THREE STEPS TO DIGITAL TRANSFORMATION IN LIFE SCIENCES MANUFACTURING

Honeywell

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MANAGEMENT SUMMARY

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Life sciences manufacturing is transforming in ways no one could have imagined even a few short years ago.

To drive success in today's new pharma reality, manufacturers of all sizes and scales need to accelerate innovation, while at the same time optimizing processes, reducing lead times, and ensuring the highest levels of data integrity, product quality, compliance, and safety.

That sounds like a tall order, but it's easier than you think with a digital platform that's purpose-built for the new pharma reality.

In this white paper, we'll examine some trends that are transforming the industry, discuss some of the common speedbumps on the road to innovation, and explore how a highly adaptable new platform from Honeywell accelerates innovation in life sciences manufacturing to offer unprecedented process transparency and continuous process improvement as a formidable competitive advantage.

THE NEW PHARMA REALITY

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The pandemic showed the world what's possible when innovation in life sciences manufacturing is dramatically accelerated. The last couple years also caused a surge in the number of pharma companies adopting a digital-first model while simultaneously challenging industry norms.

According to a recent report from Deloitte, visionary leaders in life sciences manufacturing plan to continue driving investments "focused on long-term, strategic digital objectives—using automation, smart factories, and artificial intelligence to transform manufacturing and build supply chain resilience." [1]

OPPORTUNITIES AND CHALLENGES

Today's rapidly evolving industry presents manufacturers with a range of dynamic opportunities and challenges driven by competition, technology, personalized medicine, smaller batch production, contract manufacturing, a shift toward biologic portfolios, and increased regulations.

To take advantage of these new opportunities, and overcome challenges, manufacturers of all sizes need to employ digitalization at scale, with new technologies that enable the agility and flexibility they need to drive success in one of the world's most complex and competitive industries.

1. Source: www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-dei-global-life-sciences-outlook-report.pdf

INDUSTRY MEGATRENDS

SHIFT INTO BIOLOGICS
Biologics accounted for > 40% of total Pharma Revenue (2019), projected to be >50% by 2024

PRECISION MEDICINE
Over $10B invested in CMO/CDMO expansions to support cell and gene therapy manufacturing since Jan. 2020

PERSONALIZED MEDICINE
The reduced cost of genetic sequencing has enabled development of personalized treatment plans and targeted therapies focusing on a patient's genetic and molecular makeup

INCREASED REGULATIONS
FDA data integrity initiatives requiring improvements in quality and manufacturing data capture, reporting and auditing

INDUSTRY RESPONSES

FLEXIBLE MANUFACTURING
- Modular manufacturing facilities (skids) to support a broader product portfolio
- Deliver facilities faster due to time-to-market pressure for maximum business potential capture

SINGLE USE SYSTEMS (SUS)
- Supports smaller scale production platforms such as Precision and Personalized Medicine
- Lower cost of investment, flexibility for expansion & reduction in change-over time
- Increased local production capabilities

DIGITALIZATION
- Driving the need for unified data platform – convergence of IT and OT
- Support of continuous manufacturing with predictive quality data
- Focus on improving manufacturing efficiencies (OEE)

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WHAT'S SLOWING INNOVATION?

Data is the underpinning element across life sciences. Now more than ever, it's critical for life science companies to begin the digitization of their manufacturing processes. Without real-time access to high-quality data from across the enterprise, the ability to thrive in the new pharma reality and leverage new technologies will be severely limited.

Moving away from using and managing paper, or unstructured data in electronic form like spreadsheets, or document files, is just one part of digital transformation. Pharma 4.0 digital maturity requires integration of data from across manufacturing operations, automation of manual tasks, and embedded analytics in the workflows of connected frontline workers in order to remain competitive. In addition, descriptive, predictive, and prescriptive analytics, ML and AI all require digital transformation.

Here are some of the speedbumps life sciences manufacturers face on the road to innovation. [1]

- Pharma is a highly regulated industry. It's estimated that approximately 30% of staff time is spent on documentation-related activities, including product dossiers, machine logs, batch records, and more.
- Accuracy is only 91% when documentation tasks are performed manually.
- A biotech batch record can comprise between 5,000 to 45,000 manual entries, and data is often logged and transferred manually to paper. This is not only time consuming, but it also increases the risk of errors. The biggest delay in batch releases is related to the quality function, specifically around missing batch information and the clarification process to ensure a complete batch record.
- It is reported that the average asset utilization in pharma, measured as overall equipment effectiveness (OEE), is 35 %. A big reason for such significant underutilization is poor management of assets and equipment. Despite advances in equipment technology, implementing solutions for performance monitoring and operator training often lags.

