DATA-DRIVEN PERFORMANCE IN LIFE SCIENCES QUALITY MANAGEMENT

Quality is shifting from conformance to performance

Honeywell

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MANAGEMENT SUMMARY

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In a survey of 161 life sciences industry professionals, 76 percent cited quality data as very important or extremely important to their teams and leadership.[1]

As Deloitte states in its Global Life Sciences Outlook Report, "Data is now the currency of life sciences, and mobilizing data throughout the enterprise, transforming work, and using technology symbiotically will be fundamental to advancing digital transformation."[2]

This digital transformation, ushered in by Industry 4.0 technologies -- including artificial intelligence (AI), machine learning (ML) and the Internet of Things (IoT) -- and enabled by digital/cloud-based enterprise quality management systems (EQMS), is empowering life sciences quality teams to access tremendous volumes of data from every aspect of their companies' operations (e.g. R&D, manufacturing, external suppliers), from multiple systems (e.g. ERP, CRM, MES, PLM, LIMS.) at an unprecedented rate.

But data is useless unless it is meaningful and actionable. Quality teams must be able to segment relevant data and structure it in a way that allows them to identify and measure those key performance indicators (KPI) most important to their organizations.

This is more critical than ever as the role of quality shifts from conformance to performance. Whereas in the past a quality team could focus its efforts on maintaining regulatory compliance, today senior executives expect them to break out of this silo and have a direct and meaningful impact on operational and economic performance throughout every area they touch: From research and development (R&D) through manufacturing and out to external suppliers. It all comes down to the quality team's ability to drive top line revenue through the faster delivery of higher quality drug products to the market with minimal complications and waste.

This paper presents the opportunity for quality teams to impact enterprise-wide performance; what data, processes and systems are imperative to this effort; and a model that quality teams can leverage to establish, measure and track KPIs that align with their companies' overall performance goals.

THE OPPORTUNITY

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Most manufacturers in the life sciences industry have built their quality teams and systems around regulatory compliance, viewing quality as a standalone department with a single focus.

Their executives often view quality and its role in maintaining compliance as an area of added cost - an essential function that helps "keep the lights on" without adding any additional business value.

In doing so, they are missing out on a significant opportunity for top line revenue impact that comes from getting higher quality drug products to the market sooner. Because the quality function interacts with every aspect of the enterprise, it can serve as an insight engine uncovering hidden nuggets of data from throughout the product lifecycle and feeding them into the quality feedback loop to drive continuous improvements.

Compliance is no longer the end game; rather, it is a byproduct of a company's efforts to improve product quality, product safety, product efficacy and continuity of supply (both current and new products).

Those manufacturers that have elevated the role of quality beyond the conventions of compliance to become agents of change throughout their organizations are able to identify and address issues faster and sooner to reduce costs, avoid recalls and protect patient safety, while at the same time maintaining regulatory compliance.

Specific areas of impact include:

Limiting risk and recalls
According to McKinsey & Company, digitation and automation of processes ensures better quality and compliance by reducing manual errors and variability, as well as allowing faster and effective resolution of problems. Use cases of this approach have demonstrated more than a 65 percent reduction in deviations and over 90 percent faster closure times.[4]

Improving product quality patient outcomes and customer satisfaction
When a product functions as intended, outcomes are improved and satisfaction among customers (clinicians, consumers) is higher. When questioned on their driver for quality improvement initiatives, two-thirds of senior executives and quality professionals report that it is customer demand for quality.[5] A quality culture requires a continuous loop whereby quality data is relayed back to R&D and manufacturing teams to help drive continuous improvements.

Driving operational excellence
The infusion of quality throughout people, processes, products and technologies drives company-wide operational excellence. It can result in reduced cycle times, cost savings, increased margins and additional performance-oriented outcomes. Research from McKinsey & Company reveals that manufacturers in the life sciences industry leveraging advanced analytics could improve Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) by 45-75 percent.[6]

Accelerated time to market
Access to actionable quality data can reduce errors and related setbacks during the product development cycle, enabling a manufacturer to deliver its product to market sooner. Cutting the cycle down by even a month could potentially pay for any quality improvement costs—and more.

Strengthening the value chain
The quality of a manufacturer's value chain has a direct impact on the quality of its processes and products. McKinsey & Company examined 40 quality incidents across eight different industry sectors and found over 40 percent were due to supplier quality issues.[7] Manufacturers that implement rigorous and thorough quality management programs that extend out to their suppliers can not only improve product quality but also save time and money by minimizing risk and errors related to their business partners.

In increasingly cost constrained global healthcare markets, life sciences companies that leverage analytics for advanced data driven decision making over the next one to three years will gain a decisive advantage over their peers.[8]

WHAT QUALITY NEEDS NEEDS TO SUCCEED

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DIGITIZATION AND DATA

In order impact economic performance, quality teams need immediate access to accurate and meaningful data throughout the enterprise, and the analytics capabilities to pull and present insights that will resonate with the impacted stakeholders. They must be able to proactively address potential issues or act on opportunities upstream, rather than reacting to problems that have already snowballed downstream into costly deviations, complaints, and corrective and preventive actions (CAPA).

