tetrascience

Creating "The Digital CDMO" with Andelyn Biosciences

CASE STUDY

Results: Launched "The Connected Plant" at two new gene therapy manufacturing facilities with TetraScience

- TetraScience provides the data infrastructure, automation, and engineered data Andelyn requires to become "The Digital CDMO"
- Lays the foundation for AI-enabled workflows
- Powers an easy-to-use search for all assay data
- Consolidated every independent data store (40+) across the scientific organization into a single-source-of-truth
- 100% of Andelyn's 9 years of legacy assay data uploaded to the Tetra Scientific Data Cloud™
- Eliminated manual data transfers, reduced manual data processing, and established compliant data processes
- Data from 9 core instrument suites automatically harmonized into AI-ready Tetra Data

"TetraScience is the core platform for our scientific data and a real differentiator and accelerator to our business."

—Bryan Holmes, Vice President Digital & Technical Solutions at Andelyn Biosciences

Andelyn BIOSCIENCES

Background

Andelyn Biosciences is a gene therapy contract development and manufacturing company (CDMO) that specializes in AAV (adeno-associated virus) and lentivirus manufacturing.

A leading CDMO:

- 20+ years of viral vector manufacturing experience
- 75+ INDs
- 450+ cGMP clinical batches

Company History:

2017: Nationwide Children's Hospital (NCH) opens a dedicated cGMP facility, setting the stage for Andelyn Bioscience's pioneering journey

2020: To expedite gene therapy delivery to patients, Andelyn within NCH embarks on enhancing their data and manufacturing capabilities

2021: Andelyn partners with TetraScience to create "The Connected Plant"

2022: Andelyn opens a 185,000 sq/ft gene therapy manufacturing facility—the world's first Tetra Scientific Data Cloud-native CDMO facility

Challenge: Defining a data strategy for new gene therapy CDMO facilities

When Andelyn Biosciences broke ground on two state-of-the-art gene therapy CDMO facilities they understood that an optimal scientific data strategy was foundational to their success. Data, as they saw it, was a primary asset. Because while Andelyn produced physical products, such as viral vectors, another core product was the entire data set required to develop and deploy gene therapies.

Furthermore, proper data management was pivotal for creating future-ready facilities that could leverage AI and advanced data technology, enabling "smart" factory use cases that are on the immediate horizon. Their mission, therefore, was to become "The Digital CDMO," a fully digital development and manufacturing organization that harnesses the power of modern technology to cohesively maximize the value of data, drive compliance, and ensure critical data assets are secured to provide unmatched digital access for clients.

Incorporated in 2020

The Andelyn Plasmid Center

Research and GMP plasmids

- Third floor of Nationwide Children's Hospital
- AAV adherent and suspension systems
- Plasmid manufacturing
- Central repository for legacy data spanning several years

Opened in April 2022

The Andelyn Development Center

Preclinical manufacturing development

- 42,000 sq/ft
- Process development
- Solution prep, touchdown, and storage
- Research production
- Analytical development
- Support space

