

PHOTO BY NICOLAS



DIGITAL
TRANS-
FORMATION

Leveraging Life Sciences Data for Intelligent Decision-Making

Industry 4.0 is compelling many life sciences organizations to rethink their business model, focusing less on products and more on data. To ensure the best health outcomes for patients and to create value for all stakeholders, CIOs must draw

insights from the vast amounts of data at their disposal to support intelligent business decisions. With the rapid introduction of data-driven tools for use in clinical trials and product development, effective integration is essential.

CIO

SPONSORED BY



Honeywell

Quality 4.0 and Integration

Quality 4.0 is a term that reflects what quality has tried to be all along, says Kiyoshi Inoue, a director at Honeywell, who is responsible for enterprise IT, digital transformation and business process optimization projects. “What Quality 4.0 is really saying is that quality is not a separate aspect of what you do but that quality is baked into how you operate because essentially a good quality philosophy means that you understand what you’re supposed to do.”

With Quality 4.0, quality departments are inherently more empowered because every activity performed is already quality-focused, meaning that every job is completed as it is supposed to be, based on standard operating procedures.

In the life sciences and healthcare industries, optimizing quality increasingly requires advanced methods of deriving insights from data. Clinical trials to test pharmaceuticals in development, for example, require not only high-quality data but also the integration of data isolated in silos.

There are many ways of capturing data from clinical trials, including Excel spreadsheets and a variety of homegrown systems. They all function essentially as databases of

what was done and what was found – such as results of experiments or laboratory tests. Insights tend to be gathered in spreadsheets.

Traditional data management systems, by their nature, place limitations on what can be learned. “If data is captured in spreadsheets, you might find that steps 1, 2, 3 lead to outcome A whereas 2, 3, 4 lead to outcome B and 1, 5, 6 to outcome C,” says Inoue. “If you don’t bring this data together, you don’t see the patterns. Your knowledge is limited to the particular silo. The data is usually not collated in a way that you can correlate it to get insights.”

This is true of many kinds of data capture systems, from electronic health records to systems used to ensure safety during pharmaceutical development, for example. It’s difficult to make correlations between data sets that don’t have things that are correlated. “People who work in apple orchards worry only about apples. People who work in orange groves worry only about oranges,” says Inoue. “If you’re trying to make a new fruit juice that uses both apples and oranges, the growers can tell you everything about apples and everything about oranges from their separate silos, but they can’t tell you how those two come together.”

The data may all be good-quality data, but it’s not integrated. A good

quality management system (QMS) can help make the necessary connections to derive more meaningful insights. Further, it can help in other areas – such as efficacy in a clinical trial, says Inoue.

PHOTO BY SEAN ANTHONY EDDY



A QMS that can keep pace with the volume, variety and speed of data will ensure the smooth connectivity necessary to deliver safe, effective products to patients while creating business value. CIOs can leverage intelligence and insights extracted from quality data to make data-driven decisions, streamline quality processes and drive continuous business improvements.

Quality 4.0 and Emerging Technologies

Through seamless data exchange, a Quality 4.0 system provides the speed and scale to blend traditional quality assurance with emerging technologies such as artificial intelligence (AI), machine learning (ML), robotic process automation (RPA) and the internet of things (IoT). These integrations enable CIOs to improve decision-making, achieve cost reductions, streamline compliance and improve operational efficiency.

“You could have IoT monitors that would measure the temperature of the room in which something is being produced,” suggests Inoue. “You would know that if it goes over a certain temperature, that batch is dead – and the monitors could warn you ahead of time. They could tell you the temperature is trending up, and you could have an automatic trigger that would turn the temperature down faster than a human could.”

Speed can make a critical difference in life sciences data management. Modern QMSs are essential to balance the need for speed with the risk of cutting corners.

“Batch release is a great example of this,” says Inoue. “If you rush to release a batch, you may end up with a massive recall. You want to make sure the patients get the medicines they need, but if you rush it too fast and you don’t know that it’s safe, you could end up with a massive recall.”

Advanced analytics can help provide the necessary information to determine whether a batch is safe for release.

A robust QMS provides built-in reporting functionality and dashboards that offer real-time visibility into the quality metrics, trends and performance indicators CIOs require in order to develop effective analytics and AI/ML strategies.

