move forward with dedicated quality management systems (QMS). Instead, they rely on sub-optimal systems that may well slow their company's progress and increase risk.

Typical old-style approaches include:

Paper-based methods to record quality events

Spreadsheets (or collections of spreadsheets)



Homegrown, database-driven systems

In many cases, companies employ a mixture of the above, with different systems for different tasks or different product lines. For example, it's not uncommon for companies to use one system to record complaints, and another, separate system to manage CAPAs. This only exacerbates the more fundamental problem, which is that all of these approaches were designed to gather and store data, not facilitate processes. Quality control demands both.

New, cloud-based technology offers an accelerated path towards a modern system that's both affordable and comprehensive. This eBook details a three-step process for making the move quickly and smoothly.

1 "Improve Quality Maturity by Addressing the Top 5 Challenges." LNS Research. November 2015.

Operational Problems

From an operational perspective, manual and legacy systems create two major problems:

Reduced Efficiency

Manual systems such as binders or collections of spreadsheets often require that data be transcribed from one system to another. And homegrown systems can become quickly outdated or out of maintenance. Keeping up can be a time consuming process in itself. It also invites errors that eventually have to be resolved, creating even more work down the line. In sum, most manual and legacy systems are cumbersome and slow.

Limited Visibility

Without real-time information or a modern dashboard view of events, it is very difficult to keep tabs on what tasks/action items are coming due. Did a complaint initiate the CAPA that was intended? Was a non-conformance issue resolved on time? Questions like these come up on a regular basis, and they can be difficult to answer. It's even more difficult when real-time answers are required and there's no dashboard to provide them.

Business Consequences

These problems with efficiency and visibility have serious business consequences.

Compliance. Creating the reports required by various regulatory bodies with the requisite data in the proper formats is unnecessarily complicated and time-consuming.

Audits. With data residing in multiple locations, it's very difficult to respond to auditors' demands once they show up. In addition, an old or disorganized system makes a bad impression on auditors and affect the outcomes in negative ways.

Vendor management. Collecting and assembling metrics on vendors can be so time-consuming that updating supplier scorecards can take weeks. Not infrequently, the results are out of date by the time they're ready to view.

Financial risk. Quality problems cost money. At minimum, dealing with quality glitches diverts resources from profit-generating activities. In the worst case scenario – a recall – huge sums can be at stake. Most quality events fall somewhere in between, but they all have a negative effect on the bottom line.

21%

of companies have deployed a dedicated quality management system[1]

1 "Improve Quality Maturity by Addressing the Top 5 Challenges." LNS Research. November 2015.

Accelerating Quality Management

In spite of all these problems, there are real barriers to moving to a new system, in the form of time, effort and cost. Many companies don't have the funds or the technical personnel to support the implementation of a traditional QMS. The very term "enterprise" can be intimidating to smaller companies, or companies with sparse IT resources.

Fortunately, technology is evolving to meet the quality management needs of these companies and accelerate their move to a more powerful system. The advent of the cloud is one of the most important developments in this regard, and there are strong indications that its acceptance is almost universal.

of organizations are running applications in the cloud or experimenting with infrastructure-as-a-service[1]

of enterprises have a hybrid cloud strategy, up from 74 percent in 2014[1]

of enterprises are using a public cloud, while 63% of enterprises are using a private cloud[1]

1 RightScale. State of Cloud Report, 2015.

Many companies have adopted “cloud first”, all-digital IT strategies, meaning that business units wishing to have non-cloud solutions need to justify the reasoning behind their choice, and show why an on-premise solution is best.

The cloud approach does indeed have many benefits:

Lower Cost. One of the most interesting cloud-based offerings is software-as-a-service (SaaS). In the SaaS model, the software resides in the cloud, and is accessed via the internet. For SaaS customers, this means no hardware purchases, no installation, no IT staff training, and no maintenance, and none of the costs associated with these. All of these features taken together substantially reduce the cost of quality.

Faster time to value. The fact that there is no set-up with a SaaS offering (no hardware purchase, installation, etc.) not only reduces cost. While IT departments may be involved in evaluating a particular SaaS system, they don’t have to read instruction manuals or get involved in making sure the system works before it goes live, all of which takes time.

