

INNOVATING MANUFACTURING FOR THE PATIENT

Accelerating Product Release for Novel Therapies

Honeywell

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The life sciences industry has shifted to a patient-centric approach, leading to the development of novel products like precision medicine that require proactive quality management solutions.



Product release or disposition is a complex and costly process that involves data from various sources and systems—AI-enabled quality management can help expedite the process, improving efficiency and effectiveness.

This white paper reviews how AI and other digital innovations can help quality teams and regulators automate monitoring, reporting and response processes, and enable real-time visibility from development to delivery, resulting in better management of product supply, safety and cost.

We'll also consider the five levels of autonomous operations that life sciences companies can achieve with AI, from rule-based to autonomous agents, and the focus areas where Honeywell AI can transform operations, such as adaptive plant-wide optimization, predictive asset performance monitoring, generative AI-based co-pilots and sustainability applications.

The Honeywell Life Sciences portfolio of TrackWise Digital®, the Life Sciences Applications Suite and the QualityWise.ai® analytics layer is uniquely positioned to enable the revolution of precision and personalized medicine and ensure that customers can accelerate delivery of their groundbreaking therapies to the patients.

THE RISE OF THE PATIENT-CENTRIC VALUE CHAIN IN LIFE SCIENCES

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In the past decade, the patient has become the center of the life sciences value chain, ousting the practitioner, provider, purchaser and payer from their lofty positions of power.

Gone are the days when the surgeon chooses sutures based on personal preference. Now the chief procurement officer makes that buying decision. And while the health insurance company still has a big influence on treatment regimen, patients have growing influence on how, when, where and with what they are treated. CVS Health's acquisition of Aetna and their resulting expansion, represents the first combination of retailer and payer. A patient-centric value chain enables this amazing change. A patient-centric view recognizes the patient at the core—and their increasing power. The typical supply chain operations reference (SCOR) model of "Plan, Source, Make, Deliver...and Quality" is rapidly expanding past the manufacturer's warehouse and the hospital's receiving dock to the treatment room and patient's home.



PRECISION MEDICINE AND QUALITY MANAGEMENT SOLUTIONS

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One of the greatest examples of patient-centric novel products that rely heavily on proactive quality management systems (QMS) are the amazing innovations in precision medicines.

The FDA saw a record number of personalized medicine applications in recent years, more than any other drug type in general. In 2017, the FDA approved the first three gene therapies and authorized the first health-related genetic test to be sold directly to the consumer. The precision medicine market continues to accelerate and is expected to grow at a rate of 11.5% through 2027.¹

Manufacturers are accelerating the development and approval of medical products like CAR-T and other cell therapies. Such products are manufactured for a patient's specific genome, most likely directly in the hospital clinic. How will quality teams manage quality risk or bound a recall? What QMS solutions will life sciences need to fully realize this vision?

We know that several of our most valued customers already have lifesaving, life-changing precision medicine therapies that are required to be delivered to the patient in days, not weeks or months, from the time of manufacture. TrackWise Digital and our QualityWise.ai advanced analytics capabilities are playing a critical role in expediting the product disposition process.

Batch release or product disposition is a multi-billion-dollar problem for the life sciences industry and not only is it costly, but every day that a product is awaiting release is a day a patient doesn't have the drug or device they need. The problem is of course a complex one. There are several factors that contribute to cost, and time associated with the challenge; complexity of system architecture, silos of data, supply chain complexity,

product complexity, and regulatory pathway to name a few. Very simply, the process demands manufacturing data, typically sourced from a manufacturing execution system (MES), testing data, typically sourced from a laboratory information management system (LIMS) and quality data, typically sourced from the QMS. If the enterprise resource planning (ERP) system is the gate that needs to open to release the product, then the QMS is the key to that gate.

PRODUCT RELEASE AND THE ROLE OF AI

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One significant contributor to the lengthy product release timeframe is the fundamental need to disposition all the deviations, nonconformances and corrective and preventive actions (CAPA) that were inevitably generated during the manufacturing process.

The volume and frequency of repeat deviations is a particular burden to the process. The solution is to eliminate these repeat deviations and ideally any such quality event from occurring in the first place. We are targeting this solution with our development of quality by design (QbD) and continuous process verification (CPV) solutions—the topic of another paper.

However, in lieu of the nirvana of review by exception (RBE) or even real time release (RTR) transformations that such solutions will inevitably bring, the AI-enabled QMS solutions delivered by Honeywell play a unique role in reducing the impact of deviation and quality event management, to accelerate product release and enable our customers to bring those release times down to days versus weeks as required.

TRACKWISE DIGITAL

TrackWise Digital is a fully integrated, closed-loop system that connects each step of the lifecycle of a quality event. When a deviation is identified it must be captured and documented. Root cause analysis is performed, CAPAs are defined, executed and measured for effectiveness. Often those CAPAs will generate product, process or equipment change controls. These are frequently tied to a raw material, component supplier or contract manufacturer and the critical link to supplier quality arises. Documents need to be changed and staff need to be trained on the impact and changes implemented. In TrackWise Digital all these elements are managed digitally in a truly connected manner with performance analytics and dashboards provided at each step.

