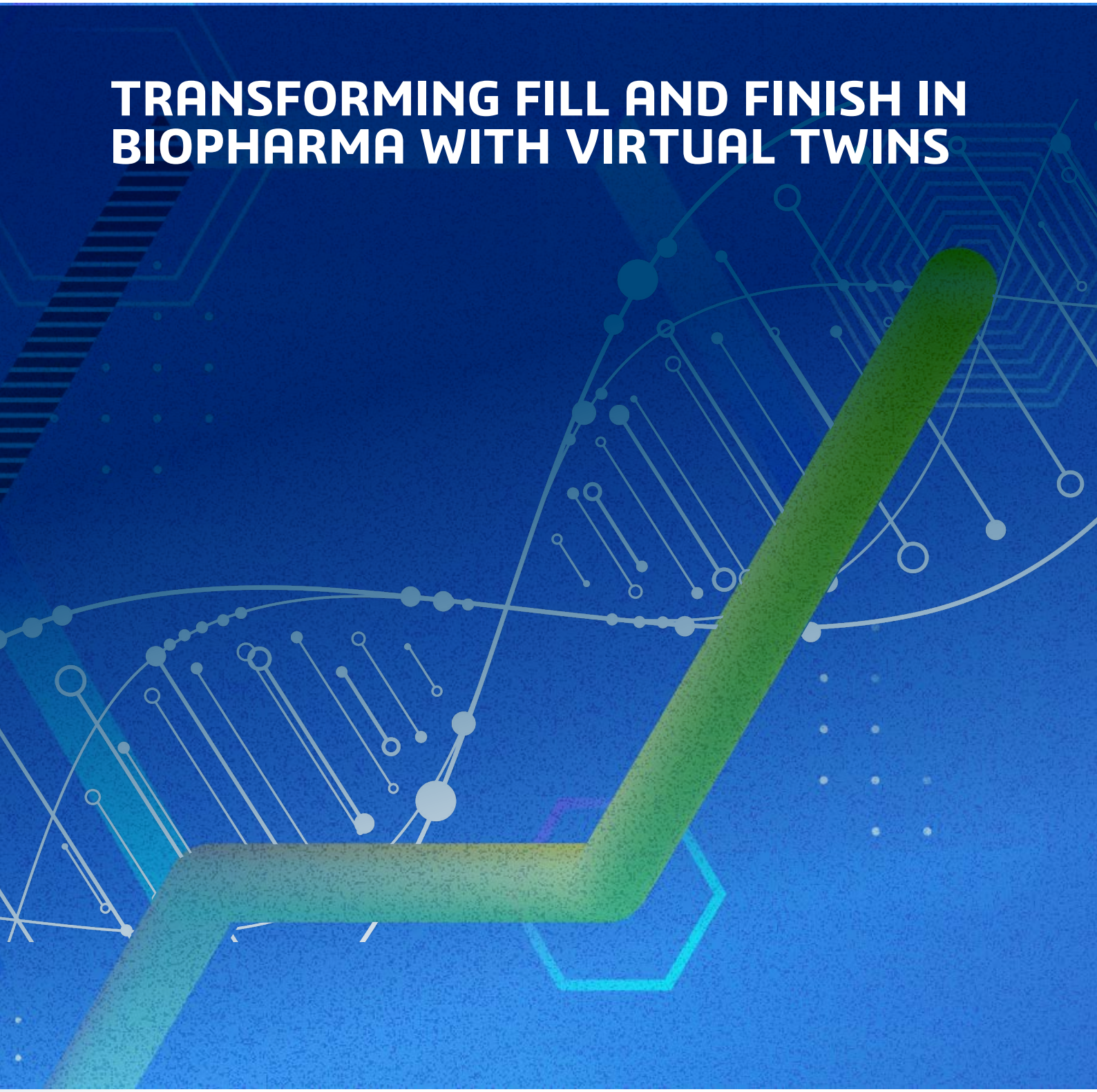
DASSAULT SYSTEMES

TRANSFORMING FILL AND FINISH IN BIOPHARMA WITH VIRTUAL TWINS



TRANSFORMING FILL AND FINISH IN BIOPHARMA WITH VIRTUAL TWINS

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INTRODUCTION

Virtual twin technology replicates the real world, simulates future scenarios and accelerates innovation. If there's one domain where innovation is urgently needed, it's pharmaceutical manufacturing, specifically **biopharmaceutical manufacturing**.

