Unifying Quality Management with Modern Solutions:

Key Requirements for Managing Quality in a Complex Value Chain

A New Way Forward: Unifying Quality Management

With globalization, outsourcing, and increasing product complexity, organizations need to seamlessly incorporate partners and different functional areas into key quality processes. With streamlined operations and a complete, real-time view of quality, companies can make faster and more informed decisions. Increasing research and development costs, and pricing pressure from increased competition are driving companies to further reduce costs, accelerate new product development, and decrease time to market without compromising on quality.

Incorporating External Parties into Quality Processes

With the outsourcing of key functions, quality processes now span internal and external parties. In 2016, the FDA handed out 934 483 forms to medical device companies highlighting the major quality management problems facing these organizations.[1] Leveraging systems that directly engage key stakeholders and compile processes and documentation with real time visibility into information is essential for quality management operations to maintain compliance.

In 2016, one of the most commonly cited areas for 483 forms was non-compliance with corrective action and preventive action (CAPA) regulations, "most often that 'procedures for preventative and corrective action have not been (adequately) established.'"[1] The second was a lack of inadequate compliant procedures as outlined in 21 CFR 820.198. These types of non-compliance issues can be avoided by managing all content in one centralized, electronic quality management system.

For many quality organizations, communication with partners is fragmented across channels such as email, phone calls, and file shares. Audits are the primary method for gaining visibility.[2] Incorporating partners into quality processes provides continuous access to up-to-date information. And augmenting real-time processes with periodic audits enables a holistic view of supplier performance and earlier awareness of potential issues.

Cloud-based quality management systems (QMS) securely bring together internal groups, partners, suppliers, and newly acquired organizations. Easily accessible and with a flexible security model, they ensure the right access, to the right content – every time. With a single source of current quality information, all stakeholders can track critical processes to speed cycle times, and gain a deeper understanding on how quality events are related.

Coloplast, a Denmark-based medical device maker, leveraged the cloud to help their employees efficiently and compliantly collaborate and share content. They required a system that supported compliance and was secure, and easily accessible across a range of devices. "It was difficult to find a content management system that met our compliance requirements without heavy customization. As a life sciences platform, Veeva Vault had all of the industry functionality we needed," said Orit Magyar, head of quality systems and processes at Coloplast.

> "It was difficult to find a content management system that met our compliance requirements without heavy customization. As a life sciences-specific platform, Veeva Vault had all of the industry functionality we needed."
>
> – Orit Magyar, Head of Quality Systems and Processes, **Coloplast**

1. http://medcitynews.com/2017/04/4-key-compliance-issues-medical-device-companies/?rf=1
2. https://www.veeva.com/resources/gain-control-over-quality-when-working-with-contract-manufacturers/

Other processes that can benefit from using cloud to directly engage partners:

- **Technology Transfers** – Quickly exchange procedures, specifications, notebook pages, methods, batch records, and other related information. Also track status, monitor partner performance, and get a complete audit trail of all activities.
- **Supplier/Contractor Manuals** – Share relevant procedures and documents with partners. With modern cloud applications, the same document is securely shared simultaneously with one or multiple partners.
- **Batch Disposition Process** – Control and track all communication including the review, version changes, and acceptance of supporting quality information from contract manufacturers (CMOs).
- **Non-Conformances, Deviations, Investigations, and Corrective and Preventive Actions (CAPAs)** – Gain visibility into CMO generated events and ensure process alignment.
- **Supplier Change Notifications** – Ensure consistent workflows across suppliers, and get real-time visibility into change notifications and easily connect them to downstream processes.
- **Audits** – Allow partners to respond directly in the system and enable quality teams to efficiently track and manage audits.

Seamless Processes Across Functional Areas

Many business processes require coordination of multiple systems and departments. Enabling seamless workflows across functional areas eliminates manual overhead and provides greater efficiency and control.

Bringing Together Content and Quality Process Management

Unifying quality content and process creates a single source of truth and a consistent user experience, reducing training, potential errors, and number of systems to manage and maintain. Users no longer need to login or toggle between multiple interfaces such as a QMS and an enterprise document management system to support a single business process. Data is also more valuable when it does not exist in a silo and can be effectively leveraged.

Use cloud to manage with partners:

- **Quality agreements and manuals**
- **Manufacturing documentation**
- **Technology transfers**
- **Issues and deviations from CMOs**
- **Supplier change notifications**
- **Audit responses**
- **Other quality documents, records, and data**

Enabling Complex Processes

Modern solutions utilize a single, integrated platform which unifies quality management – developing a strong foundation for applications to work with each other and external systems.

For example, a manufacturing change control is managed in QMS but often impacts many downstream documents as well as emerging or approved regulatory filings. With legacy systems, there is a manual and tedious process to ensure all impacted documents and regulatory files are identified and amended. By utilizing an integrated solution, QMS change actions can connect easily with applicable documents and regulatory tasks, increasing efficiency and visibility. A QMS that works with content management or regulatory systems saves valuable time and resources managing audit templates and artifacts, version controlled supporting materials, or detailed impact assessments.

Having applications designed to work together empowers organizations to support new or complex business processes for greater alignment and streamlined operations.

