Veeva MedTech

WHITE PAPER

Harmonizing Quality and Regulatory to Streamline and Speed MedTech Product Lifecycle

Connect quality and regulatory to speed time to market

In medtech, quality assurance and regulatory affairs functions are closely aligned, and many aspects of each department's work affect the other. Unfortunately, most companies lack connected systems to streamline information sharing and take advantage of these alignments for greater efficiency and cost savings.

As a result, they face significant challenges and slowdowns when manually sharing information between the quality and regulatory departments. These inefficiencies hurt the bottom line and they will only be exacerbated by an expected increase in regulatory enforcement and remote audits.[1] Medtech companies will be subject to greater regulatory demands, such as increased data requirements, as well as an expectation to have all product information readily available to regulators.

The good news is that companies have a window of opportunity to prepare now by streamlining processes and connecting QA and RA on a single digital platform with the same information available to all relevant parties in real-time. With more efficient, real-time information-sharing between quality and regulatory, companies can expect faster time to market, higher-quality products and bottom-line improvements across the product life cycle.

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Drive collaboration with a single source of truth

While quality event management may be commonly served via point solutions within medtech organizations, the proliferation of spreadsheets to manage regulatory information still seems prevalent today. The use of spreadsheets clouds visibility for the enterprise, and the issue is often compounded by the need to replicate the spreadsheet for use in different functional areas or business units. This way of working creates inefficiencies and does not provide the single source of truth that organizations seek; it creates viscosity rather than velocity. An organization's ability to access and consume the right data and content rapidly – and in turn, formulate and execute a business decision with speed – is a competitive advantage one would forgo in this operating model. It takes a lot of time and effort to sift through and reconcile the data by having to bubble it up locally, regionally and globally. By the time key information with top-line revenue impact reaches company leadership, it is often already stale.

When quality and regulatory departments need to collaborate on processes such as complaints, change control, or other quality events, employees spend time on non-value-added activities such as phone calls, emails, spreadsheets and other manual approaches to share information and plan next steps when they should be focusing on product enhancements and innovation to address the event.

These data silos, disparate among regions and between the QA and RA departments, can be particularly problematic for the growth-by-acquisition model often employed by medtech organizations when companies are required to integrate legacy systems post merger and acquisition.[2] M&A activity is expected to begin rebounding this year when the world moves beyond the pandemic, highlighting the fast-growing need for better data sharing across the QA/RA landscape.[3]

Beyond data silos, additional problems with current approaches include:

- Human errors, such as transcription mistakes, lack of documentation, incorrect data and data loss;
- Errors due to tracking changes across multiple documents and records;
- An overburdened quality department amid ongoing staffing shortages[4];
- Lack of systems to support the regulatory department in determining market impacts from quality events.

