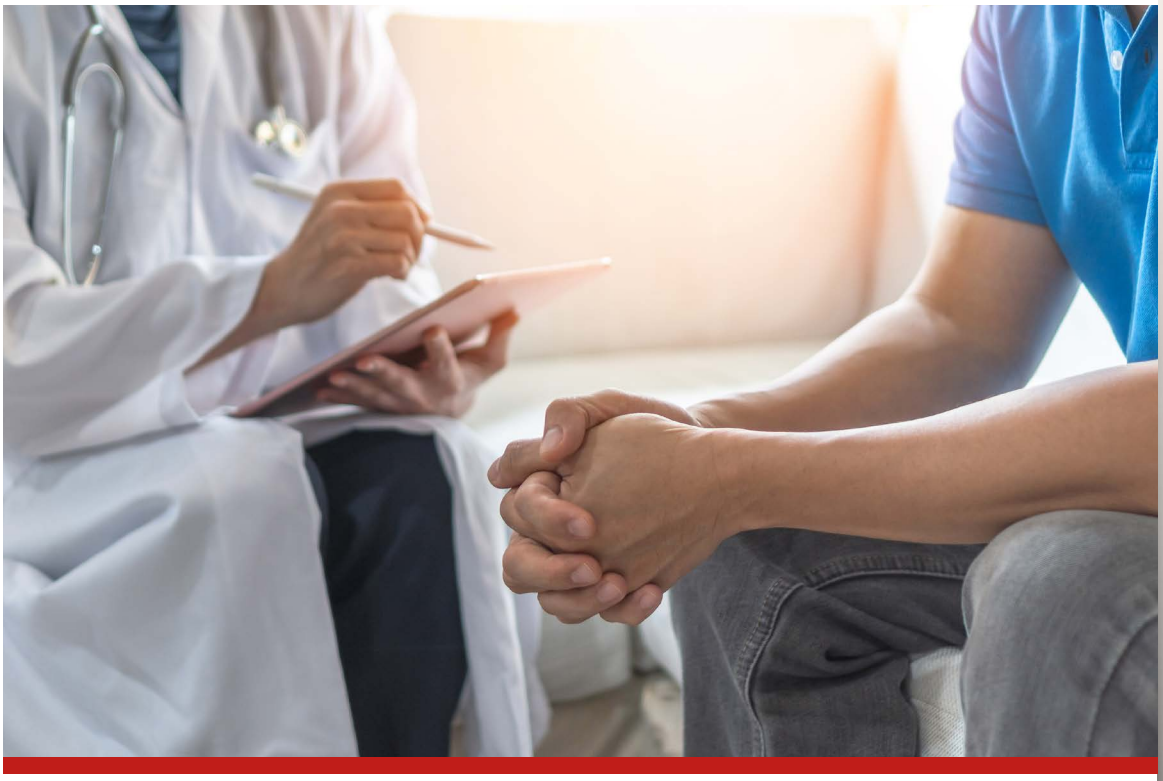

PHOTO BY CHINNAPONG

DIGITAL TRANS-FORMATION

Quality: The Link Between Platform, Processes and Patients

Effective quality management in healthcare and life sciences today means much more than achieving compliance. In this industry, the patient is the center of the universe. CEOs and other senior decision-makers expect quality management to optimize the patient's health, safety and customer experience while delivering meaningful outcomes for the organization and the population they serve. That requires a modern approach that connects everything on the value chain – from research

CIO

SPONSORED BY salesforce | Honeywell

and development to manufacturing to supply chain management. The goal: to deliver top-quality medical products to the market with the utmost urgency to meet patient and business needs. Proven platforms and processes and trustworthy partnerships are critical.

Key quality imperatives

Healthcare and life sciences enterprises face many industry-specific pressures, as the need to prioritize patient health and safety is critical. Healthcare firms tend to commit substantial chunks of their manufacturing budgets to quality — often 25% to 30%.[1] They are faced with costly drug and medical device recalls, quality issues with suppliers and vendors and losses due to cyberattacks.