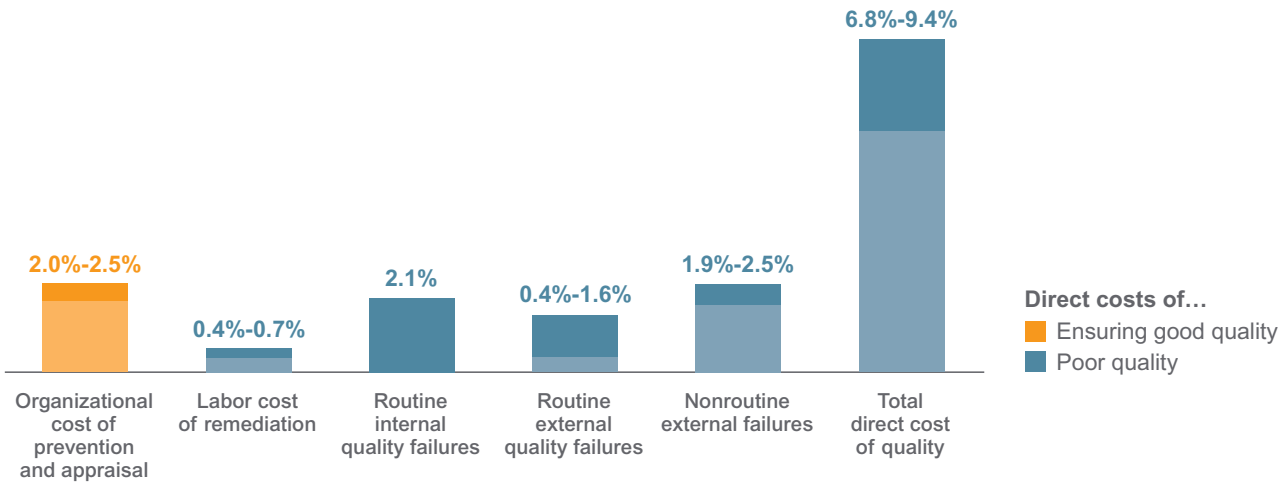
Enriching Quality Information

The supply chain landscape is complex. Systems for managing quality are multiplying in silos. Enriching quality information with other related data drives better decision-making. Companies struggle to maintain a holistic view of quality operations and understand how events are tied to upstream or downstream processes. Unifying quality and other systems brings together disparate sources of data for greater visibility and proactive risk management. It can potentially avoid millions of dollars in remediation, product recall/destruction, and fines.

McKinsey published a survey to understand the costs and revenue losses from non-routine, poor quality events – between the leading and lagging performers in the medical device industry. They found that the direct cost of quality in the medical device industry is $26 billion to $36 billion annually.[3]

Direct Cost of Ensuring Good Quality and Costs of Poor Quality

PERCENTAGE OF SALES*



*Estimated sales of $380 billion.

Source: Health Research International; McKinsey analysis

3. http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturing-the-value-of-good-quality-in-medical-devices

Holistic Supplier Quality Management

Bringing supplier and quality performance information together in one place provides greater understanding of vendors for more prudent business decisions.[4]

When ongoing oversight is conducted in a cloud-based system, the supplier's quality profile becomes a continuous, growing, permanent record – increasing understanding of a vendor's quality performance and risk. Supplier quality metrics provide early on, clear indication of emerging issues and is leveraged to drive behavior in subsequent stages of the supplier quality management (SQM) lifecycle. For example, reported ongoing quality issues can be used to determine if the vendor meets the original criteria or adhered to the supplier quality agreements.

Quality indicators based on historical performance are aggregated to form a supplier risk profile and provide an objective measure for vendor comparison – driving prioritization of resource allocation.

Summary

Real-time global oversight of quality can help mitigate risks with remote, external, or newly acquired manufacturing facilities – preventing delays in drug approvals and millions of dollars in loss revenue. Unifying quality management provides a more complete view of quality operations and allows greater understanding of how events are related. With up-to-date information for critical decisions, quality is no longer a bottleneck in getting products to patients. Modernizing quality systems can improve product quality, advance patient outcomes, and reduce costs and risks while ensuring compliance with regulatory requirements.

Modern systems make it easier to work with internal or external parties and across different functional areas. Complex operations such as change control require coordination of multiple systems and teams. Bringing together applications such as content and process management solutions simplifies workflows and provides greater visibility to all stakeholders and of potential impact. Breaking down organizational and application silos also enables data to be more effectively leveraged. Quality information can be enriched with other related data to provide powerful insights for better decision-making such as determining the most viable or effective vendors, or the ones at greatest risk that need more support.

Vault Quality Suite

Veeva Vault Quality is a suite of applications that enables the management of quality events from event origination to changing controlled content on a single cloud-based platform. Connecting quality processes with critical documentation, Vault QMS and Vault QualityDocs accelerates and streamlines event identification, correction, and change management. This end-to-end visibility equips organizations to respond to quality events faster, and provides a complete picture of quality management activities to regulators.

4. http://www.pharmtech.com/getting-and-staying-ahead-global-quality-demands

About Veeva Systems
Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 550 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit **www.veeva.com**.

Veeva Systems
Global Headquarters
Pleasanton, California, USA
4280 Hacienda Drive
Pleasanton, California 94588
+1 925 452 6500 | info@veeva.com | veeva.com