Opened in October 2022

The Andelyn Corporate Center

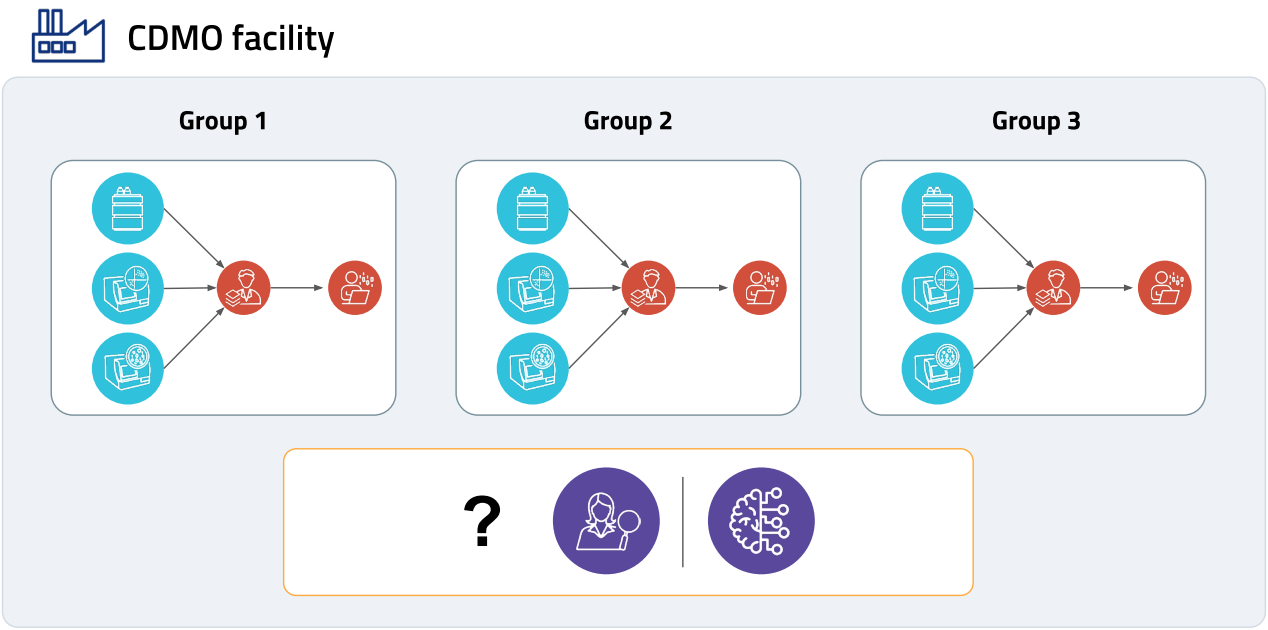
Advanced GMP facility

- 185,000 sq/ft
- 8 manufacturing suites
- 2 purification suites
- 2 cell-culture suites
- 2 fill/finish suites
- Plasmid manufacturing space
- Quality control
- Analytical lab
- Process development

However, building a data infrastructure for a “Digital CDMO” required a complete rethinking of how their data was captured, managed, stored, and accessed.

While Andelyn occupied a corridor on the third floor of Nationwide Children’s Hospital (NCH), they leveraged NCH’s security and data processes. These processes were mainly paper-based. When they did adopt some digital processes, progress was modest. Scientists simply shuttled USB sticks between instruments and their desktops. For an advanced gene therapy production suite, this disconnected lab environment was untenable, as it was time consuming, error prone, and not secure.

The problem with disconnected labs in a CDMO facility



Disconnected labs require manual data transfer and processing.

Data is stored in silos across the organization

Scientists and AI programs can’t access or interpret data.

Andelyn’s disconnected lab spaces had no “data flow.” Data was siloed in scattered instruments, USB drives, and scientists’ personal computers. At one time, Andelyn used over 40 unique and disconnected data stores. Furthermore, data was often trapped in vendor-proprietary formats. This meant that data would have to be manually transformed for reuse in future AI projects, informatics applications, or analytic tools. For their new facilities, which would house 50+ discreet instruments from 40 different vendors, this would create rate-limiting and expensive manual workflows.

Another consequence of disconnected lab spaces was lack of data access. Scientists who wanted to investigate data associated with an assay had to spend significant amounts of time searching for historic data packets. At one point, scientists were sifting through filing cabinets. Later, they were manually parsing through PDFs that were saved ad-hoc across the organization. Locating data in this type of environment was incredibly time-consuming, laborious, and limited scientists’ ability to work on high-value analysis and experimentation.

Furthermore, Andelyn understood that AI uses similar access methods as scientists (API or SQL powered search). Inaccessibility, therefore, would quickly devolve from an inconvenient resource drain to an organizational vulnerability.

