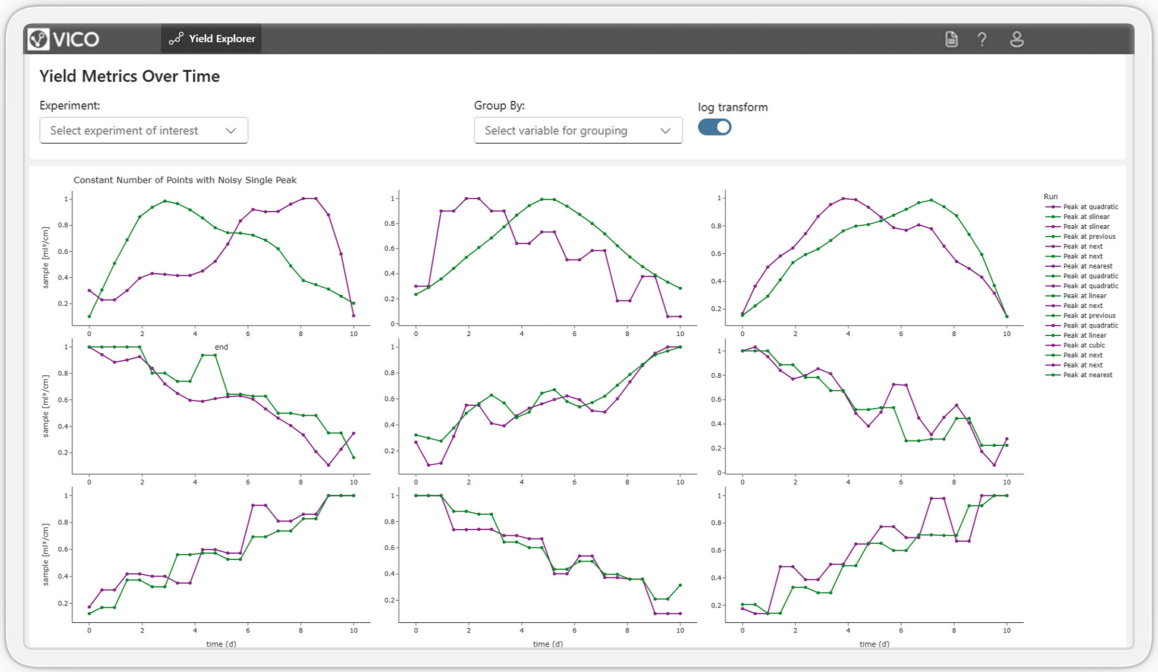
Genedata

Data in Motion. Accelerated CMC Decisions.

VICO



Data-Driven CMC: Meeting the Demands of Modern Drug Development

In biopharma, the pressure to demonstrate drug quality is intensifying, driven by evolving regulatory expectations and the growing complexity of therapeutic modalities. Chemistry, Manufacturing, and Controls (CMC) plays a central role in ensuring product quality and patient safety, yet CMC-related challenges remain a significant cause of regulatory delays and non-approvals. As the regulatory landscape becomes increasingly data-driven, success depends on having regulatory endpoints grounded in robust, interoperable data. However, this data is often dispersed across siloed systems, buried in millions of documents, and locked in diverse formats. By accessing and connecting this data across programs, technologies, indications, and assets, organizations can proactively meet regulatory requirements, accelerate development, and reduce risk to patients.

Moving from **document-centric workflows** to a **data-centric ecosystem** requires addressing several key challenges.

Fragmented Digital Ecosystem

Using too many disconnected tools and platforms can slow adoption, create inefficiencies, and increase the risk of data errors.

Data Quality and Governance

Incomplete, inconsistent, or poorly traceable data across the product lifecycle can undermine scientific integrity and regulatory success.

AI Dependence Risks

Uncritical use of opaque models without human oversight may compromise decision quality, especially in regulatory contexts.

Navigating Change Management

Resistance to new technology and limited digital literacy can hinder transformation and slow progress.