Better user experience. Today’s business users have come to expect a consumer-grade experience on a par with what they expect from LinkedIn, Amazon, Google, and other major providers. People who are deeply involved in R&D and seeking solutions to help patients live better lives aren’t disposed to spend time in software training classes mastering an unfamiliar interface. SaaS systems typically leverage the standard browsers users are already familiar with, and provide intuitive user interfaces.

Anywhere, anytime access. Modern SaaS approaches let users access data on their tablets and smart phones, just as they do with their consumer apps.

A Three-Step Approach for Quality in the Cloud

Companies that have been leveraging paper, manual, homegrown or other outdated methods to manage quality, can take a simple, three-step approach to accelerate their all-digital quality management initiatives.

Step 1: Start on the Right Path

Don't simply digitize your existing methodologies. This is a common misstep. It can lead to

- ✓ workflows that are overly complicated
- ✓ workflows that are not effective (i.e. not "complicated" enough)
- ✓ duplicate workflows that would normally be consolidated
- ✓ all of the above

Also, don't feel you need to re-invent the wheel. Rather, leverage quality workflow best practices that have already been established and proven. This means working with expert providers who are knowledgeable in the field.

Carefully define what parameters you need (and don't need) to measure in order to get the end results you want: visibility, efficiency, cost control, risk management and regulatory compliance. It's important to find a balance when it comes to data capture. On the one hand, you can't measure what you don't capture. On the other hand, gathering data that's not relevant to your goals is a waste of time and money. Whatever your decision, make it easy to capture what's needed. This will help ensure efficiency, visibility and transparency.

Finally, work to establish a culture of quality across the entire business. Quality is not just a function relegated to the quality team. It has visibility across departments and job functions throughout your company. For this reason, including all these constituencies as you build or standardize your quality management system is important.

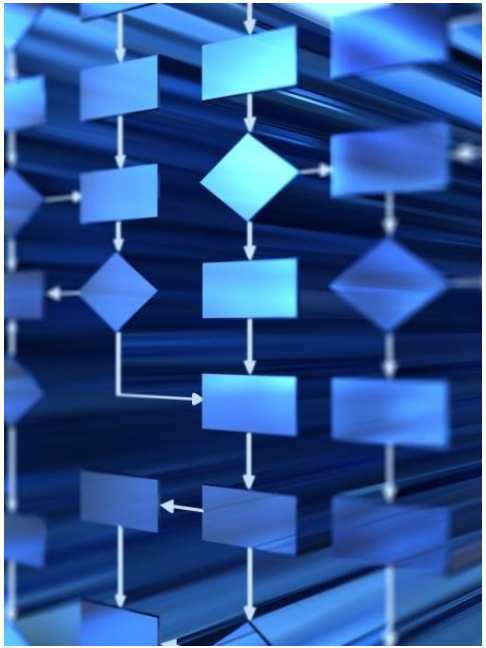
Step 2: Deploy Quickly and Effectively

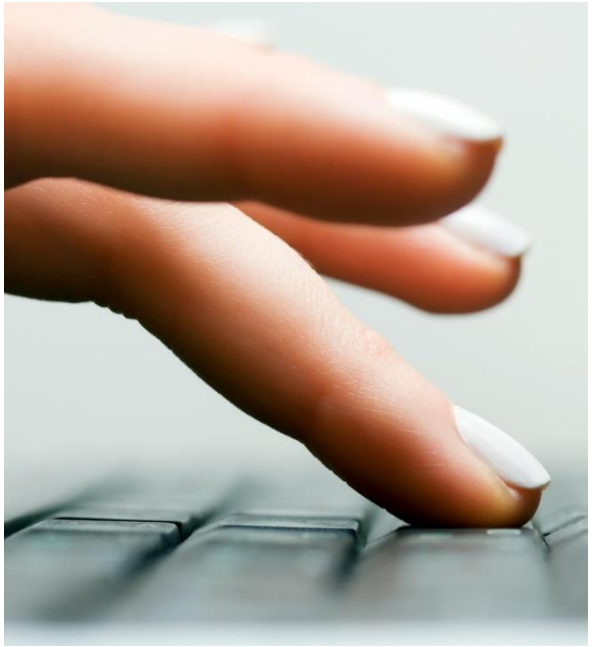
Utilize an easy-to-configure solution that leverages the best practices from Step 1. Avoid intensive customization, and don't attempt to solve the problem by overly configuring a system that wasn't designed for quality management in the first place. Using well-established best practices from Step 1 and choosing a quality-specific system will help you avoid gaps in accountability and in the quality workflow. Avoiding gaps is especially important when it comes to compliance.