Lack of connectivity and automation also led to compliance challenges. Andelyn originally adopted the NCH's paper-based data management strategy. A paper-based strategy is still acceptable for a hospital adhering to HIPAA compliance standards. However, Andelyn's regulatory efforts are focused on GMP, 21 CFR Part 11, and other FDA guidelines. The paper-based processes, and later the "sneaker-net" processes of moving data from one software to another via USB stick, made compliance much more difficult to achieve. The organization found USB transport laden with risks of virus and malware, and manual transfers laden with errors.

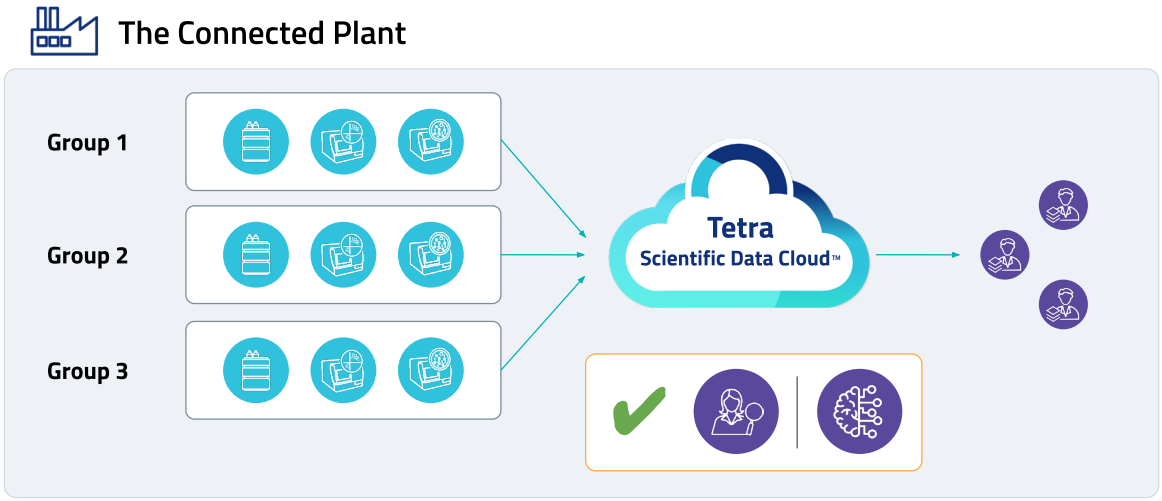
After observing that the existing data infrastructure would preclude their "Digital CDMO" aspirations, Andelyn decided to pursue what they called "The Connected Plant." The Connected Plant would provide the free flowing data, centralized data access, digitalized compliance, and future-facing adaptability that Andelyn required. However, piecemealing a data solution for The Connected Plant with several vendors didn't appeal to them, as they ran the risk of re-creating silos at a higher level. Since they were starting without a legacy footprint, they wanted to identify a vendor that could help them mature their data both horizontally (from every group and instrument) and vertically (evolving from integrations, to data engineering, to AI-readiness), within a durable and robust partnership.

Solution: Build The Connected Plant on The Tetra Scientific Data Cloud

Partnering with TetraScience allowed Andelyn to implement their "Connected Plant" strategy by leveraging the Tetra Scientific Data Cloud in their two new gene therapy facilities. They chose TetraScience because the Tetra Scientific Data Cloud is the only scientific data solution that can provide connectivity between their instruments and software applications while also engineering that data so it can be searched, accessed, and interpreted by scientists, analytical applications, and AI.

Since opening their two new facilities, Andelyn has migrated 100% of their nine years of assay data into the platform, connected 90% of their instrumentation, harmonized data for nine core instrument suites (PCR, flow cytometers, chromatography, etc.), and enabled assay data packet search for every group across the organization.

Universal data access and storage through The Connected Plant



The Tetra Scientific Data Cloud connects every group within Andelyn's new facilities (analytical development, viral vector core operations, plasmids, quality control, and process development) to a centralized data platform where data is contextualized and harmonized.

Data is both automatically published to scientists and searchable throughout the organization. Meanwhile, data is prepared for future analytics and AI utilization.