Among life sciences industry professionals surveyed, 58 percent anticipate using quality data to improve cross-functional performance, up 17 percent compared with 2018.[9] While these manufacturers understand the value of data to performance-based quality management, their technological capabilities are holding them back. In the same survey, one-third of respondents named access to complete and accurate data as a top obstacle. The main roadblock is their current quality management systems (QMS), with nearly half of survey respondents (46%) reporting data access and analysis as the biggest challenge with existing QMS.[10]

The life sciences industry is currently in the middle of a digital transformation where Industry 4.0 technologies, such as AI, ML and IoT, are revolutionizing data collection and management. Those who are embracing these innovations are seamlessly accessing the data they need to move from reactive to proactive quality management, while those still stuck with manual processes are lagging further behind.

Life sciences companies with outdated QMS platforms and manual processes are so far removed from the level of maturity required for proactive, performance-based quality management that it is unlikely they will ever catch up. Those that have invested in their quality teams and technologies over the years with electronic and automated enterprise quality management systems (EQMS) in place and access to data and analytics are well equipped to leverage Industry 4.0 technologies and achieve digital transformation.

Nearly half of life sciences industry professionals (47%) anticipate quality budgets to increase; 15 percent say they plan on purchasing an integrated EQMS in the next 12-16 months, and 12 percent say a cloud-based, digital platform is a top consideration for a new quality management system.[11]

THE NEXT STEP: ACTIONABLE INSIGHTS

So far, this paper has explained the opportunity for life sciences quality management teams to impact their companies' economic and operational performance, and the need to digitally transform quality management processes so that teams can access timely and relevant data on which to base their decisions. But once they have that data, how do they use it?

EXAMPLES OF DIGITALLY ENABLED QUALITY MANAGEMENT

Digital enabled quality management isn't a future state – it's happening today – and those manufacturers that are leveraging it are making significant and rapid improvements throughout their operations. By implementing Industry 4.0 technologies, such as artificial intelligence (AI), machine learning and natural language processing, companies are generating more meaningful insights faster, increasingly efficiency and productivity, and freeing up quality teams to focus on decision making not data management.

Examples include:

- **Managing Complaints:** A digital EQMS that applies machine learning and natural language processing to auto-categorize the intake of complaints and quality events drives productivity and intelligent decision-making across the organization.
- **Predicting Risk:** AI-augmented decision making embedded into core quality management workflows enables teams to predict risk and make recommendations they can act on. The value of this approach is in streamlining workflows and routing, allowing quality experts to prioritize high-risk areas.

INTRODUCING THE POSE DATA SEGMENTATION MODEL

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The POSE model helps quality teams structure relevant data to create meaningful insights—driving the right behaviors and effective actions. It addresses four areas where quality can have a major impact on a company's operations: Process, Operations, Supplier Quality, and Effectiveness.

In the next section, we provide examples of key performance indicators (KPIs) for each of the POSE model areas. Please note that this is just a sampling of the KPIs that a company can identify and measure through the POSE data segmentation model. A company can use the model to identify those KPIs most relevant to its own quality operations.

PROCESSES

The repeatability and predictability of processes designed to manage quality and compliance are key to driving better performance. One example of how to measure the efficiency and effectiveness of these processes is through complaints per million (CPM). To create insights for the CPM KPI, a company needs two critical data sources: The EQMS for data on product quality complaints, and the ERP system for sales distribution data.

The quality team must aggregate, summarize and present the product quality complaints data in a way that makes it easy for them to build insights. They must also supplement it with lot and manufacturing information. As for the ERP data, the team must aggregate it by sales by region and product category. From this aggregated and segmented data, the quality team can determine its CPM.

By gaining insights into its monthly CPM rate, a manufacturer can measure quality and performance across manufacturing sites and lots, and take action based on this information. For example, if the CPM is too high on a specific lot, the company may choose to conduct a recall.

OPERATIONS

The ability to consistently manufacture a product from start to finish without rework or reprocessing of lots is critical to operational performance. One valuable KPI related to a company's operations is the Right First Time (RFT) rate. RFT is a meaningful KPI because it is a leading indicator for operational excellence, providing insights on a manufacturer's total failure/ defects per product (APR).

In order to calculate the RFT rate, a company needs its deviations and CAPA from its EQMS, and batch information from its ERP system. Just like the CPM KPI, it is important to have the data aggregated and summarized from both of the systems in order to calculate the correct RFT percentage.

A low RFT rate could be an indication of an ineffective quality process. In this case, the operations team can propose root cause failures to R&D through the feedback loop for continuous improvement.

SUPPLIER QUALITY

A company can evaluate and compare suppliers based on historical and current performance. A critical KPI in this area is the supplier risk score, which indicates supplier risk based on qualitative and quantitative factors. In essence, it indicates confidence level relative to performance.

