

Seizing the Multi-Value Opportunity in Pharma:

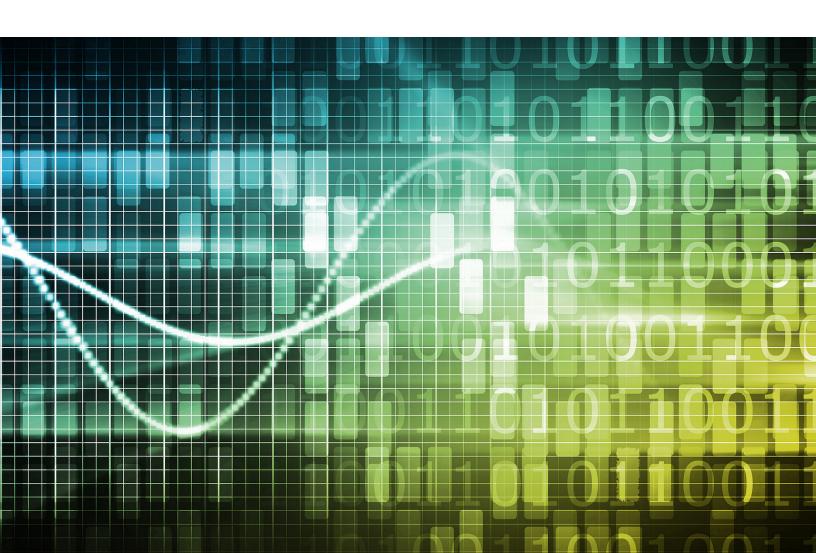
A Strategic Blueprint for Pharma Manufacturing with Mareana Connect™



Executive Summary

Pharmaceutical manufacturing is under increasing pressure to enhance efficiency, ensure compliance, and foster innovation amid stringent regulations and market complexities. <u>Gartner</u> proposes a solution: implementing platforms that simultaneously deliver multiple business outcomes rather than focusing on singular objectives. This approach is vital for pharma companies to remain competitive, enabling them to streamline operations, improve decision-making, and meet evolving regulatory demands.

Mareana's Connect™ Platform embodies this multi-value approach by integrating data from manufacturing, quality control, and analytical development. It enables pharma companies to meet today's challenges while driving future innovation. It positions manufacturers to adapt swiftly, maintain high-quality standards, and optimize performance across the value chain.



Understanding the Multi-Value Opportunity in Pharma Manufacturing

In a keynote at the Gartner Supply Chain Symposium, Gartner's VP Analyst Tom Enright urged supply chain leaders to focus on investments that provide "simultaneous sources of value," such as efficiency, growth, and compliance, to align with broader organizational priorities.¹ This approach allows companies to unlock multiple business outcomes with a single platform investment.



"It is up to supply chain leaders to identify and prioritize those investments that will deliver simultaneous sources of value, in line with their team's strengths and stated priorities."

— Tom Enright, VP Analyst, <u>Gartner</u>

In pharmaceutical manufacturing, this strategy is crucial. Traditional platforms typically address only one area, such as efficiency or compliance. However, pharma companies now face increasingly complex challenges, including stricter regulatory demands², supply chain disruptions³, and the need for faster innovation⁴. A multi-value approach is necessary to meet these overlapping demands simultaneously, providing a comprehensive solution that improves performance across all key areas.

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https://www.pharmamanufacturing.com/home/article/33035505/2024-pharma-predictions-regulations-sustainability-and-culture

https://www.pharmaceutical-technology.com/sponsored/the-new-frontiers-of-supply-chain-disruption-and-how-pharma-firms-are-responding/

⁴ https://www.mckinsey.com/capabilities/operations/our-insights/todays-industrial-revolution-calls-for-an-organization-to-match

Blueprint for Implementing a Multi-Value Platform

Implementing a multi-value platform requires a strategic approach to ensure maximum benefit. Below is a step-by-step blueprint to guide pharmaceutical companies through this process:



Assess Holistic Needs

Evaluate current processes with a focus on areas that need simultaneous improvements in efficiency, compliance, innovation, and quality. Prioritize key performance indicators (KPIs) that span multiple functions (e.g., production yield, regulatory timelines, product quality).



Tailor a Multi-Value Digital Strategy

Ensure that your digital strategy supports cross-functional integration of real-time data and Aldriven insights. Align it with specific pharmaceutical needs, such as regulatory compliance and R&D collaboration.



Select a Multi-Value Platform

Choose a platform designed specifically to provide multi-dimensional benefits like real-time monitoring, Al-driven process optimization, compliance automation, and cross-departmental collaboration.



Integrate Cross-Department Data

Facilitate seamless data sharing between R&D, manufacturing, and quality control teams. Ensure all departments can access real-time insights to enhance collaboration, decision-making, and innovation across the entire organization.



Pilot High-Impact Areas First

Focus the initial phase on high-impact areas, such as batch release, compliance checks, or yield optimization. Implement the platform gradually through Proof of Concept (PoC) to gather feedback and refine it.



Monitor for Multi-Value KPIs

Continuously track KPIs across efficiency, compliance, innovation, and quality. Use the platform's real-time insights to iteratively improve processes and align strategy as new demands emerge.