Key Takeaways

- The new pharma reality requires agility and flexibility.
- Digital transformation is driving the need for a unified data platform.
- Insights from data enable operational excellence and manufacturing efficiencies.
- A lean modular digital application with low infrastructure requirements is critical.
- Unlocking data from disparate systems before, during, and after manufacturing is a powerful tool for optimizing operations and continuous improvement.

OPERATIONAL REALITIES

30%

PERCENTAGE OF STAFF TIME SPENT ON DOCUMENTATION-RELATED ACTIVITIES

5,000–45,000

AMOUNT OF MANUAL ENTRIES THAT CAN BE ASSOCIATED WITH A BIOTECH BATCH

35%

THE AVERAGE ASSET UTILIZATION IN PHARMA (OOE) IS JUST 35%

91%

ACCURACY IS ONLY 91% WHEN DOCUMENTATION TASKS ARE DONE MANUALLY

Source: McKinsey, Operations can launch the next blockbuster in pharma, Feb.16, 2021

1. Sorce: www.mckinsey.com/business-functions/operations/our-insights/operations-can-launch-the-next-blockbuster-in-pharma

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A NEW PLATFORM FOR A NEW ERA

To give life sciences manufacturers the ability to move forward in Pharma 4.0 digital maturity, Honeywell developed the new Manufacturing Excellence Platform, using proven SCADA, Historian, and MES technologies. A flexible, modular solution that makes it easy for operations of widely ranging sizes and complexities to digitize, orchestrate, and accelerate optimization of all aspects of production, the Manufacturing Excellence Platform drives increased efficiency, quality, and compliance, while maintaining the highest levels of data integrity and security.

MODULAR, ADAPTIVE AND SCALABLE

The Manufacturing Excellence Platform enables manufacturers to choose the starting point of their digital transformation journey and quickly and easily move forward from there. The modular platform adapts to a manufacturer's current needs and seamlessly integrates with other Honeywell and third-party systems, including ERP, QMS, LIMS and DCS. More capabilities can be added as the journey to Pharma 4.0 maturity continues.

HONEYWELL MANUFACTURING EXCELLENCE PLATFORM
CLEAR INSIGHT INTO WHAT'S HAPPENING NOW AND WHAT'S HAPPENING NEXT

SYSTEMS INTEGRATION
Integration with ERP, QMS, LIMS, DCS and other systems.

COMPLIANCE & VALIDATION
Streamlines validation ensuring process and data security.

INTELLIGENT OPERATIONS
Provides end-to-end production visualization.

REAL-TIME INSIGHTS
Identifies progress and delays relative to a reference batch.

DIGITIZE WORK PROCESSES
Eliminates costly errors inherent in paper-based systems.

MODULAR DEPLOYMENT
Starts small and scales easily across production lines and sites.

FASTER BATCH RELEASE
Reduces operator actions and signatures.

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THREE STEPS TO DIGITAL TRANSFORMATION

The new Honeywell Manufacturing Excellence Platform streamlines digital transformation for life sciences manufacturers into three easy steps.

STEP ONE:
ACCELERATE INNOVATION

- Digitize
- Integrate
- Become audit ready

STEP TWO:
GET REAL-TIME INSIGHTS

- End-to-end visibility of your production process and batch release
- Role-based information for the right person at the right time
- Data put in context means actionable information

STEP THREE:
ACHIEVE CONTINUOUS IMPROVEMENT

- Enable data analysis
- Use powerful historical data
- Accelerate reviews and batch release

MANUFACTURING EXCELLENCE PLATFORM AT A GLANCE

- **UNIFIED PLATFORM**
- **FASTER CORRECTIVE ACTION**
- **OPTIMIZED QUALITY**
- **ENHANCED DATA INTEGRITY**
- **IMPROVED DOCUMENTATION**
- **AUDIT READINESS**

THE MANUFACTURING EXCELLENCE PLATFORM SOLVES TODAY'S CHALLENGES

ACCELERATE INNOVATION

DIGITIZE
Move to paperless workflows, and digitize production execution

BECOME AUDIT READY
With real-time batch reporting

INTEGRATE
Data from different systems seamlessly – ERP, QMS, LIMS, DCS, skids

GET REAL-TIME INSIGHTS

END-TO-END VISIBILITY
To Orchestrate production more efficiently

PUTS DATA IN CONTEXT
To identify exceptions and address issues before they impact yield or delay production

ROLE BASED INFORMATION
Delivers the right information at the right time for each user role, from operators to management, enabling proactive action

ACHIEVE CONTINUOUS IMPROVEMENT

ENABLE DATA ANALYSIS
With production status dashboards, limit trends

POWERFUL HISTORIAN
Allows golden batch comparisons, and batch comparisons over time

ACCELERATE REVIEWS AND RELEASE
By supporting review by exception and role-based access

THE SMARTER WAY FORWARD

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ACCELERATE INNOVATION

Honeywell's new Manufacturing Excellence Platform provides real-time, end-to-end production visualization and dashboards for multiple user roles, from operators to management.