It is noteworthy that more than 300 drugs and medical devices were recalled in 2021–2022,[2] for example. In the U.S., the number of FDA-approved suppliers for active pharmaceutical ingredients or medical devices is limited, and such products and medicines are subject to strict controls. If there are shortages or delays, companies cannot easily find a new regulator-approved source.[3]

A recent report placed the cost of healthcare-related ransomware attacks in 2021 at $7.8 billion.[4] And IBM reported that the average cost of a healthcare data breach was $10.10 million, an increase of 42% since 2020.[5]

In the current challenging global economy, many quality organizations are looking for greater efficiencies and cost savings to do more with existing — or, in some cases, fewer — resources. At the same time, they want to go beyond being a cost center and become more of a revenue or value generator. Quality is closely tied to customer satisfaction. By providing high-quality products and services, companies can improve customer loyalty and trust, leading to increased revenue and profitability.

CIO challenges

In the healthcare industry today, many CIOs are struggling to rapidly enable new technologies at scale. While striving to align operations with business objectives, they must contend with disparate systems that are often encumbered by manual processes.

In many cases, such a situation can be traced to how the company evolved through its growth, says Kiyoshi Inoue, a director at Honeywell, with responsibility for enterprise IT, digital transformation, and busi-ness process optimization projects.

"This often leaves CIOs with multiple duplicate systems in the ecosystem that often do not talk to one another. CIOs often are looking to simplify their landscape and unlock the value of their data by performing analytics across all of their data sets."

Integrating quality-related data from multiple sources is critical to optimizing patient-centricity. Providers can get a more complete picture of a patient's needs, which supports better decision-making that can lead to improved outcomes.

"High-level analytics systems are very good at situational awareness," says Inoue. "AI is essentially trying to assimilate pieces of information with knowledge and then be able to make decisions without having a full data set. That's something humans are really good at. What computers can do is offer suggestions that make human decision-making easier."

Effective quality management

A good quality management system (QMS) delivers value for healthcare and life sciences organizations and reduces risks to patient health and safety. Modern systems can anticipate problems before products ship out, so that patients are never exposed to the dangers associated with defects. In addition to keeping low-quality products from going to the customer, effective quality management ensures more stability in the supply chain, which means that customers will not experience shortages.

Life sciences organizations typically have vast amounts of data collected from diverse sources. There is tremendous interest in using artificial intelligence and machine learning (AI/ML) and other digital tools to tap into these data troves, gaining fresh insights that can lead to improved quality control and added value. Better, more quality-assured products lead to an improved customer experience with fewer recalls, which ultimately results in less reputational risk and greater trust.

Digitization of critical quality processes can improve data integrity and accuracy and connect quality and operational data across disparate systems. Modern QMSs that leverage the industrial internet of things (IIoT), AI/ML and advanced analytics can optimize process performance and operations across the enterprise, increasing manufacturing speed and agility while improving product quality and lowering quality-related costs.

"Good quality management practices also ensure that you are looking at the root cause of your issues or barriers," says Inoue. "This approach

allows you to innovate and resolve issues faster."

PHOTO BY GORODENKOFF

Cloud computing

The widespread adoption of cloud computing by healthcare and life sciences organizations has had a significant impact on the speed of innovation.

A cloud-native QMS provides a secure, compliant data management environment. The main difference between cloud and other QMS models is data accessibility, Inoue says. "With systems that are not cloud-native, it's harder to get to your data because it's physically located somewhere. You have to create a physical root saying, 'Wire 1, go to wire 2,' and that's you. When it's in the cloud, you're just connecting to one box, one cloud, to gain access to data."

As a fundamental component of Industry 4.0, also known as the Fourth Industrial Revolution, the cloud supplies the necessary infrastructure for the deployment, integration, and management of advanced technologies such as the internet of things (IoT), AI/ML and big-data analytics.

Industry 4.0 enables manufacturers to implement real-time monitoring of manufacturing processes, detecting quality issues as they happen and thus reducing the risk of defects and recalls. Manufacturers can collect data from machines and equipment and analyze it to improve equipment effectiveness, reducing downtime and controlling maintenance costs. Industry 4.0 tools can be used to train workers, improve safety, enhance productivity and enable better-informed decisions.

