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DIGITAL
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Connecting Quality Management, Patient-Centricity and Business Value

To drive quality and enable insights, life sciences organizations must integrate their data lakes, enterprise applications and manufacturing processes. Connectivity enables scientists, laboratory technicians and suppliers to carry out efficient,

effective research and product development. When properly integrated, application programming interface (API)-connected sensors and instruments provide data that can have a deep impact on patient health and well-being. An integrated end-to-end

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approach maximizes productivity, accelerates product releases, speeds time-to-market and reinforces patient-centricity.

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Current life sciences challenges

Among common quality challenges for life sciences and healthcare organizations are siloed operations, data and decision-making; supply chain complexity; material disruptions; and weak employee buy-in for a culture of quality – typically due to lack of workforce skills or relevant knowledge.

Kiyoshi Inoue, a director at Honeywell, is responsible for enterprise IT, digital transformation, and business process optimization projects. He says data integration should be at the top of the priority list for most organizations:

“The challenge is that organizations that aren’t mature may not have it at the top of the list just because they have to address other issues to get there. Usually, when you’re worried about data, that means you’ve solved almost all your other problems. Data integration tends to be the end state or the final goal for many organizations in a digital journey.”

The connected life sciences ecosystem

Life sciences companies can gain quality and operational insights by integrating data from across the value chain with predictive analytics powered by the latest digital technologies. A secure, scalable technology platform can help life sciences companies in any stage of their digital transformations to build better products, improve business and patient outcomes and maintain effective regulatory compliance.

A quality management system (QMS) is a set of collaborative tools that help organizations manage quality-related processes, meet compliance and make insightful decisions that drive proactive quality.

A closed-loop QMS captures data points across the entire product life cycle to help achieve those benefits. In essence, closing the loop means that when a quality issue is identified,

the QMS triggers an investigation into the root cause. In the case of a defective pharmaceutical product, for example, were the ingredients properly mixed? How was it packaged? How was it stored and shipped? Was the dosage correct? How was it administered?

In an integrated ecosystem, closed-loop quality feedback stretches from research and development to suppliers to the patient, providing secure, fully traceable end-to-end supply chain visibility. The closed-loop approach facilitates communication through all stages of product development, shortening the time to diagnose a quality issue and potentially keeping an inferior or unsafe product from reaching the consumer.

The earlier a problem is detected, the better. Tracking development from the beginning can expose flaws before the product reaches the supply chain, resulting in less waste and reduced costs.

Collaboration in a changing world

Recent changes have made collaboration for quality management more challenging but also more important than ever before. Many materials required for manufacturing life sciences and healthcare products have become more scarce and costly, notes Inoue.

“The intersection between quality manufacturing and logistics has become a real point of collaboration,” he says. “The people who know if a product is safe to ship are often the quality people. The people who want to know if it can be shipped are usually the logistics people, and the ones who know for certain if there is a problem are the manufacturing people. These three groups need to communicate. The more they communicate, the faster they can identify root causes, eliminate scrap, prevent the loss of materials, and avoid recalls.”

Collaboration has changed in part due to people working remotely because of the pandemic. However, another important driver of change is the increase in usable data generated by digital systems. More predictive capabilities have emerged in the marketplace, leading to more benefits from collaboration.

Within organizations, effective collaboration is critical because quality is not a separate function, Inoue points out. “Quality should be ingrained in how you work and how you operate.”

The benefits of track-and-trace capabilities

Whether it’s applied to the life cycle of a product or a single ingredient, track-and-trace helps uncover and isolate issues that must be resolved. In life

sciences manufacturing, problems are often related to an active ingredient, says Inoue, and understanding the chain of custody from the supplier to the warehouse is helpful.

For example, suppose that some miniscule bits of metal from scrap material fell into a formulary for pills. Track-and-trace can identify the manufacturing line, day, and time of day when the mishap occurred.

“If you don’t have track-and-trace, you don’t know. So essentially, every single pill must be scrapped, potentially resulting in the loss of millions of dollars in work in progress or finished goods because there’s no understanding of where the root cause could be,” says Inoue.