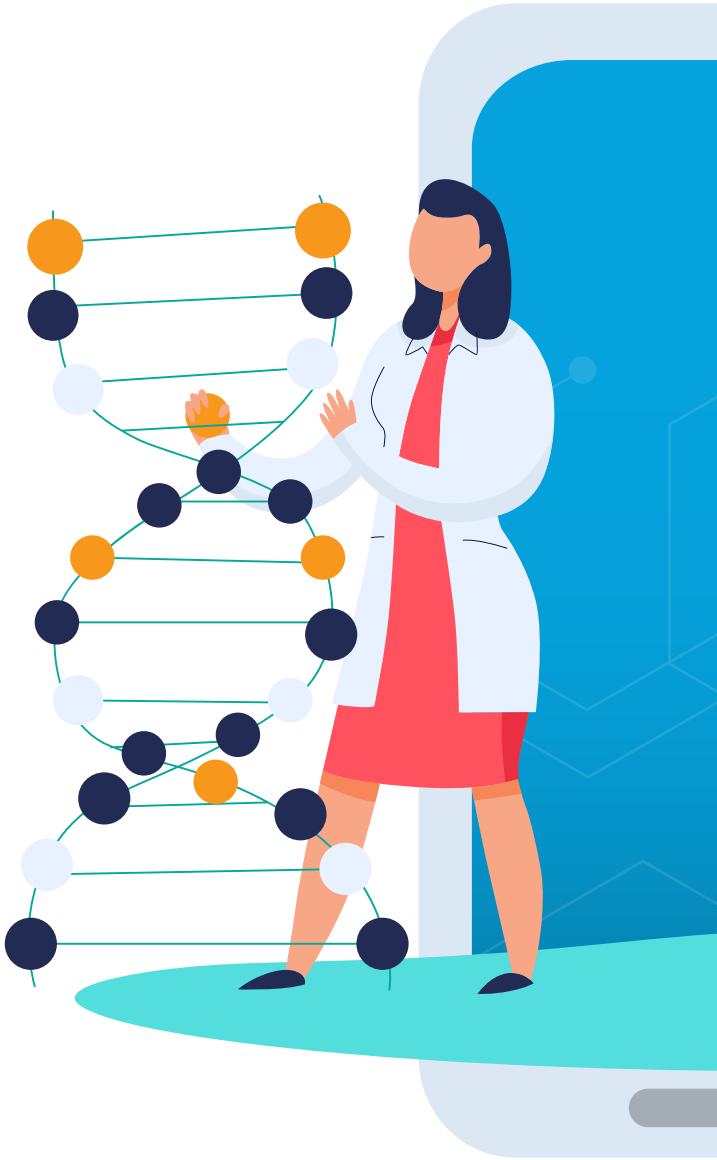
This all leads to compliance risk and poor quality.

The regulatory department faces significant pressure from company leadership to understand market impacts. With tens of thousands of products across the globe, a single change can implicate hundreds of product registrations.

Pressure on both the quality and regulatory departments is expected to continue to increase as regulatory enforcement picks up, including recalls and inspections. As remote audits become more common, it will be critical to have proper systems in place to allow real-time data sharing that is easily accessible on a single digital platform to ensure accuracy. In addition to typical inspection data, organizations have continued to innovate during the pandemic, generating information and processes they will need to clearly articulate to inspectors. And as they say, if it isn't documented, it didn't happen.

"With tens of thousands of products across the globe, a single change can implicate hundreds of product registrations."

— Brian Scogland,
Director of Strategy,
Veeva MedTech



Consequences of suboptimal QA/RA collaboration

Companies working with siloed systems or manual processes across quality and regulatory risk serious financial and compliance consequences, including poor inspection readiness, regulatory body sanctions such as Form 483s, warning letters and consent decrees, all of which slow product development and time to market.

Current manual processes bring a greater risk of missing or incorrect information. Losing entire spreadsheets is not unheard of and results in a failure to register products appropriately. This can lead to slower commercialization or even product removal from the market, affecting patient health and companies' bottom lines. Companies also risk market and regulatory consequences post-merger if quality events at the new company are ill-managed and improperly mitigated.

Companies can also be hit with serious regulatory consequences for product changes that are poorly documented or not communicated properly to authorities.[5,6] For example, the FDA may give a warning to companies for unsubmitted product changes significant enough to represent a new product, which would require a separate application.[7] If that happened, the company could be forced to take the product off the market, resulting in significant financial loss, brand erosion and internal resource strain.

Finally, there is a greater need for accurate, complete, and electronically available information in remote inspection environments. Companies without automated change control and strong systems to link the quality and regulatory functions will lack an essential facet of inspection readiness.

Modernize systems to enable automation and drive speed

Medtech companies need to modernize systems and processes to drive efficiency, enable remote auditing, and speed the total product development lifecycle. That modern approach should include connected systems across QA and RA that provide a single source of truth and the capability to automate change control.

Using a connected solution, QA can track quality events such as product nonconformances and complaints, establishing a trend that requires escalation into a corrective and preventive action process and may require updated labeling. As part of resulting change control to update the labeling, QA then initiates impact analysis, including a regulatory impact assessment, as part of the overall change plan. Upon approval of the plan, the regulatory team is notified and can begin work on assessing and mitigating regulatory impacts in the Regulatory Information Management (RIM) system. Once all actions have been completed, the quality management system team is notified so QA employees can move change control forward for final approval and post-approval actions. This is achieved harmoniously without either side having to straddle both systems.

