



WHITE PAPER

Future-Proofing a Pharma Manufacturing Legacy through Digital Quality Transformation

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THE MANUFACTURING ENVIRONMENT IS DRAMATICALLY BEING RESHAPED

The life sciences manufacturing environment is dramatically being reshaped with the advent of AI. Digital technology and processes are increasing operational efficiency, safety and improving production performance. The acceleration of digitization efforts represents a golden opportunity to transform manufacturers' operations into integrated, agile environments that excel and empower their workforces through AI.

However, many shop floors do not have an integrated view of their manufacturing operations. They are often characterized by isolated pockets of data that's critical to a global enterprise. As industries adopt technological advances and rapidly move into the fourth industrial revolution, it is essential to assess the impact of these isolated data pockets on the workforce, customers and the safety of patients.



THE CURRENT STATE OF QUALITY

ASQ defines Industry 4.0 as “the revolution driven by exponential growth of disruptive technologies and the changes those technologies bring to the workplace, the workforce, and the markets organizations serve. Quality 4.0 is the term that references the future of quality and organizational excellence.”

Digital transformation is a key component of Quality 4.0. It allows companies to capitalize on the sea of data and make that data accessible and actionable to provide insights that power human decision-making and real-world automation.

Manual processes will not support the move towards manufacturers' need for faster, complete data tracking and visibility.

Some of the current roadblocks are:

- Not enough people
- Time for validations
- Rewriting processes and procedures
- No clear guidance for regulatory bodies
- Lack of data resources
- Lack of sufficient workforce skills
- Unawareness of how to define AI
- Cybersecurity risk
- Implementation



The Rise of Digital and Data

There are three key areas in the rise of digital, including:

1

Data-Centric Analytic Tools

Quality 4.0 solutions like AI/ML and high-speed networks that generate real-time data have augmented human decision making. Using ML and predictive analytics for better signal detection and faster decision-making increase productivity and patient safety.

2

Unified Cloud

Life sciences companies have been moving data and applications to the cloud, often as Software-as-a-Service (SaaS). These moves accelerated in 2019 and 2020 with the sudden move to remote work and collaboration that resulted from the COVID-19 pandemic. Among 14 business-critical applications for life sciences companies, two-thirds are already deployed in the cloud, with that proportion expected to near 90% by 2022, according to findings by IDC. Ease of collaboration, coordination with other systems, automatic revision management and reduced IT support has made this migration an easier decision for life sciences IT executives as legacy systems age.¹

3

Data Democratization, Transparency and Collaboration

The evolution of cloud-based software solutions has made data-related insights more accessible. While digital-enabled companies were quick to adopt these technologies, others have not yet taken advantage of the insights these solutions offer.²

Life sciences manufacturers who want to optimize quality data analytics have a company-wide cloud-first strategy, and digital transformation champions are ready to accelerate toward digital.

Making the Move to Digital Quality Management

Proactive quality drives higher quality, helps organizations meet compliance and enables improved business outcomes across the entire life sciences value network. Achieving proactive quality relies on harmonizing data, people, technology and processes to identify and correct issues early on. The goal is to cultivate a proactive—and, ultimately, predictive—mindset inside and outside of your organization. To achieve this, organizations need a digital-enabled QMS that connects quality data across manufacturing, suppliers and the entire value network to facilitate proactive decisions that drive better business outcomes.

Organizations that move to digital quality management will benefit from:

- Leveraging cloud and digital to reduce costs and improve efficiency
- A mobile enabled and digitally powered workforce with connected QMS
- Validated and harmonized data and processes
- Reduced IT burden and infrastructure overhead
- The ability to support business continuity with minimal disruption and reduced risk
- Built-in mobility and scale to support growth, outsourcing and mergers and acquisitions
- Improved efficiency and decision making



NURTURE A CULTURE OF QUALITY BY DIGITIZING WORKFORCE MANAGEMENT

Leading manufacturers are embracing digitization initiatives to stay competitive in the global economy. Those that include workforce management in strategic planning understand the value of productive, informed and engaged human resources.

Research from BCG³ and Deloitte⁴ recognize some barriers and provide information to adapt and overcome:

- Develop an internal team/working group tasked with researching, developing and deploying AI.
- Develop a vision and roadmap and define how Quality 4.0 and digital technologies such as AI promote business strategy and create sustainable competitive advantage.
- Make digital, proactive quality part of the leadership agenda.
- Invest in digital quality talent and upskill and reskill current employees.
- Invest in data readiness and Infrastructure and form an alliance with your technology vendors to gain access to AI.
- Start small and scale-up. Identify pain points and pilot projects to resolve those pain points, and then expand. Identify which use cases provide the most business value.
- Foster a quality culture that strives to shift to proactive and predictive quality and embraces technology and data.
- Engage with your regulators, the FDA and other regulatory bodies. You'll quickly find that not only are they undertaking a digital transformation, which is undoubtedly true in the case of the US FDA, but that they also encourage such a shift.