Engage and Train Teams

Tailor training programs to focus on maximizing the platform's multi-value capabilities, emphasizing cross-functional collaboration and real-time decision-making.

The Multi-Value Advantage of Mareana Connect™

Mareana's Connect™ Platform embodies Gartner's multi-value strategy by delivering measurable outcomes across efficiency, compliance, quality, and innovation. It helps pharmaceutical manufacturers streamline operations while upholding stringent compliance and product quality standards.

By integrating real-time data from manufacturing, quality control, and R&D, it fosters cross-departmental collaboration and accelerates decision-making, driving operational agility and innovation. This holistic approach enables companies to overcome key challenges while achieving business-critical goals simultaneously.

Improved Manufacturing Efficiency

Connect™ integrates real-time insights and Al-driven decision-making to optimize workflows, reduce bottlenecks, and maximize production output. It also ensures full traceability throughout the production lifecycle.



Real-Time Process Insights

Monitor manufacturing processes to detect inefficiencies and optimize workflows in real time.



Maximized Yield

Al tools adaptively manage production, increasing output and minimizing waste.



Full Traceability

Ensure seamless tracking and data integrity from raw materials to final products.

Faster Investigations

Connect™ speeds up investigations by leveraging advanced data genealogy, batch comparisons, and real-time monitoring, minimizing downtime.



Data Genealogy

Trace the entire data lineage across batches for rapid comparisons and accurate analysis.



Real-Time Failure Identification

Review production data against specifications to detect and rectify deviations in real time.



Root-Cause Analysis

Leverage real-time and historical data to resolve deviations quickly and efficiently.

Continuous Improvement

Connect™ empowers pharmaceutical manufacturers to optimize processes continuously using data-driven insights and real-time analysis.



Multivariate Analysis

Advanced tools identify inefficiencies and drive ongoing optimization.



Process Optimization

Use historical and real-time data to simulate and improve workflows before implementation.



Scalability

Easily scale optimized processes from small trials to commercial production.

Streamlined Compliance and Faster Batch Release

Connect™ automates compliance and accelerates batch release by providing traceability and reducing the time required for audits.



Automated Compliance Checks

Rule-based automation catches deviations early, streamlining batch approvals.



Predictive Quality Monitoring

Data-driven insights predict quality trends, enabling proactive measures.



Audit Readiness

Comprehensive logging and audit trails simplify compliance processes and ensure transparency.

Cross-Functional Collaboration

Connect™ centralizes data access, enabling real-time insights and fostering collaboration across R&D, manufacturing, and quality control.



Data Availability

Centralized data allows seamless collaboration between departments for faster decision-making.



Seamless Collaboration

Teams across functions can share insights, improving both speed and accuracy in operations.



Cross-Department Integration

Unified data ensures teams align processes across the value chain effectively.

Data-Driven Decision-Making

Connect™ supports informed decision-making through extensive historical and real-time data, improving process development and analytical methods.



Historical Data Analysis

Analyze large datasets to optimize method development and validation.



Predictive Modeling

Use data-driven insights to predict outcomes and reduce risks.



Decision Support

Provide accurate, data-based predictions for better alignment across departments.



Figure 1.

Unlocking Muti-Value with Connect™: Real-Life Examples



Case in Point 1

With Mareana's multi-value platform, a global pharmaceutical company transitioned to continuous manufacturing, reduced delays with real-time product quality evaluations, and accelerated the rollout of its Real-Time Release (RTR) program by 18 months. The platform also harmonized complex data quickly, improving overall efficiency. This initiative saved \$1.4M in implementation costs and generated \$100M.

Source: Mareana



Case in Point 2

A global pharmaceutical company increased yield by \$200M/year using Mareana's multivariate analysis for process optimization and large-molecule production scale-up. Connect™ enabled rapid data contextualization and completed the rollout for seven large molecules in just three months, improving overall production efficiency.

Source: Mareana



Case in Point 3

Connect™ was used to analyze CAR-T manufacturing data, identifying key factors contributing to slow cell growth. By creating a comprehensive batch genealogy and applying advanced analytics, the platform optimized media composition and activation protocols, significantly reducing batch failures. It delivered multiple value outcomes by improving yield and consistency, reducing costs, and ensuring regulatory compliance. Additionally, predictive models provided proactive interventions, enhancing patient outcomes and enabling better communication with caregivers about treatment timelines.

Source: Mareana

Mareana's Connect™ Platform clearly demonstrates the power of multi-value solutions, delivering outcomes across efficiency, compliance, quality, collaboration, and innovation. These multi-value platforms position pharmaceutical manufacturers to stay competitive and continuously evolve in a fast-paced, highly regulated industry.



Conclusion

As the pharmaceutical industry grows more complex, adopting multi-value platforms is crucial for maintaining competitiveness and agility. Manufacturers who implement these systems can streamline processes while quickly adapting to future challenges and innovations.

Connect™, a multi-value platform, offers multiple benefits simultaneously, including enhanced efficiency, compliance, quality, and innovation. With real-time insights, data-driven decisions, and automated compliance, it ensures continuous operational improvement while meeting regulatory demands.

By adopting Mareana Connect™, companies not only optimize their operations but also future-proof their processes, ensuring long-term success in an increasingly regulated and competitive market.

Citations

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