In order to calculate the supplier risk score KPI, a quality team needs supplier complaint investigations, CAPA and audit findings data from its EQMS, and aggregated lot reworked and lot released data from its ERP system. Just like the previous examples, the data from both systems must be aggregated and summarized to gain insights.

If the quality team identifies a supplier with a low score, it can mitigate risk by escalating the issue to management so that the company can identify an alternate supply source.

EFFECTIVENESS

A quality team can measure whether corrective actions taken have effectively addressed a specific problem and prevented repeat occurrences. One example of a KPI in this category is the CAPA effectiveness rate, which indicates the elimination of repeat failures and the effectiveness of a company's CAPAs.

Both of the data sources required calculate this KPI – the CAPA and effectiveness data, and deviations - are contained within the EQMS. But in order to accurately measure its CAPA effectiveness rate, a quality team must aggregate its CAPA and effectiveness data and deviations, as well as its deviations post CAPA.

With this information, a quality team can gain insight into the number of deviations after a CAPA has been implemented, and use this information to drive increased capability in root cause identification. If its CAPA effectiveness rate is low, a company may choose to update personnel training as one step toward improvement.

THREE STEPS TO GET STARTED WITH THE POSE MODEL

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Manufacturers in the life sciences industry that are interested in moving beyond compliance and securing meaningful and actionable insights can get started with the POSE model by taking the following steps.

Step 1: Integrate your systems
In order to reach the level of data access, aggregation and analysis required to identify and measure POSE Model KPIs, a manufacturer must integrate its EQMS with its enterprise resource planning system (ERP) and other platforms containing quality related data, including laboratory management information systems (LIMS) and customer relationship management (CRM) systems. It must also put into place processes and systems that enable ongoing measurement reporting for continuous improvement.
The most effective and efficient way to achieve this integration is through a cloudbased EQMS. Because digital/ cloud systems more easily integrate with other systems (both internal and third party), and facilitate data inputs from multiple sites and users, they serve as the central repositories of quality data required for enterprise-wide visibility and impact. With a digital/cloud-based EQMS in place, the manufacturer can then leverage Industry 4.0 technologies (e.g. AI, machine learning, natural language processing) for faster insights and action.

Step 2: Clearly understand and define objectives and stakeholders
A company must establish its quality goals (e.g. complaints are processed timely, accurately, efficiently and consistently), determine which stakeholders must be involved in achieving these goals (e.g. R&D, vigilance group, investigational oversight, regulatory, senior management), and decide not only what type of insights these stakeholders need in order to achieve them (KPIs) but also when they need them (e.g. real-time, quality/ annual reporting).

Step 3: Define your escalation path
Once the objectives and stakeholders are understood, the quality team should define its escalation path to drive insights into the right actions by having trigger points within its reporting data and performance indicators. No value is created by insights if they are not acted upon.

Among leading considerations for QMS are performance features for data and integration. When asked for top considerations when evaluating a new QMS, one-third of respondents (30%) named data and analytics reporting, while 21 percent cited integration with enterprise resource planning (ERP), product lifecycle management (PLM) and other systems.[13]

Life science companies sit on a wealth of data, usually locked away in different technical and organizational silos. Some are already linking and mining their data sets to improve their pipelines, products, and strategies. But there remains a huge opportunity to create further value from data and analytics using internal and external data sources to drive superior results.[12]

CONCLUSION

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The future of life sciences quality management is performance, not conformance.

While the quality function will always be responsible for ensuring their companies comply with global regulations, life sciences executives expect and demand far more of their quality teams than checking the compliance box. Today's performance-based quality teams are having a meaningful and measurable impact on their companies' bottom lines.

In order to make this fundamental shift, a quality team must break out of its silo and broaden its focus to how it can improve economic and operational performance throughout all of the areas that it touches (e.g. R&D, manufacturing, external suppliers). This requires strategic decisions based on accurate and timely data rather than best guesses or hunches.

When considering quality not as a department but as an objective that must be achieved throughout each and every aspect of a manufacturer's operations, the challenge of identifying and measuring quality metrics becomes evident. In order to understand the state of quality throughout the product lifecycle, life sciences quality teams need an EQMS that integrates with all other essential operational systems (e.g. ERP, CRM, MES, PLM, LIMS) to facilitate the collection, aggregation and segmentation of quality data at each stage. Those that have transitioned to a digital/cloud-based EQMS platform can seamlessly integrate this information for comprehensive, real-time decision-making, and are positioned to leverage the game-changing analytical tools that Industry 4.0 has to offer.

Once a quality team has systems and data in place to access and analyze its performance, it must establish quality KPIs aligned with corporate objectives so it can set goals, assess current state, enact change and measure results in a way that resonates with the C-suite. The POSE data model offers an effective and efficient way for small quality teams at mid-sized and emerging companies to achieve this.

Source

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