DIGITAL MOVES PROACTIVE QUALITY FORWARD

Safety is the number one priority for all manufacturing companies. A proactive approach may include mitigating site-based risk with processes that ensure the proper authority can make decisions and execute. Heavy reliance on manual processes and static communications negates efforts to create proactive culture.

While the industry has made some progress towards this vision of proactive quality, one of the main reasons it hasn't achieved this promise even after years of defining and articulating it is that many of these necessary technological advancements simply weren't available in the GMP environment. This is only realized through innovations such as AI and NLP and their application to the quality system discipline. Real-time visibility into what is happening within safety processes is paramount.

The value and benefits of augmenting the expertise of quality teams with the speed and power of AI are clear:



We can now perform consistent categorizations with timely reporting and risk assessment.



We can carry out faster, more effective investigations and avoid redundancy.



We can improve prioritization and view the next best actions for quality events.



Perhaps most importantly--we can optimize signal detection and trending, minimizing errors, compliance risk and associated regulatory actions.

Predictive analytics can reduce the number and severity of quality events over time. The associated productivity and ability to offset quality unit headcount increase with business growth is vital. Ultimately, all this adds up to higher quality products, safer patients, a more secure supply chain and unparalleled levels of global regulatory compliance. Such a paradigm shift can only go on to further improve the culture of quality.

The ability to leverage disruptive technology like AI is the key to unlocking this promise of proactive quality. AI in the QMS augments decision making, ultimately enabling predictive analytics with capabilities like:

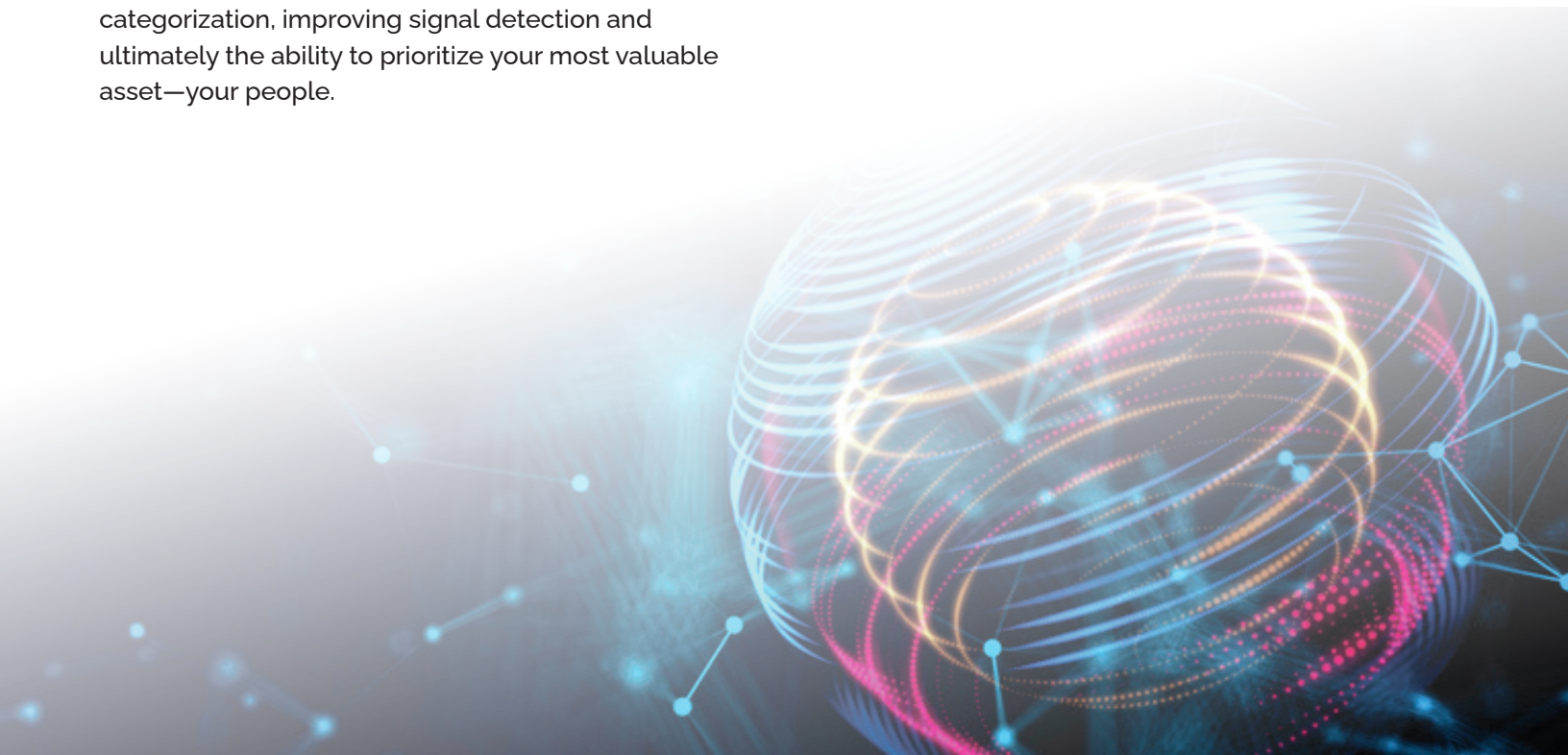
Auto-Categorization

Auto-categorization points the AI engine at single records, individual complaints or quality events. The algorithms then consume all the structured and unstructured data in that record, often large volumes of text entered by the quality professional. The AI then suggests to the user the most likely categories of critical data elements within that record with an accompanying statistical probability—complaints type, reportability, severity and so on.