TetraScience technology has therefore become a foundational component of Andelyn's plan to become the "Digital CDMO," where data is one of the primary assets they deliver to customers. Here are a few of the TetraScience capabilities that are leveraged by Andelyn:

Integration, harmonization, and publishing

The Tetra Scientific Data Cloud automatically replatforms, reengineers, and publishes data to prespecified data targets. For Andelyn's scientists, this means that by the time they get back to their desk after running an assay, the file is waiting for them to download.

Searchable, centralized data storage

The Tetra Scientific Data Cloud enables search by providing two features. First, it centralizes all of Andelyn's data in a single-source-of-truth. Second, it automatically contextualizes data with appropriate metadata such as stage, source, instrument, site, and group. This allows both scientists and AI programs to locate, search, and access data easily.

Automatically generated audit trails and cloud-secured data

The Tetra Scientific Data Cloud allows Andelyn to completely eliminate all their paper- and USB-based processes. The Tetra Scientific Data Cloud also provides automated audit trails and is fully compliant with GxP and 21 CFR Part 11 electronic records requirements.

A future-proof data infrastructure

The Tetra Scientific Data Cloud provides a future-proof foundation for Andelyn in three ways. First, it is vendor agnostic and can integrate with any third-party vendor. Andelyn can add or remove any instrument or application without interfering with their core data processes. Second, TetraScience has partnerships and industry-leading expertise at the intersection of life science and data. They can inform best practices and help identify new collaborative opportunities as Andelyn expands its data capabilities. Third, the Tetra Scientific Data Cloud contextualizes and harmonizes data so it can be accessed and interpreted by analytical tools and AI. This means that Andelyn is ready to accelerate as fast as technology does and they won't be left behind, cleansing decades of legacy data.

> **"TetraScience is the cornerstone of The Connected Plant strategy."**
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> **—Scott Brown, Architect, Connected Plant at Andelyn Biosciences**

Significance: Building the Digital CDMO through connected plants

Outcomes	Impact
Built the "Connected Plant" at two new gene therapy facilities	• Facilitates the data capabilities, digital development, and modern data technology that Andelyn requires to become "The Digital CDMO"
Centralized data storage	• Consolidated every independent data store (40+) across the scientific organization into a single-source-of-truth • Uploaded 100% of Andelyn's 9 years of legacy assay data into the Tetra Scientific Data Cloud
Automated data workflows	• Data from 90% of instruments is available to scientists moments after performing an experiment, eliminating the need for manual data transfers for these instruments • Data from 9 core instrument suites automatically harmonized into AI-ready Tetra Data (qPCR, dPCR, plate readers, spectrophotometers, osmometers, flow cytometers, particle sizers, chemidoc imaging for protein analysis, and chromatography), greatly reducing the need for manual data processing • Greatly reduced data integrity issues, enabled simpler compliance and the reallocation of scientists' time to high-value analysis and experimentation
Enabled search capabilities	• Every scientific group within the organization (analytical development, viral vector core operations, plasmids, quality control, and process development) can now search and access assay data using intuitive key words such as stage, source, instrument, site, and group; greatly reducing time wasted manually searching for data
Established compliant data processes	• Eliminated the risk of manual errors and greatly reduced the chance of a regulatory infraction due to data integrity issues • Data activity is tracked within the Tetra Scientific Data Cloud, providing a compliance-friendly audit trail
Future-proofed data infrastructure	• Laid the foundation for AI-enabled workflows • Andelyn can glean unprecedented insights as they begin tracking assay trends over time, helping them optimize processes and improve their gene therapy products

Building better medicines with better data

Andelyn Biosciences and TetraScience have partnered to create a system that maximizes the value, accessibility, and integrity of Andelyn's scientific data. Together, we have set the standard for data in CDMO facilities.

Andelyn can now grow alongside data technology, leveraging exciting tools like AI to catalyze innovation in gene therapy manufacturing so they can bring more treatments to more patients.

To learn more about how TetraScience can maximize the value your scientific data and enable AI, visit tetrascience.com