Why? Because efficient biopharmaceutical manufacturing is no longer an operational necessity — it's a key differentiator. As the industry faces increasing pressure to deliver innovative therapies quicker, safer and at scale, the way we design, operate and optimize production must evolve.

By combining real-world data with modeling, simulation and artificial intelligence (AI), virtual twins are enabling manufacturing companies to make better decisions, faster. Within pharmaceutical operations, there's one area where virtual twin technology can deliver outsized value: **Fill and finish**.

This white paper explores how **virtual twin** technology, especially when delivered **as a service**, helps biopharmaceutical companies and contract development and manufacturing organizations (CDMOs) improve agility, reduce risk and accelerate time to market at this critical stage.

Through five strategic use cases and real-world key performance indicators (KPIs), you'll discover how continuous value delivery strategies are reshaping fill and finish, from key stakeholder communication and layout optimization to operator training and aseptic control.

Whether you're scaling up, onboarding a new therapeutic product or building your digital roadmap, this is where transformation begins.

CHAPTER 1: A CHANGING WORLD

Biopharmaceuticals are large, complex molecules such as proteins, antibodies or living cells, manufactured using biological processes. They differ from traditional pharmaceuticals, which are typically small-molecule drugs produced through chemical synthesis. Biopharma products are more sensitive, require sterile handling and often rely on personalized or highly targeted treatments, making manufacturing more complex and quality-critical. This complexity has significant impacts on production processes.

CATALYSTS OF INDUSTRY TRANSFORMATION

Biopharmaceutical manufacturing is undergoing a profound transformation. What used to be a stable, well-understood operational model is now being tested by an unprecedented combination of **scientific innovation, regulatory complexity** and **speed-to-patient imperatives**.

The industry is no longer defined by a handful of blockbuster products. Today, drug pipelines include **highly targeted therapies**, from **mRNA-based vaccines to cell and gene therapies (CGT)** and **antibody-drug conjugates (ADCs)**. Each of these introduces **new requirements** for handling, scale, sterility and precision.

At the same time, **speed to market has become critical**. When every week of delay in production can cost lives, agility is not a luxury, it is a responsibility.

Several converging forces are reshaping the biopharma industry:

1. **Pricing constraints and increasing demand:** Despite patent cliffs and tightening margins, the rise in chronic diseases, aging populations and a growing global patient base are fueling demand for a wider range of therapies and in larger volumes.
2. **Reshoring and supply chain resilience:** Geopolitical shifts and global disruptions have exposed the vulnerabilities of traditional manufacturing and logistics networks, prompting a shift toward resilient manufacturing strategies and more localized, flexible and secure supply chains.
3. **Technological advancements from the competition:** Digital-native competitors are emerging with leaner, more flexible infrastructures. On the flip side, cutting-edge capabilities (such as flexible automation, advanced simulation and AI-driven analytics) are unlocking new ways to produce, monitor and scale drug manufacturing with greater precision and agility.
4. **Sustainability and innovation:** Sustainability goals are pushing companies to rethink resource-intensive operations. At the same time, personalized medicine, faster development cycles and a growing emphasis on biologics have intensified the need for more specialized and responsive manufacturing environments.

Together, these drivers are creating a tipping point in how therapies are designed, produced and delivered.

A NEW MANUFACTURING LOGIC

Biopharma companies must now balance speed, scale and compliance in ways that legacy models cannot support. To achieve their objectives, they must build smarter factories.

This means adopting new paradigms such as:

- **Modular and flexible production lines** that can adapt to new formats and volumes
- **Generative design** for processes, facilities and equipment layout
- **AI-driven optimization** tools and virtual companions
- **Cross-functional collaboration** in a digital, model-based environment

The technologies that enable these paradigm shifts are powerful, but they are also **difficult to master**. Each advancement introduces complexity. Integrating multiple systems, managing data continuity and ensuring compliance — all while accelerating timelines — require a level of digital maturity that many organizations struggle to build internally.

