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 generics and payers 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 outsourcing of key functions, quality processes now span internal and external parties. For the third fiscal year in a row, more than 50% of the warning letters are to compounding pharmacies or outsourcing facilities – highlighting major quality challenges with externalization.[1] Leveraging systems that directly engage suppliers, contract test labs, and contract manufacturers enables real-time visibility into information essential for quality management operations.

The Pharmaceutical Research Manufacturing Project collected and analyzed data from manufacturing sites to identify factors that contribute to manufacturing and deviation performance. They found that automated and electronic processes for "reporting deviations, tracking deviations by lot, tracking deviations by type of issue, and tracking people assigned to resolving the deviation – and centrally storing the data – universally corresponds to superior manufacturing performance metrics."[2]

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.[3] 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.

Karyopharm Therapeutics, a clinical-stage pharmaceutical company, leveraged the cloud to streamline collaboration with contract manufacturers, accelerating processes such as batch releases and increasing operational efficiency by 30%.[4] Karyopharm's partners also found they were more efficient. "With cloud, we can stay fully aligned on projects at all times and have information at our collective fingertips for regulatory needs and project planning. Best of all, Karyopharm won't have to come back to us years later to request documents," states Leslie Aucoin, program manager, Piramal.

1. https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-fy-drug-gmp-warning-letters-0001
2. https://apps.olin.wustl.edu/faculty/nickerson/results/PMRPFinalReportSept2006.pdf. "Pharmaceutical Manufacturing Research Project. Final Benchmarking Report." September 2006. Jeffery Macher. Jackson Nickerson.
3. Achieving global supply chain visibility, control, and collaboration in life sciences. Axendia research report. 2010
4. https://www.veeva.com/resources/gain-control-over-quality-when-working-with-contract-manufacturers/

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

- **Technology Transfers** – Quickly exchange procedures, specifications, notebook pages, validation methods, batch records, and other related information. Also track status, monitor and compare 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).
- **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. Modern solutions take a platform approach – developing a strong foundation for applications to work with each other and external systems. Users no longer need to login or toggle between multiple interfaces to support a single business process, and data is more valuable when it is effectively leveraged.

Use cloud to manage with partners:

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

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. In contrast, modern solutions easily connect QMS change actions with applicable documents and regulatory tasks, significantly increasing efficiency and visibility. A QMS that effortlessly works with content management or regulatory systems also saves valuable time and resources managing audit templates and artifacts, version controlled supporting materials, or detailed impact assessments.

Many targeted therapies on the market today are specialized biologics that require different manufacturing and distribution techniques, and cost on average 22 times more than alternatives.[5] Having applications designed to work together empowers organizations to support new or complex business processes for greater alignment and streamlined operations.

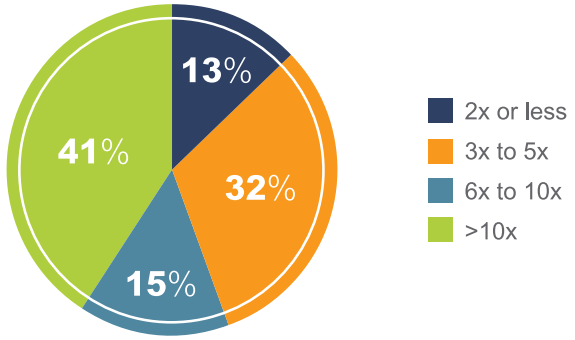
5. https://www.brookings.edu/blog/health360/2015/05/19/health-policy-101-how-the-trans-pacific-partnership-will-impact-prescription-drugs/

Enriching Quality Information

The supply chain landscape is complex and systems for managing quality are multiplying in silos. Companies struggle to maintain a holistic view of quality operations and understand how events are tied to upstream or downstream processes. Unifying quality 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.

The Parenteral Drug Association (PDA) and International Society of Pharmaceutical Engineering (ISPE) ran a joint survey to "understand the cost of poor quality and benefits of good quality systems" in pharmaceutical manufacturing. In the study, 41% of respondents estimated "cost to correct a critical observation received from a Health Authority in a reactive mode was more than 10 times greater when compared to early and proactive correction of the same critical observation."[6] Impact from consent decrees can also be significant, costing well over $2 billion.[7]

On average, how much greater is the cost to correct a critical observation reactively versus proactively



Source: PDA/ISPE Joint Pharmaceutical Quality Survey 2011

Holistic Supplier Quality Management

Enriching quality information with other related data also drives better decision-making. Bringing supplier and quality information together in one place provides greater understanding of vendors for more prudent business decisions.[8]

When ongoing oversight is conducted in a cloud-based system, the supplier data becomes a continuous, growing, permanent record – increasing understanding of a vendor's performance. 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, data obtained in supplier qualification is used to monitor the vendor on an ongoing basis to determine if they meet the original criteria or adhere to 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.

6. https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/Manufacturing/UCM287130.pdf
7. http://www.pharmamanufacturing.com/articles/2012/033/
8. http://www.pharmtech.com/getting-and-staying-ahead-global-quality-demands

Summary

Incorporating partners and sites around the world into quality processes is critical with complex supply chains and heavy dependency on foreign manufacturing. Real-time 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. With greater transparency for all parties, business relationships can transform into closer partnerships.

Modern systems make it easier to work with internal or external parties. Complex operations such as change control require coordination with multiple teams. Streamlining processes across functional areas simplifies workflows and provides greater visibility to all stakeholders and of potential impact. Breaking down organizational 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.

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.

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-base 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.

About Veeva Systems
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