The lean modular system follows the path of least resistance to continuous improvement, whether it starts with connecting to data sources to gain insights for process improvement, automating manual tasks, or digitizing paper and unstructured electronic data for production or non-production activities. The platform enables life sciences companies to:

- Move to paperless workflows and digitize production execution.
- Become audit ready with automated data collection and reporting that's compliant with FDA regulations for electronic signatures and records.
- More effectively manage quality events and CAPA.
- Seamlessly integrate data from ERP, QMS, LIMS, DCS, skids, shop-floor equipment, and systems at all levels of the manufacturing hierarchy.

GET REAL-TIME INSIGHTS

Accelerate production and close the feedback loop with real-time access to actionable information throughout batch execution and release.

- End-to-end visibility enables efficient production orchestration.
- Putting data in context in embedded analytics allows manufacturers to identify exceptions and address issues before they impact yield or delay production.
- Proactively manage quality events and CAPA.
- Role-based information delivers the right information at the optimal time for each user role from operators to quality and management.

ACHIEVE CONTINUOUS IMPROVEMENT

The Manufacturing Excellence Platform drives continuous improvement for pharma and biologics manufacturers—from digitizing paper-based or unstructured electronic data processes, to seamless integration with your current systems, to real-time batch reporting and audit readiness. Honeywell's new platform is designed to:

- Enable data analysis with production status dashboards, embedded analytics and reporting and analytics.
- Access powerful historical data to evaluate and optimize processes by analyzing data for batch comparisons, quality deviations and critical process parameter excursions.
- Optimize processes for quality events and CAPA.
- Accelerate reviews and release by supporting review by exception and role-based access.
- Shorten approval cycle times for recipe, manufacturing, and other process improvements.

CONCLUSION

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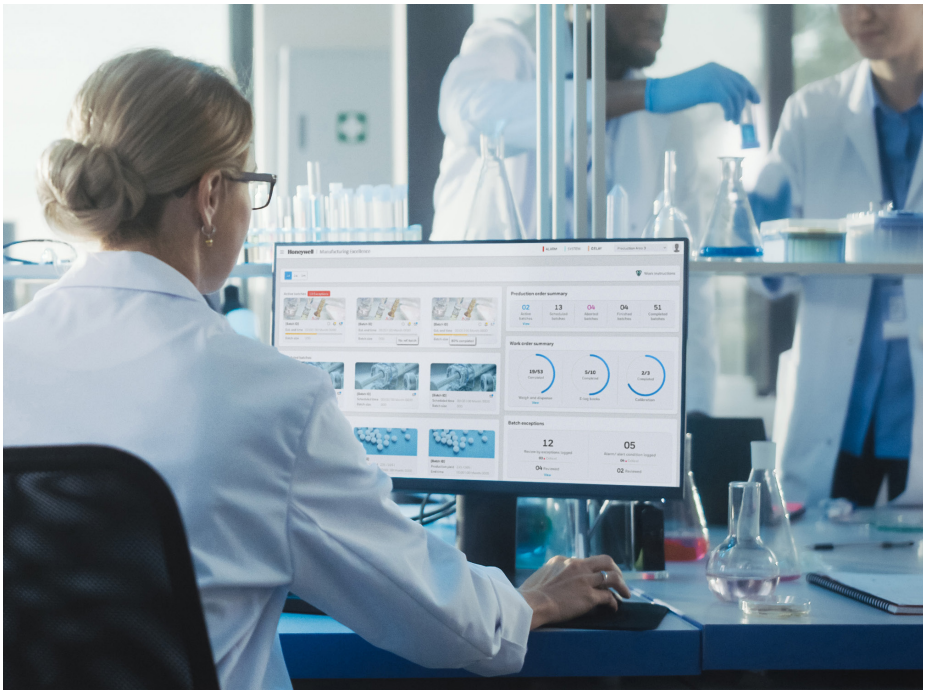
THE LEADER IN ACCELERATING INNOVATION

The Manufacturing Excellence Platform is a powerful new solution that draws on Honeywell's proven expertise in process control, SCADA, and batch historian technologies, as well as manufacturing execution systems to support pharma manufacturers in their path to achieve increased efficiencies, faster decision making and real-time operation optimization through digitalization.

The platform is built for life sciences pharmaceutical segments ranging from Active Pharmaceutical Ingredient (API) manufacturers and Contract Drug Manufacturing Operations (CDMO) to Biologics and Cell & Gene Therapy producers in stages of product development from clinical trials to commercialization.



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