The remaining fields and requirements of the process and the associated records then autopopulate the users' acceptance of that suggestion. This augments human decision-making to increase the timeliness of these critical actions, providing consistent categorization, improving signal detection and ultimately the ability to prioritize your most valuable asset—your people.

IIoT Connectivity

Finally, with IIoT enabled quality management, AI connects the QMS to the shop floor to detect anomalies in manufacturing operations and create and triage quality events to address potential issues near real time. This reduces the cost of poor quality by preventing the distribution of products that may have resulted in a recall or patient harm. The IIoT-enabled capabilities include a contextualized product disposition workflow to review and approve batches for market release. Users can achieve faster time to market by reducing the time required to review batches while maintaining the same quality standards.



Harvard Medical School assistant professor Obermeyer stated in a 2016 interview:

APPLICATIONS FOR AI

Deloitte released a fascinating paper in November of 2020,⁴ They stated that AI is most effective when deployed strategically across the entire enterprise, allowing a life sciences company to reap enormous benefits. For manufacturing, applying AI technologies can help reduce manual oversight in manufacturing operations and allow tighter control of quality and operating costs through:

- Proactive quality control through using Machine Learning (ML) to assess manufacturing data
- Automated batch release
- Optimized yield and output

“In 20 years, radiologists won't exist in anywhere near their current form. They might look more like cyborgs: supervising algorithms reading thousands of studies per minute.”³

Where are AI and other innovative technologies being used across the life sciences industry?

MEDICAL
DEVICE
COMPANIES*

R&D

DRUG
DISCOVERY

CLINICAL
STUDIES

MANAGEMENT
OF ELECTRONIC
HEALTH
RECORDS

CLINICAL
HISTORY DATA

RADIOTHERAPY
AND
RADIOLOGY

*Medtronic Diabetes devices, GE Healthcare, Phillips Healthcare Medical Imaging Solutions

“ Proactive Quality is the Destination; Digital Technologies are the Vehicle.”

AN INTEGRATED DIGITAL TRANSFORMATION STRATEGY

With the right partner, digitization can bring a comprehensive, integrated platform to the manufacturer environment. Based on the pillars of safety, security, productivity and compliance, the solution benefits from automation, integration and real-time data visibility.

Quality 4.0 value propositions fall into six categories, according to ASQ⁶:

- 1** AUGMENT HUMAN INTELLIGENCE
- 2** INCREASE THE SPEED AND QUALITY OF DECISION MAKING
- 3** IMPROVE TRANSPARENCY, TRACEABILITY AND AUDITABILITY
- 4** ANTICIPATE CHANGES, REVEAL BIASES AND ADAPT TO NEW CIRCUMSTANCES AND KNOWLEDGE
- 5** EVOLVE RELATIONSHIPS, ORGANIZATIONAL BOUNDARIES AND THE CONCEPT OF TRUST TO UNCOVER OPPORTUNITIES FOR CONTINUOUS IMPROVEMENT AND NEW BUSINESS MODELS
- 6** CULTIVATE A CULTURE OF QUALITY AND EXCELLENCE THAT TRANSLATES INTO ALWAYS DOING THINGS RIGHT FIRST TIME

Sparta Systems, a Honeywell company, provides end-to-end quality management solutions backed by decades of experience in vertical manufacturing markets. TrackWise Digital offers a comprehensive portfolio of solutions that are field proven to ensure safe and secure operations.

As Industry 4.0 is leveraging to reshape the manufacturing industry, companies must prioritize the transformation to digital technology. Proactive quality allows you to stay several moves ahead. Quality 4.0 simply applies Industry 4.0 advanced digital technologies to enhance traditional best practices in quality, not replace them.

We defined the characteristics a business would need to reach a maturity level where proactive quality was a differentiator over five years ago. We are now delivering the technology, maturity and environment required to make such a paradigm shift.

A significant competitive advantage is gained by applying AI to the quality management system, from the shop floor to the C-suite. Manufacturers that use digital to redefine the meaning of quality excellence are those that will win.³ The barriers to adoption are clear and not insignificant, but we will overcome them. Remember, "Industry has the ethical obligation to use these innovations in service of public health."

“ Industry has the ethical obligation to utilize the innovations afforded to us, in service of the public health. We must work together to realize this capability- to augment but not replace human decision making.”

Because the best in the world, make the next move, first.

“ To the customer, it is not AI that matters—it's the fact that magically, the business process got done. People don't buy AI. What they buy is the solution to a real problem that they have. If it happens to use AI, then it happens to use AI, but that doesn't matter to them in the end as long as the task is completed on time and with accuracy.”⁵



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Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.

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