Quality 4.0 and the Physical Environment

Quality 4.0 capabilities include:

- **Automation of workflows and manufacturing systems**
- **Review by exception to limit review to elements with failure or anomaly**
- **Connection of clean rooms, cold storage, water systems and environmental monitoring systems**
- **Real-time anomaly capture — that is, detection of manufacturing anomalies and assessment of risk levels to automatically initiate actions**
- **Electronic batch record and visualization, which entails automation of batch record processes to track and manage production data**

■ Electronic work instructions and reporting

In terms of the physical environment, the QMS works to optimize the way products are manufactured and stored. “It helps isolate where the problems are,” says Inoue. “It’s the aggregator of all the IoT devices regulating temperature, for example. If the thermostats in a particular sector are at the right temperature, then everything is OK. If one falls out, then it’s a problem. It helps to pinpoint the problem.”

Aside from temperature, a QMS could be monitoring medical devices for things like viscosity, hardness or flexibility, says Inoue. With pharmaceuticals, it could be monitoring ingredient mixtures, the humidity of the room, the temperature of the boiler, the amount of pressure, the air and water quality, the pH level and so forth.

Quality 4.0 and Embracing Change

For many organizations, the benefits of using advanced technologies to monitor production data and manufacturing systems and processes may seem like more of a “want to have” than a “need to have.” It might seem safer and less costly to maintain the status quo than to enter unfamiliar territory.

However, one of the most daunting challenges facing many CIOs is a patchwork of multiple internal systems used to manage different aspects of quality and compliance. A modern QMS provides a centralized platform to harmonize disparate systems. It can serve as an integration hub to reduce complexity and enhance data visibility and accessibility.

Furthermore, the stakes are high for companies that rely on expert operators who will either leave or retire, notes Inoue. “It’s hard to replicate individual expertise,” he says, “and if you’re relying upon a network of human relationships and individual knowledge that is hard to extrapolate, that is risky.”

TrackWise Digital Quality Management System

Honeywell's TrackWise Digital QMS is built on Salesforce's software-as-a-service (SaaS) platform, which includes industry-leading quality process accelerators, superior dashboards and aggregated reporting capabilities.

“It plugs and plays with a lot of systems and has features and functions that are familiar to many organizations,” Inoue says. “If your shop is

standardized on Salesforce, you would have a customer relationship management (CRM) system with Salesforce, and you might have document management and other systems with Salesforce. And then if your quality management is with Salesforce, you have more and more resources that help build, integrate and manage similar systems.”

TrackWise Digital provides AI-enabled quality insights through features such as autocategorization, autocorrelation, root cause analysis, improved signal detection and trend analysis to reduce the impact of human errors and significantly boost productivity.

It offers world-class QMS interoperability through an industry-leading supply chain system architecture, plus rapid deployment capabilities and decreased time-to-value. TrackWise Digital reduces the burden on IT with faster validation and



PHOTO BY GORODENKOFF

gives users a modern and mobile experience. Additionally, the business can gain access to the latest product features and updates with minimal upgrade effort and system downtime.

TrackWise Digital enables speed and agility by streamlining and harmonizing quality data and processes. Quality and IT teams can focus on delivering new capabilities, ensuring the availability of safe and effective products and minimizing the risk of customer complaints or recalls.

Overall, TrackWise Digital offers CIOs at large enterprises a comprehensive solution to enhance business performance and achieve measurable improvements across multiple key metrics.

The Intelligence/ Quality Connection

Intelligence must be connected across a life sciences organization to achieve safety, efficacy and regulatory compliance in drug and medical device development. TrackWise Digital provides the framework for organizations to create standard

operating procedures that result in compliance and makes it easy for auditors and inspectors to verify that an organization is following its processes and procedures correctly. Cross-functional integration is necessary to create synergy throughout the value chain, and the elimination of data silos supports effective quality management across the organization. Integrating the entire ecosystem, including external suppliers, improves product quality and patient safety.

“A good quality management system shows that you are in control,” says Inoue, “meaning you are doing things as you’re supposed to. The more predictable you are, the better you are as a supplier, the better you are as a customer, the better you are as a producer. So, it’s not just cost – it’s reputation. It’s effectiveness.” ♦

Learn more about | TrackWise Digital.