QUALITYWISE.AI

When that deviation arises, QualityWise.ai auto-categorization helps the quality professional with instant visibility to the potential categorizations of deviation type, severity, and associated risk, among other parameters; right there on the same screen as the TrackWise Digital application. QualityWise.ai Insights auto-correlates that deviation against the entire current and historical quality data set stored in TrackWise Digital, immediately providing the quality professional visibility to same or similar deviations, from across the business as well as CAPAs, nonconformances, change controls and complaints that may have the same or similar origins.

For example, the AI shows that a CAPA was closed 3 years ago, but the root cause has possibly returned. Maybe that CAPA wasn't as effective as first thought. It shows the quality professional how many times that same deviation has occurred and been repeated in every plant or product across the business.

Ineffective root cause analysis is one of the US FDA's biggest concerns on the industry today. QualityWise.ai root cause advisor (RCA) offers the quality professional the potential causative factors, enhancing root cause analysis to help ensure they get to true root cause—augmenting human decision making, not replacing it.

HONEYWELL PRODUCT QUALITY REVIEW

Most recently, with the launch of the Honeywell Product Quality Review (HPQR) application, the quality event lifecycle is further enhanced as the arduous process of completing annual product reviews is not only digitized and automated but optimized to provide even greater insight and improved signal detection.

Our latest architectural design weaves a data fabric across the various systems of record and sources of data that exist in the business, democratizing that data and exposing it to the advanced analytics and visualization platform on top of which the HPQR application operates.

Combining these process and analytical powers, delivered by our industry leading quality and supply chain experts, on the world leading software platforms with unparalleled user experience, provides a life sciences manufacturer with the opportunity to not only dramatically improve the efficiency of managing those deviations and their resulting activities but, perhaps more importantly, the effectiveness of these essential accountabilities. This results in reduced occurrence of such deviations, reduced repetition, greater root cause effectiveness and a significant reduction in the time it takes to resolve such issues and their impact on product release in the journey of that product from manufacture to patient.

Recently, the Honeywell Life Sciences Customer Advisory Board drafted its perspective on the application of AI in the discipline of quality across the industry.

“We believe AI will be transformative, evolving from basic rule-based systems to dynamic, self-adapting autonomous agents, seamlessly integrating with your existing frameworks. This progression will amplify human decision-making and problem-solving capabilities, unlocking innovation and strategic insight, essential for tackling complex business challenges. Our AI will enable industry to tackle new frontiers previously unapproachable. This journey extends beyond gradual improvements; it will propel us into uncharted territories, laying a foundation for visionary, future-centric solutions”.

THE BENEFITS OF AUTOMATION AND REAL-TIME VISIBILITY FOR QUALITY AND SAFETY

AI-enabled solutions, advanced analytics and other digital innovations can help quality teams—as well as regulators—improve efficiency and productivity by automating monitoring, reporting and response processes.

This type of automation can help to:

- **Reduce human error**, for example in the transcription of quality data from machine reading to manual recording or input into a spreadsheet.
- **Enable real-time, end-to-end visibility** from development to manufacturing to supply chains and delivery, helping life sciences companies improve everything from inventory management to supply chain planning.
- **Adjust processes and track medications in real time**, for better management of product supply, safety and cost.
- **Enhance patient safety** via patient support programs that could also improve customer relationships and outcomes.

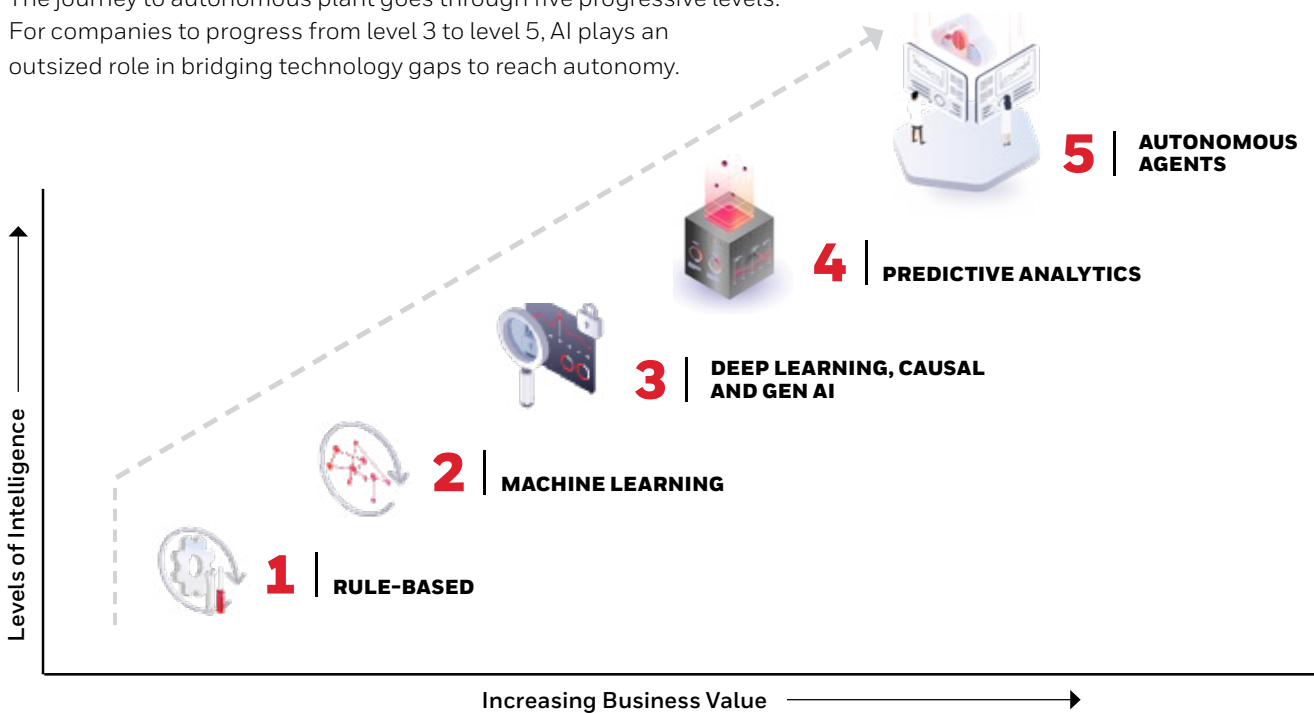
There's no reason to think that the pace of innovation will decrease any time soon. Quality teams will need to adopt a proactive quality mindset to maintain the safety of their customers and their company's brand reputation.