Genedata Vico™ is a secure, collaborative, **GxP-compliant solution** that seamlessly integrates diverse foundational data sources to collect and automatically transform CMC data into contextualized, analysis-ready **data products**. Each data product is consumer-aligned and built on a set of multimodal data tables defined by a robust data model, governed by ontologies and business rules, and tailored to specific user groups and objectives—enabling **confident decision-making** across the organization. In addition, the platform offers **out-of-the-box, AI-powered analytical and visualization tools** for scientists, along with a **high-performance computational environment** for data scientists. Its data layer, combined with built-in AI systems and application-specific dashboards, empowers scientists and data strategists to make decisions grounded in comprehensive, high-quality evidence. This ensures every insight is not only relevant but also actionable. A **strong governance framework** ensures data integrity, traceability, and compliance, supported by automated validation and metadata management to facilitate regulatory submissions.

Inside Genedata Vico: A Decision-Centric Approach to CMC

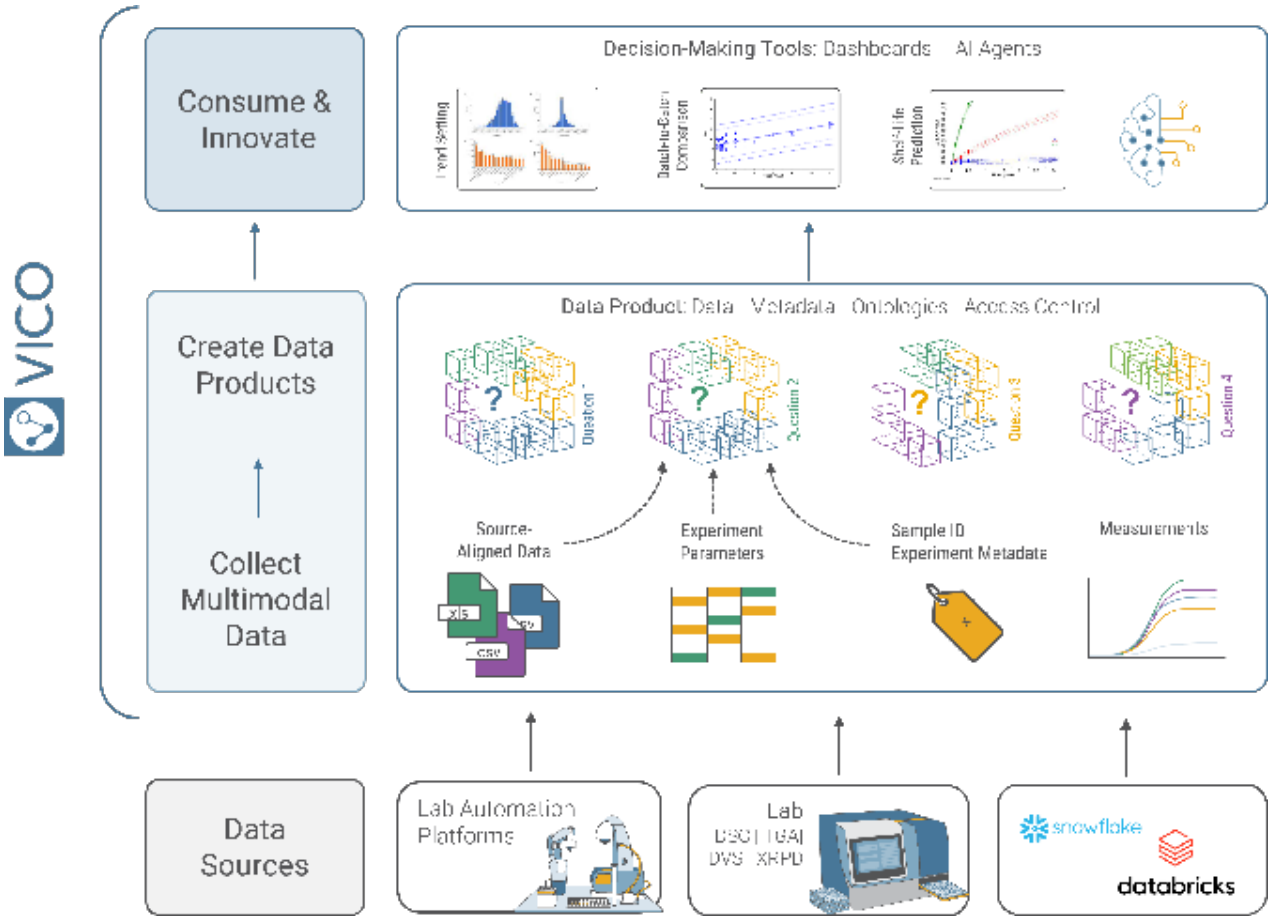


Figure 1. Genedata Vico collects and integrates data from diverse experimental sources, automatically transforming raw inputs and processed files into governed, FAIR, and ALCOA-compliant data products tailored to specific use cases. These data products can then be consumed through custom dashboards and AI agents by scientists and data strategists to generate actionable insights.

Example Applications

Multi-Modal Data Integration for Complex Modalities

The platform integrates CMC data across diverse modalities, providing a comprehensive view of product properties and behavior.

Impact: Unified data enabling faster decision-making and shortening development timelines

Enabling AI-Driven Root Cause Analysis

The platform enables AI-powered analysis across multi-parameter data from ongoing experiments and failed batches—identifying deviations and guiding corrective actions.

Impact: Faster investigations, reduced batch failures, and improved process robustness.

Real-Time Monitoring of CQAs Across the Lifecycle

Dynamic dashboards track CQA trends across development, clinical, and commercial stages, enabling proactive risk management and lifecycle control.

Impact: This supports ICH Q12 principles and helps teams anticipate quality or regulatory issues early.

Why Genedata Vico?

Improved Data Access & Reusability

Seamlessly integrates multi-source CMC data into a metadata-rich repository, enabling easy access, retrieval, and reuse across programs, assets, and lifecycle stages.
