CONFORMANCE TO PERFORMANCE

How Pharmaceutical Quality Drives Performance

Honeywell

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MANAGEMENT SUMMARY

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The rapid growth of the pharmaceutical and biotechnology industries has been accompanied by an escalation in the complexity of drug-safety regulations -- particularly when it comes to data integrity.

What seems like an almost daily onslaught of regulatory requirements for these organizationscan be overwhelming, and it is especially so for emerging and mid-sized drug companies. Drug regulators in the United States, Europe, and the United Kingdom have responded to this growth and complexity by stepping up inspections in order to stay ahead of potential product recalls.

The U.S. Food and Drug Administration (FDA) and the European Union Drug Regulatory Authorities (Eudra) have issued a plethora of warnings, recalls, and product bans across the globe. The profits of companies that receive warning letters are directly impacted as a result of lost productivity, increased downtime at manufacturing plants, product import bans and—in some cases—drug shortages.

Despite the growing number of regulations, the number of Adverse Drug Reports (ADRs) continues to climb. Since 2000, the FDA has had more than 14 million ADRs, of which 1.4 million resulted in death. ADRs have surpassed 1 million since 2013 and have been nearing 2 million each year since 2015. The increase in ADRs and calls both inside the agency and from consumer advocacy groups have resulted in more determined and detailed government monitoring of production and efficacy.

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FROM CONFORMANCE TO PERFORMANCE

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The Pressure to Change

With regulatory scrutiny increasing in coming year, the pressure is on to extend focus beyond regulatory conformance toward quality performance.

Much of that pressure comes from a global healthcare industry that is demanding drug makers change their view on data integrity and quality systems. Increased demand for drugs to treat chronic diseases has raised expectations among stakeholders for better, more efficient, and cost-effective tracking of treatments—from go-to- market, to manufacturing, to patient outcomes.

While many enterprise pharmaceutical and biotech companies have begun investing in their quality systems, it's not uncommon to find mid-size or emerging manufacturers manually entering data into spreadsheets or using systems that are unable to electronically share information.

> In the mid-to-late '90s, it was about how do you read the regulations and stay out of the FDA's crosshairs. The idea of business efficiencies wasn't at the forefront. But, as regulations grew, that began to change. It's been a scramble for a lot of these organizations ever since.

Emerging and mid-sized companies, often already short on resources, must closely monitor expenditures related to contract manufacturing services and strategic partnerships, all while keeping an eye on regulatory compliance. Yet, few have sought the benefits of instituting a quality management system (QMS) software platform. Such a solution is fully integrated, automates processes like event tracking and audits, and creates a single system of information that can easily be accessed and mined. Advances in technology have even opened up the ability to acquire data from more sources both within an organization and outside of it. Technology costs also have eased, making quality management software more accessible and easier to maintain.

Additionally, integrating a quality system into the manufacturing process can alert manufacturers to when production standards are not being met and corrective action needs to take place. A QMS can also integrate and streamline the manufacturing processes across production facilities, geographic locations and newly formed or merged organizations, thereby driving higher operational excellence and reducing cycle times.

Large pharmaceutical companies are moving in the direction of using big data and predictive analytics to pull and process information that had previously been siloed in different systems.

But perhaps one of the best near-term benefits of quality management software for mid-size and emerging organizations is one that migrates data from separate silos like quality, manufacturing, post-market surveillance, and R&D into a single global system.

While big pharma is looking at certain molecules, on the other side you have the new enterprises. From the small end of the spectrum, preclinical quality data can help them find inefficiencies. For them, the payoff is when we move away from the manual collection.

QUALITY DATA AND THE SUPPLY CHAIN

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Targeting The Weakest Link

Perhaps one of the most notable strengths of a quality management system is the ability to target one of the biggest problems facing pharmaceutical and biotechnology companies—the supply chain.

Companies use quality systems to look at what has happened with suppliers in the past, determine if they are at risk and take preventive actions, such as making provisions to find new suppliers. A good system can assess suppliers regularly and generate supplier scorecards and risk index.

Buy-in from senior management is integral to the successful implementation of a quality control system as well as the development of quality key performance indicators (KPIs), identification of stakeholders, goals, and timelines. While the KPI can be a subjective goal, it is not a subjective measurement.

Just because you have data doesn't mean you can create metrics. You want to have a model like the POSE Data Model to group things like processes, operations, supplier quality, and effectiveness to express a KPI. Many times, a company will be focused on one particular thing, like in-house complaint metrics, while ignoring supplier quality data. POSE is a simple model that allows you to step back and ask whether you are hitting all the right benchmarks.

THE POSE DATA MODEL

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The POSE data model helps quality teams structure relevant data to create meaningful insights that drive 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.

PROCESSES
Assess the repeatability and predictability of procedures designed to manage quality and compliance to measure complaints per million.

OPERATIONS
Monitor the consistency and accuracy of end-to-end manufacturing to determine right-first-time percentages.

SUPPLIERS
Evaluate and compare suppliers based on historical and current performance for percentage of defective products received.

EFFECTIVENESS
Measure whether corrective actions taken have effectively addressed a specific problem and prevented repeat occurrences.

The model helps ensure you have an effective quality system in place by having a good process and well-defined KPIs. But it's also essential to have a feedback loop to communicate what is going right and what is going wrong.

An effective quality system should be a single, accessible, electronic repository of data captured from all quality processes. It should be automated, accurate, easy to use, and complete, and it should have open communication and collaboration with internal and external business units, partners, and suppliers. Employing a fully integrated corrective and preventive action (CAPA) system provides automatic routing, notifications, and escalations that can reduce tedious and time-consuming manual processes. This reduces the time needed to act on quality and safety issues while reducing production and operation costs. It also makes it easier to show regulatory inspectors that the right corrective actions have been taken if there is an issue during manufacturing.

RISK VS. REWARD

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Considering the implementation of a new quality system is a strategic question that can vary on the size of the organization.

Yet, given the complexities of the industry, data integrity should be seen as a sustainable competitive advantage and not a risk. There is little doubt regulators and business partners will demand faster access to detailed information about a company's quality operations. Mid-size to startup manufacturers will either start upgrading their systems to meet coming regulatory changes and support their own growth or they will be left behind.

For more information
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Conformance to Performance | Rev 1 | 12/23

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