THE AUTONOMOUS OPERATIONS JOURNEY

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The autonomous operations journey is important to address the aging workforce, drive greater asset productivity to compete, reduce human errors in an increasingly complex operational world and facilitate rapid scaling.

The journey to autonomous plant goes through five progressive levels. For companies to progress from level 3 to level 5, AI plays an outsized role in bridging technology gaps to reach autonomy.



1 Rule-Based | Controlling

- Automation, if-then statements, validation rules in TrackWise & TrackWise Digital

2 Machine Learning | Measuring, Correlating, Categorizing

- QualityWise.ai, auto-categorization, insights

3 Deep Learning, Causal and Gen AI | Observing, Understanding (natural language processing (NLP)), Creating

- QualityWise.ai root cause advisor
- Data transformation from unstructured to structured

4 Predictive Analytics | Predicting, Emerging

- CPV, multivariate analysis (MVA)
- Emerging insights

5 Autonomous Agents | Executing, Learning, Adapting

- AI executes steps autonomously and can react and adapt to changing situations without additional human input
- There are learning mechanisms in play for humans to learn from AI, for AI to learn from humans and for both to learn from predictions and outcomes to continuously improve

FOCUS AREAS OF HONEYWELL AI

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There are several focus areas where Honeywell AI will rapidly transform operations:

- **Adaptive plant-wide closed-loop optimization**
- **Predictive asset performance monitoring**
- **Generative AI-based co-pilots for smart workforce**
- **Sustainability applications for active energy and emissions management**

Only a few companies, like Honeywell, who have transformed themselves into an industrial AI software enterprise have the experience, the data and the domain expertise to deliver above-operational capabilities safely. Honeywell already has several AI-enabled products on the market today. With industrial operations, our Honeywell Asset Performance Management (APM) and Honeywell Forge Performance+ for Buildings solutions analyze process improvement learnings using AI models. The AI models support the workforce with technology solutions that help identify performance gaps.

Honeywell Forge for Buildings uses AI and machine learning (ML) to help building owners and operators with building health and sustainability. Honeywell Forge Sustainability+ for Buildings | Carbon and Energy Management uses sensor data and ML algorithms to continuously monitor and automatically adjust building controls at the zone level.

TrackWise Digital leverages AI for enhancing quality related decision-making capabilities, providing a shift from reactive to proactive and preventive quality.

QualityWise.ai provides powerful, AI-augmented quality processes, unlocking the value of operational data to augment decisions, applying NLP and ML throughout the QMS to improve signal detection, increase operational efficiency and ensure patient safety. QualityWise.ai supports TrackWise Digital with auto-categorization, and insights auto-correlation.

MANAGING DISRUPTIONS WITH THE HONEYWELL LIFE SCIENCES PORTFOLIO

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The disruptions introduced by Industry 4.0 have fundamentally altered the life sciences industry, transforming it into the “Factory of the Future.”

AND THE FUTURE IS HERE.

A revolution in medicine has arisen to accompany this latest industrial one, in many ways as a result of it. The rise of combination product, biologics, gene and cell therapies and the rapid innovation in precision and personalized medicine, demand equally innovative approaches to quality management and the application of truly digital enablers such as AI.

The Honeywell Life Sciences portfolio of TrackWise Digital, the Life Sciences Applications Suite and the QualityWise.ai analytics layer is uniquely positioned to enable this revolution and ensure our customers get their groundbreaking therapies and treatments to the patients they serve in the accelerated manner they demand.

SOURCE

¹ Precision Medicine Market Size, Share, Report 2022 to 2030. (n.d.). <https://www.precedenceresearch.com/precision-medicine-market>

For more information

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IS
WHAT
WE
MAKE IT**

