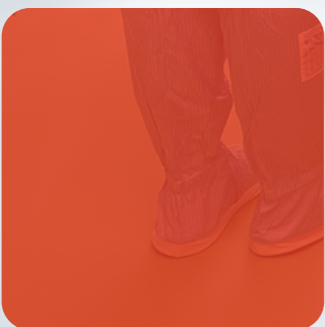


# Empowering CDMOs with the Connect™ Platform:

Enhancing Client Offerings and Internal Operational Agility



# Executive Summary

This white paper examines the dual benefits that Mareana's Connect™ platform brings to Contract Development and Manufacturing Organizations (CDMOs). By delivering both client-facing advantages and internal operational efficiencies, Connect™ supports CDMOs in elevating their service offerings while optimizing their internal processes. These comprehensive benefits allow CDMOs to provide differentiated services, enable data monetization, improve internal data management, and achieve a scalable digital roadmap.



## Introduction

As CDMOs become increasingly integral to the pharmaceutical supply chain, they face mounting pressures to provide advanced, data-driven services while streamlining their internal operations. Mareana's Connect™ platform offers solutions to meet these dual challenges, empowering CDMOs to enhance client experiences and internal efficiencies simultaneously.

# External Advantages: Enhanced Client-Facing Services

## Differentiated Service Offering

Connect™ allows CDMOs to offer clients real-time visibility, customizable reports, and data-driven insights, setting them apart from competitors and adding significant value to client relationships.



### Transparency and Visibility

Clients receive real-time data access, allowing them to monitor production processes and quality control remotely, fostering trust and reliability.



### Customized Analytics

CDMOs can offer tailored analytics and reports, enabling clients to make informed decisions based on detailed production insights.

## Data Monetization with Data as a Service

With Connect™, CDMOs can turn their manufacturing data into a revenue-generating asset through a Data as a Service (DaaS) model, giving clients on-demand access to critical data.



### Continuous Process Improvement:

Clients benefit from actionable insights for yield optimization and process adjustments.



### Enhanced Decision-Making Support

Real-time data aids client planning, production scaling, and compliance adjustments, adding strategic value.

## Operational Advantages with Early Data Access

Connect™'s real-time data sharing ensures that clients have immediate access to production data, improving operational efficiency and responsiveness.



### Proactive Issue Detection

Early data visibility enables clients to identify and resolve issues before they impact production.



### Strengthened Client Relationships

Transparent data sharing builds client trust and fosters long-term partnerships.

# Internal Advantages: Operational and Compliance Efficiencies

## Improved Data Management and Compliance Readiness

Connect™ streamlines internal processes for CDMOs, especially those handling extensive compliance documentation, batch records, and data traceability.



### Batch Genealogy and Traceability

Complete data traceability from raw materials to final products simplifies compliance, ensuring quick response to audits.



### Reduced Manual Burden

Connect™ digitizes batch records and processes, reducing error-prone, manual data entry and ensuring compliance with regulatory standards.

## Scalable Digital Roadmap for All Site Types

Connect™'s flexible framework supports CDMO sites with varying technological capabilities, creating a unified digital structure across all locations.



### Standardized Operations Across Sites

Connect™ enables consistent processes at sites with differing levels of automation, ensuring quality across the organization.



### Future-Proof and Scalable

Connect™'s adaptability allows CDMOs to scale digital solutions as sites modernize, accommodating growth without disrupting core operations.

## Compliance and GxP Validation Built-In

Connect™ is built with GxP validation and regulatory compliance at its core, streamlining audits and simplifying regulatory adherence.



### Robust Compliance Features

From batch records to security protocols, Connect™ ensures CDMOs are always prepared for regulatory review.



### Simplified Audits and Traceability

Detailed genealogy and audit trails reduce preparation time and streamline audit processes, lowering operational risk.

## Data Integration and Analysis for Process Optimization

Connect™ has native connectivity between data and advanced analytics algorithms through its libraries and DSS (Data Science Studio), making analysis seamless and fast and bringing focus to process optimization.



### Advanced Analysis

DSS allows creation and roll-out of advanced models for multivariate analysis and real-time analysis. These models can predict outcomes and offer suggestions for altering production parameters in real-time for better production outcomes.



### Faster Investigations and Root Cause Analysis

Investigation on probable root causes can range from simple data comparison to advanced multivariate analysis. The integrated environment allows to complete these investigations in minutes versus taking days / weeks.

# Conclusion

Mareana's Connect™ platform enables CDMOs to enhance both client services and internal efficiencies. By addressing external demands for transparency, data-driven insights, and customized reporting, Connect™ strengthens CDMO-client relationships. Simultaneously, Connect™'s internal benefits improve data management, compliance, and scalability, helping CDMOs optimize their operations. As CDMOs strive to balance client needs with operational excellence, Connect™ provides a comprehensive, future-proof solution.



## About mareana

Mareana is a leading AI-powered software company revolutionizing manufacturing and supply chain processes within the pharmaceutical and biotechnology industries. Our flagship platform, Mareana Connect™, powers a suite of GxP-compliant solutions designed to streamline operations, accelerate batch release, reduce errors, and redefine how organizations achieve compliance and operational excellence.

Our clients benefit from significant performance improvements, such as a 33% reduction in regulatory report preparation time, a 63% faster scale-up process, and a 31% decrease in root cause analysis efforts. By integrating multiple systems into a unified, CFR Part 11-compliant platform, Mareana Connect™ enables businesses to Make Confidently, Release Confidently, and Comply Confidently.



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