

# Digital Standardization: Accelerating Gene Therapy Tech Transfer with Confidence and Compliance

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In the modern biopharmaceutical development landscape, much can stand in the way of a seamless technology transfer (tech transfer): from reactive, highly manual reviews to disparate data pools, uneven version control, and siloed, disconnected information streams, the variables that serve to extend onboarding periods are all very real threats to a program's competitiveness. These days, even the most advanced foundational science can be underpinned by a data strategy reliant on Excel spreadsheets, varying in-house templates, and data dissemination strategies entirely dependent on a person or a team with competing priorities and limited resources.

The potential for rework and risk of errors that accompany tech transfers with suboptimal data management underscores the need for solutions that convene, collate, and cohere data to support decision-making and drive results. QbDVision, a structured, cloud-based platform designed to empower teams across the biotech, pharma, and CDMO industries, represents the first digital chemistry, manufacturing, and controls (CMC) toolbox for the space. By automating key development workflows within the broader product life cycle journey, QbDVision enables greater standardization, improved transparency, and increased data confidence, paving the way for smoother tech transfer and faster commercial readiness.

In a recent case study, Viralgen, a CDMO specializing in rAAV viral vector production, was able to demonstrate significant acceleration in onboarding for a sponsor seeking the commercialization of their gene therapy program, reducing the average timeline of six to twelve months to just three months. This was achieved by combining the data generated through Viralgen's platform process with the digital CMC backbone that QbDVision provides, unifying and structuring data to improve cross-functional transparency and confidence. These results represent a boon for the industry, one that may be deployed across future gene therapy tech transfers to facilitate faster, smoother scaling for these crucial modalities.

## Mitigating Compliance Risk Through Unified Data Management

The layers of compliance risk for biopharmaceutical tech transfer are often both interdependent and compounding: for example, introducing a change to a process where documentation has been inadequate, disjointed, or siloed has cascading impacts for the teams struggling to review and align updates. This, in turn, can harm the ambitious timelines many sponsors and developers have for their molecules, as operators play tag to coordinate and standardize across an organization.

The misalignment, repeated review cycles, and compliance risks that emanate from these piecemeal environments contribute to a significant cumulative burden. In contrast, a unified data model eliminates the structural constraints of document-based transfer, consolidating process definitions, historical knowledge, platform assumptions, and product-specific requirements into one validated system to allow sponsors and CDMOs to align quickly and with far greater confidence. This standardization likewise reduces the likelihood of batch failure and minimizes regulatory

exposure by ensuring that every update (whether a process parameter, calculated value, or risk assessment) is approved once and consistently reflected everywhere it is used. Rather than copying information across files, teams work from a shared, authoritative dataset, eliminating ambiguity at each stage of transfer.

For CDMOs, a standardized digital backbone allows platform knowledge to accumulate and evolve. Platform processes defined at multiple scales can be reused across incoming programs, creating a consistent starting point that shortens onboarding and accelerates process fit, while customer-provided information (typically delivered as unstructured, disparate documents) can be digitized and integrated directly into this model. Consequently, the platform becomes a continuously expanding knowledge base that, over time, captures the best available process understanding across all clients, allowing for iterative platform optimization that can improve each individual program or application.

A digital CMC approach supports a balanced path between innovation and compliance, where active regulatory filings are maintained as frozen snapshots while development teams can continue to refine platform methods, introduce new technologies, or incorporate performance improvements. New clients are onboarded onto the most current version of the platform, whereas existing clients maintain compliance with their filed processes until they choose to update.

### **Automated Scaling, Gap Assessment, and Risk Mitigation**

Digitized CMC data enables capabilities that are impractical in more manual systems. Automated scaling functions allow process definitions to remain consistent across multiple volumes and formats without manual recalculation, while calculated values propagate changes reliably across all dependent records, eliminating redundant data entry and reducing human error.

Gap assessment tools, used to compare product-specific processes to baseline platform definitions, can likewise identify differences early, enabling rapid mitigation. Because prior transfer histories are embedded in the system, teams do not start from scratch; instead, they leverage proven device configurations, validated scale transitions, and prior risk learnings. Together, these functions support faster and more predictable transfers while reducing the likelihood of deviations or late-stage surprises.

Ultimately, a digital CMC system institutionalizes governance through integrated approval workflows and automated audit trails. Every calculation, parameter change, and process update is versioned once at the source and made available across all downstream views and outputs. This ensures that teams always work from current, validated information.

For gene therapy developers and CDMOs, the move from document-centric workflows to standardized, structured data is becoming a strategic imperative. By consolidating process knowledge, reducing manual review cycles, and enabling real-time, role-based collaboration, organizations can shorten transfer timelines, reduce operational and regulatory risk. The result? Not only faster onboarding but also a fundamental shift in how process knowledge is created, maintained, and shared, allowing teams to focus their expertise on the scientific and operational decisions that matter most.

## Case Study: Digitizing Data to Compress Timelines and Reduce Risk

With four GMP suites for 250L to 500L production and three commercial suites capable of 250L to 2,000L manufacturing, Viralgen has delivered more than 1,500 batches across more than 30 AAV serotypes, achieving a 100% regulatory success rate for agency interactions linked to produced material. Central to this performance is the consistent Aava™ platform built on the Pro10™ cell line, standardized raw materials, harmonized equipment trains, and unified operational parameters, all optimized around consistent, scalable biopharmaceutical production.