Example: Glycosylation profiles in conjunction with purification results from previous batches can be used to determine optimized cell culture conditions for the next batch.

Harmonized Data for Scalable Analysis

Automated workflows and governed data models ensure consistency across diverse sources—enabling cross-technology integration and comparative analysis while minimizing manual effort and errors.
Example: Charge variant data from multiple analytical platforms can be harmonized and analyzed to identify patterns across batches, enabling predictive insights into charge heterogeneity.

Built-In Traceability & Compliance

All data products are fully traceable to their original sources and GxP-compliant, delivering transparent, reproducible, submission-ready content backed by scientific justification.
Example: Stability study results and packaging performance can be tracked back to solid form data from lyophilized biologic formulations, ensuring long-term product integrity and regulatory compliance.

Self-Service Insights for Regulatory Agility

The analytics environment, equipped with AI agents and dashboards, enables rapid evidence retrieval and real-time analysis of trends, outliers, and risks—accelerating responses to regulatory queries.
Example: Trending potency assay data across clinical batches can be instantly visualized and explored to support rapid, traceable responses to FDA inquiries about product consistency.

Innovation in Drug Development

By unlocking and repurposing data across programs and modalities, the platform drives novel insights and speeds the development of next-generation therapies.
Example: Repurpose historical fermentation and stability data to build predictive models for protein aggregation, allowing real-time assessment of formulation risks.

More Than a Platform—Your Innovation Partner

Genedata Vico doesn't just digitalize non-clinical and clinical workflows—it transforms how you activate and leverage your data. Backed by a team of scientific experts who collaborate closely with you, the platform empowers confident, data-driven decisions that demonstrate quality endpoints and elevate patient safety.

The result? Smarter science, faster approvals, and a future-ready approach to drug development.

Genedata

Genedata transforms biopharma data into intelligence by combining deep science, technology, and AI domain knowledge. From early discovery through development to the clinic, the Genedata Biopharma Platform digitalizes and automates complex data workflows, fueling innovation and data-driven decisions to maximize ROI.

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