Track-and-trace is also integral to fraud prevention, guarding against counterfeits and ensuring that products go where they’re intended and are safe for use.

The role of artificial intelligence in quality management

In the context of quality, artificial intelligence (AI) and machine learning (ML) are particularly helpful in recognizing deviations from established tolerances, notes Inoue. AI and ML can help

tighten tolerance specs, which can lead to better outcomes – less scrap, for example.

Say a manufacturing process is going out of spec. After the fifth incident, that becomes a trend, says Inoue. Without human intervention, an AI or ML system could call attention to the deviations and start suggesting possible causes: These batches were OK, but this batch is out of spec. It might be related to this cause or the introduction of this ingredient.

“So maybe you stop the ingredient,” says Inoue. “AI allows you to forecast potential problems and stop them before they become bigger, leading to larger amounts of scrap or recalls.”

In quality management, AI and ML are most useful as suggestion generators. Their effectiveness depends on data quality and management.

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“You can’t just let these models work on their own,” Inoue emphasized.

“What they do is provide a list of suggestions that a human can either accept or reject.”

Balancing quality with the need for speed

Striking a balance between quality and fast delivery of healthcare products to consumers whose well-being, and even lives, depend on them is challenging but crucial. “It’s a very tricky balance,” says Inoue.

Trying to achieve this through traditional methods can get very costly. An organization that has had a recent recall, for example, might invest a lot of human resources into creating multiple redundancies to avoid another quality problem. The result can be a significant slowdown in operations. The organization might hire thousands of temporary employees to examine thousands of spreadsheets, collecting and collating data. Based on their findings, halting batch after batch of product might be necessary.

The organization might determine it must create extra inventory to ensure enough supply to meet demand, and then it must figure out which batches to send and which to scrap. It might spend an inordinate amount of money to make up for quality issues and maintain production speed.

The analysis, communication, and collaboration tools in TrackWise Digital can help identify the causes of problems early.

“For example, you could see that there’s something wrong with an ingredient before you blend in 10 other ingredients,” Inoue says. The process can be halted without wasting nine ingredients.

When the problem is solved, a quality product can be manufactured with minimal scrap. “That helps with both the quality part of it and the speed part of it,” according to Inoue, “because really, the idea of speed and quality is to get it right the first time.”

With AI, ML and good data sets, it’s possible to confirm that processes match established parameters. Computers can do that checking, eliminating a lot of the manual steps.

The cybersecurity aspect of life sciences quality management

In the life sciences and healthcare industries, there are so many data sets and different systems that people sometimes don’t know what is secure and what isn’t. “The thing that most people don’t realize is that Excel is a massive, massive data set, and there is typically an Excel spreadsheet the corporation operates from

somewhere on a shared drive or on individuals' laptops," says Inoue. "It could potentially have a lot of important data."

When data is managed in spreadsheets and other disparate sources rather than integrated, it is much more likely to get lost or pushed out to someone who shouldn't see it. Potential negative outcomes include wrong conclusions and leaks of proprietary information to the competition.

Data security is extremely important to a healthcare organization. A lot of competitive data exists in a QMS, including formulations and core intellectual property. An organization that lacks good data and cybersecurity practices exposes competitive information to the marketplace.

"Just the release of data in itself can affect the stock price," Inoue points out. "If it's a large publicly traded company, a data or quality anomaly could create panic. That could get blown out of proportion. It could be something that was caught years ago or that was found to be completely safe, but that isn't evident to someone who is just looking at the data."

Learn more about | TrackWise Digital and look for the next white paper in this series on effective quality management: **Leveraging Life Sciences Data for Intelligent Decision-Making.**

TrackWise Digital is built on Salesforce, a stable, well-known industry platform that allows organizations to build and extend their workflows and processes without worrying about how the system functions. Salesforce puts a lot of time and effort into cybersecurity, making sure they're on the cutting edge of that," says Inoue.

The bottom line

Honeywell offers a Quality 4.0 system that integrates quality management of data and business processes with every part of the value chain – from product development to ecosystem management to supply chain monitoring and more. The benefits for life sciences organizations include improved communications, collaboration, and performance, which contribute to concrete competitive advantages. ♦