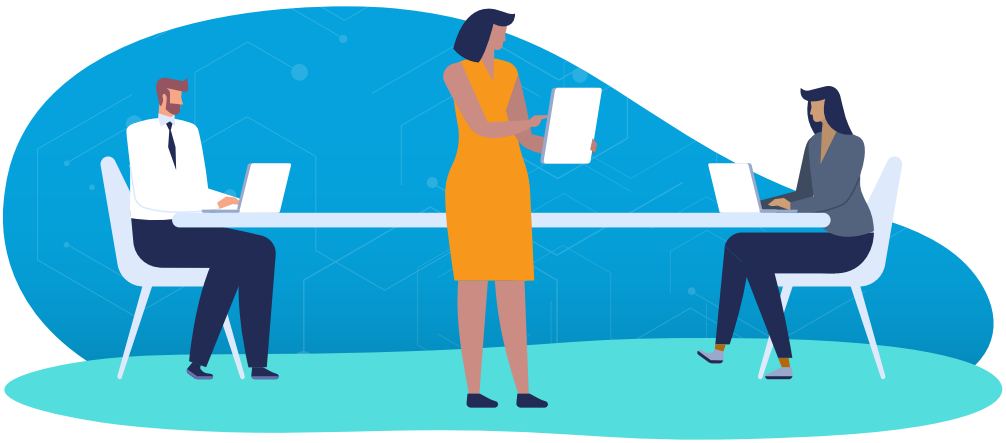
Quality and regulatory team members collaborate more effectively, as each team is notified automatically of changes and their impact on manufacturing, supply chain and commercialization in different countries. All relevant team members receive and can share the same data in real time, allowing faster responses to quality and regulatory developments. Products reach the market faster, maximizing revenue, while bottlenecks and out-of-compliance events are avoided.

Inspection readiness is also improved, as key information can be presented to inspectors directly from the system with the ability to prevent unnecessary data from being presented.

Data at your fingertips

With automated change control on a single platform, QA and RA employees have instant access to:

- **Changes to approved products, manufacturers, and suppliers**
- **Change control strategies and decisions**
- **Quality document management**
- **Decision and impact analyses**
- **Submission planning and tracking**
- **Document authoring and archiving**



Cloud solutions drive efficiency and value

Cloud solutions to connect QA and RA can drive significant value for medtech companies.

Companies should also realize significant time savings, as data is immediately available for access once it is entered. For one medtech company, creating 130 country submission records went from several hours of administrative time to just five minutes. Semi-automating the process of communicating approvals saves companies hundreds of hours per year and allows employees to focus on more strategic activities. This will enable medtech companies to continue to innovate and ultimately improve patient outcomes.

Benefits of cloud solutions

- Cross-functional activities are streamlined to reduce emails and spreadsheets
- Collaboration is improved as teams have access to real-time data
- Resources are maximized and can focus on core competencies versus manual administrative tasks
- Better decisions are possible with clear key performance indicators that identify bottlenecks and provide a complete view into processes
- Strategies can be pivoted quickly in response to new developments

Best practices for implementing a cloud solution

Companies planning to implement a cloud solution should take several steps ahead of implementation. First, they should optimize their quality management processes, by streamlining and harmonizing all associated processes to the extent possible. Sites should commit to being flexible and be prepared to change processes and behavior. Because there is a significant amount of change in behavior required, change management is critical.

A high-quality solution:

- Has built-in medtech best practices and promotes compliance with industry regulations;
- Allows for personalization and flexibility of data elements for metrics and KPIs;
- Allows QA and RA processes to be integrated into the solution in any order.

When choosing a partner, firms should seek out an organization with experience in this type of transformation, as well as with functions and domains across QA and RA in the medtech industry. A good partner will support the manufacturer through the entire lifecycle of products, not just during the initial setup.

With the right solution and the right partner, quality and regulatory teams have the information they need to get safer, higher-quality products to patients faster.

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