Yet despite this robust foundation, onboarding timelines for new clients remained a major constraint, limited not by platform capability, but by the time required to translate sponsor-specific knowledge into Viralgen's established framework. Fragmented documentation, lengthy review cycles, and manual updates across risk assessments and process definitions all served to slow execution and create avoidable gaps, rendering technical and technological expertise less effective and slowing tech transfer significantly.

To support a new client preparing for Process Performance Qualification (PPQ), Viralgen sought a more efficient way to integrate product-specific knowledge with their platform process. The goal was to compress onboarding timelines while maintaining the full quality-by-design (QbD) rigor expected for commercial readiness, including Critical Quality Attribute (CQA) risk assessment, process Failure Mode and Effects Analysis (FMEA) development, design space definition, and initial control strategy.

In prior workflows, multiple rounds of document exchange, reconciliation, and independent approvals, often spanning spreadsheets, slide decks, and PDF-based process descriptions, were needed to reach reconciliation. This approach made it difficult to ensure alignment across teams, and it created the risk of inconsistencies when updates were made in one place but not another.

To address this, Viralgen implemented QbDVision as a structured data layer to house platform knowledge, product-specific inputs, and risk assessments within a single, continuously traceable system. Prior to engaging with the client, the CDMO had already digitized its entire AAV platform, from process parameters and historical performance data to in-process testing schemes and baseline CQAs, within QbDVision. Viralgen also leveraged extensive evidence-based prework to inform their platform rAAV CQA risk assessment. Over 4,500 papers were screened, alongside 417 abstracts, identifying approximately 150 relevant papers. Ultimately, 57 key citations were used to inform the criticality assessment of CQAs. This comprehensive literature-based prework was digitized and incorporated directly into QbDVision, providing a robust, data-driven foundation for the sponsor-specific onboarding process.

**Key enablers included:**

- Platform CQA risk assessment digitized and ready for customization
- Platform Process FMEA risk assessment ready to be leveraged for product specific manufacturing processes.
- Validated process definitions at multiple scales, enabling automatic generation of small-scale model descriptions from commercial-scale records
- Direct data linking between CQAs, process parameters, and control strategies
- Real-time collaboration, where SMEs across both organizations viewed updates simultaneously
- Elimination of multi-document versioning, reducing risk of error and review-cycle overhead

Viralgen and the sponsor completed the core QbD onboarding work in only two workshops. In the first, the team reviewed the precompiled platform critical quality attribute (CQA) risk assessment and updated it with the sponsor’s product-specific attributes, enabling the generation of a finalized, product-specific CQA risk assessment within just three days. The second workshop focused on the product-specific process FMEA; leveraging platform knowledge on parameter impact on quality attributes, occurrence, and control strategies, the team was able to complete a comprehensive FMEA within a single week. With all data housed in QbDVision, every update was immediately visible to internal and sponsor SMEs, enabling real-time collaboration and reducing the need for redundant review cycles.

Within just two weeks, Viralgen completed all core QbD deliverables for the new product, including the CQA assessment, process FMEA, and identification of process characterization action items. The integration of platform and product-specific knowledge in a single source of truth allowed Viralgen to reduce onboarding timelines from the typical six to twelve months to just three months. This streamlined process minimized manual document handling, improved alignment between teams, and provided a fully traceable, compliant dataset for PPQ readiness.

By standardizing data and consolidating platform knowledge, Viralgen was able to accelerate client onboarding, cutting timelines from as much as a year down to just three months, while maintaining the rigor of QbD principles. This approach shortened timelines and strengthened confidence in process understanding and regulatory compliance, creating a scalable model for future gene therapy programs where platform knowledge continuously evolves and new sponsors can enter GMP execution more efficiently.

**Transforming Tech Transfer Through a Single Source of Truth**

The evolution of gene therapy manufacturing demands scientific innovation as well as a fundamental shift in how process knowledge is captured, shared, and leveraged. Traditional, document-driven workflows, reliant on spreadsheets, slide decks, and even several versions of the same PDF, introduce inefficiencies, compliance risk, and unnecessary delays that can extend onboarding timelines from months to over a year. As programs scale, these challenges compound, threatening both speed to clinic and overall program competitiveness.

The implementation of structured, centralized digital platforms such as QbDVision demonstrates the transformative potential of standardizing data for tech transfer. By consolidating platform knowledge, product-specific inputs, and risk assessments into a single, validated system, teams can collaborate in real time, eliminate redundant review cycles, and ensure every update is traceable, compliant, and immediately reflected across all downstream outputs. The case of Viralgen illustrates the tangible benefits: a reduction in client onboarding timelines from 6 to 12 months down to just 3 months, achieved without compromising the rigor of QbD principles.

Beyond accelerating individual transfers, a standardized digital backbone enables continuous learning and evolution across platforms. Knowledge captured from prior projects can be scaled and adapted, while innovations in process development can be introduced without disrupting ongoing manufacturing or regulatory compliance. This approach creates a scalable, resilient model for gene therapy manufacturing, one in which new sponsors can be onboarded efficiently, regulatory risk is mitigated, and teams can focus on the scientific and operational decisions that drive product quality and patient impact.