Minimize the operational impact of your quality initiative on IT, and its financial impact on your business. While the IT department obviously has to be on board, heavy IT involvement can only slow the process.

In regard to the financial impact, consider a cloud-based system, particularly if you are working with a small budget and limited resources. The reality of limited resources is one of the reasons so many organizations are considering a cloud solution.

Deploy, test and validate quickly. Make quick deployment a priority when choosing a solution and partner with a vendor that can quickly deploy, test and launch this solution with minimal disruption. Remember that if you're in a regulated industry, validation can be a huge hurdle. It's critical that your partner understand the validation process and can ensure it will happen quickly and without snags.





Step 3: Speed User Adoption

Understand that user adoption is crucial to success – and it doesn't happen automatically. You need to provide a solution that's easy to use and navigate, and not difficult or problematic even for new or casual users. (Ease of use has the additional benefit of increasing productivity and the accuracy of the data entered.)

Nothing will speed adoption like the combination of business results and a positive user experience. Browser-based SaaS systems have a significant advantage in this area. Their navigation conventions are already familiar to users, and there is no software to install.

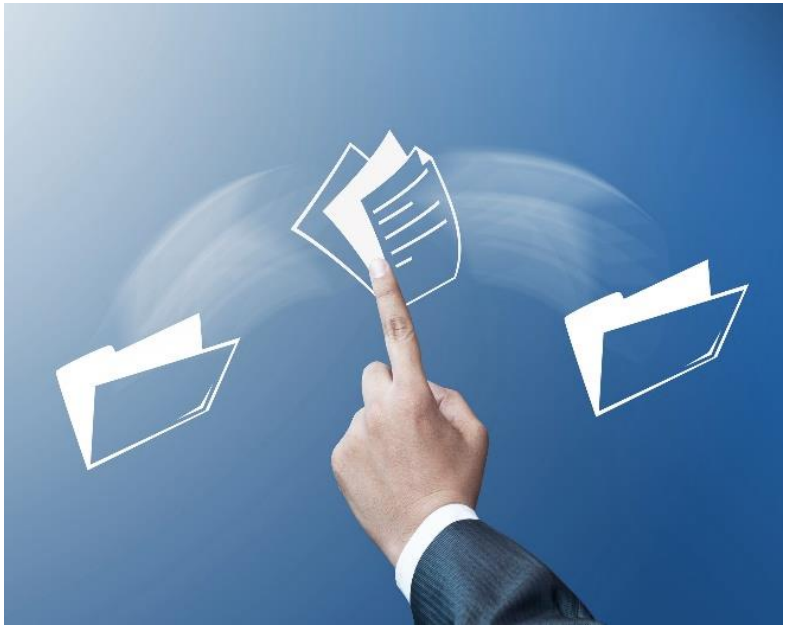
Finally, use the implementation of a modern quality control system as an opportunity to build a more collaborative environment. Quality events affect the whole company, and a system that provides visibility into quality management can help all stakeholders understand and contribute to quality improvement.

Quicker Quality

This three-step process has been proven time and again. When you start off with well-defined objectives based on best practices, choose a solution that doesn't put a heavy burden on IT, and make sure it's easy for the end-users, you can establish a system that will meet regulatory requirements and stand up to audits in a matter of weeks.

To sum up, the advent of web-based technology and SaaS solutions has changed the game for quality management. It's now possible for companies of any size to benefit from the operational and economic benefits of better quality. The most important key to success is finding expert partners with great technology who can leverage their experience to your benefit.

Resources



To learn more about how to accelerate your quality management strategy, please visit www.spartasystems.com or check out the following resources:

Video: Building on Quality

Video: Cloud Quality Management Software

Whitepaper: The Rise of the Quality Business Network

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

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