Cloud-based quality management helps healthcare and life sciences organizations enable real-time collaboration and gain end-to-end visibility, from development and manufacturing to supply chains and delivery. By leveraging AI/ML algorithms, a cloud-hosted QMS enables organizations to gain insights into patient preferences and needs, leading to better-tailored personalization of products and services.

Industry 4.0 obstacles

As is common when powerful new technologies emerge, concerns have arisen over their security. Internet-connected devices can be vulnerable to cyberattacks. The collection and processing of vast amounts of sensitive data can put privacy at risk. Security threats can evolve quickly, and it can be challenging to stay ahead of them.

Despite these concerns, Industry 4.0 technologies can be made secure through the implementation of encryption, access controls, network segmentation and other advanced measures.

In the life sciences sector, there is some understandable hesitation about Industry 4.0 due to concerns about AI risk, and organizations that have data silos may hesitate to embrace Industry 4.0 due to integration challenges, data quality issues, culture and investment costs. However, these challenges can be overcome by adopting a data-driven mindset, investing in the necessary technologies and infrastructure, and implementing cross-functional collaboration and data sharing.

Another issue that can deter some healthcare and life sciences organizations from adopting Industry 4.0 is the complexity of supply chains involving many external providers. However, implementing data standards, investing in cybersecurity measures, aligning on common goals and incentives and adopting collaboration models that share risks and rewards can go a long way toward alleviating supply chain concerns.

Life sciences organizations are sensitive to the rising total cost of quality due to increasing complexity, globalization, regulatory compliance, digital transformation and reputation risks. Yet resisting change will only exacerbate risks and associated costs while drastically curtailing an organization's ability to compete in a transforming environment.

Solving the challenge

Honeywell has established a position of leadership in the quality management market, particularly in the biopharma and medical device industries, with its flagship product, TrackWise. The company has achieved an impressive 1,000-plus global implementations and has more than a million users.

In addition to its traditional on-premises offering, Honeywell has adapted to the changing technology landscape with TrackWise Digital, a software-as-a-service (SaaS)–based QMS, and QualityWise.ai, an AI-powered solution that

DIGITAL TRANS-FORMATION

helps automate quality management processes. Of importance to many healthcare and life sciences organizations is TrackWise Digital's approach to the quality ecosystem. "You are not tied to having an all-TrackWise solution to be able to achieve your goals," says Inoue. "This allows organizations to make incremental changes to their landscape without too much disruption."

With its wealth of experience and innovative solutions, Honeywell is well positioned to continue to help life sciences organizations improve their quality management practices in the years to come.

Learn more about | TrackWise Digital, and keep an eye out for the next white paper in this series on effective quality management: **"Connecting Quality Management, Patient-Centricity and Business Value."**

1 Ulf Schrader, "Operations can launch the next blockbuster in pharma," McKinsey & Company, February 16, 2021. https://www.mckinsey.com/capabilities/operations/our-insights/operations-can-launch-the-next-blockbuster-in-pharma

2 Oxana Pickeral, "It's Time For The Life Sciences Industry To Embrace Quality 4.0," Forbes, January 25, 2023. https://www.forbes.com/sites/forbestechcouncil/2023/01/25/its-time-for-the-life-sciences-industry-to-embrace-quality-40/?sh=196cfaf03253

3 Adam Lohr, "Life sciences balance regulations with supply chain disruptions," RSM, July 12, 2022. https://rsmus.com/insights/industries/life-sciences/life-sciences-balance-regulations-with-supply-chain-disruptions.html

4 Paul Bischoff, "Ransomware attacks on US healthcare organizations cost $7.8bn in 2021," Comparitech, October 5, 2022. https://www.comparitech.com/blog/information-security/ransomware-attacks-hospitals-data

5 IBM, "Cost of a Data Breach 2022. " https://www.ibm.com/reports/data-breach