THE HIDDEN BURDEN OF TRADITIONAL SOFTWARE ADOPTION

Many companies begin their digital transformation with traditional software licensing: Purchasing tools, building in-house capabilities and attempting to integrate disparate solutions across sites.

But this model brings several common pitfalls:

- **Long time-to-value,** especially when teams must learn and configure tools from scratch
- **Limited scalability,** as each site requires local deployment and governance
- **Lack of standardization,** leading to siloed operations and inconsistent performance
- **Underutilized tools**, purchased but never fully adopted or integrated

In a global, fast-moving and resource-constrained industry, this approach is **no longer enough.**

THE THREE MANUFACTURING CHALLENGES EVERYONE FACES

Across the industry, three strategic imperatives dominate every boardroom conversation:

1. **Rolling out new lines and facilities at pace** to increase drug production capacity while maintaining quality and compliance
2. **Optimizing existing lines** to accommodate new products or increase output without rebuilding from scratch
3. **Standardizing and harmonizing equipment and processes** to reduce variability, simplify training, enable better analytics and prepare for AI-driven optimization

This last challenge, **standardization at scale**, is perhaps the most underestimated. Without consistent processes and modular equipment strategies, every site becomes an isolated project. That makes **tech transfer or scale-up** harder, costs higher and global coordination nearly impossible.

So how can biopharma companies remain agile, while also delivering reliability, compliance and repeatability at scale? The answer lies in **virtualization**.

CHAPTER 2:
THE CRITICAL ROLE OF FILL AND FINISH

THE MOST DELICATE STAGE OF MANUFACTURING

In biopharmaceutical manufacturing, **fill and finish** marks the final handoff before therapies reach patients. It's where drug products are aseptically filled, sealed, inspected, labeled and prepared for distribution. On the surface, it may appear as a closing formality, but in practice, it's **one of the most complex and high-risk stages of the entire manufacturing lifecycle**.

WHAT MAKES FILL AND FINISH SO COMPLEX TODAY

Product form factors and variability

The rise of injectable biologics, personalized treatments, and modular delivery devices has greatly increased fill and finish complexity. Manufacturers now run **multi-product lines** capable of processing **small clinical batches** and **large commercial volumes** using the same equipment. This requires accommodating a wide range of containers — such as vials, syringes, cartridges, autoinjectors and even wearable devices — while ensuring sterility, precision and full traceability.

The surge of new equipment and automation

Behind the scenes, fill and finish has evolved into **a miniaturized factory within a factory**. A single line may include everything from vial washers and depyrogenation tunnels to inline weighing systems, crimp cappers, lyophilizers, barrier isolators and serialization units.

Robotic aseptic systems are now essential. For example, **Vanrx Pharmasystems** (acquired by Cytiva in 2021) produces gloveless, robotic isolators for filling vials, syringes and cartridges — a turnkey solution for clean, flexible and high-speed filling.

Single-use technologies are also growing rapidly. They improve sterility, safety and flexibility while enabling modular, scalable plant designs. According to Cytiva, single-use systems are **more sustainable than traditional stainless-steel systems**, consuming less water and energy, and eliminating cleaning chemicals. Yet, they introduce new complexity in integration, validation, waste management and material tracking.

The emergence of next-gen therapies

As novel therapeutic modalities emerge, fill and finish evolves into a strategic bottleneck in delivering precision medicine. For **cell and gene therapies** such as those developed by Autolus Therapeutics or Roche,[4] [5] each batch may be patient-specific, with no room for error or delay. In **radioligand therapies (RLT)**, pioneered by companies like **Novartis**[6] with products like Pluvicto, radioactive compounds must be handled with extreme care, under tight time constraints, and with real-time logistics coordination.

These treatments demand a new kind of fill and finish infrastructure: **Closed, flexible, often single-use and modular**. Technologies like **robotic isolators, shielded automated lines** and **disposable flow paths** are essential to meet speed, sterility and personalization needs.

[1] "Cytiva acquires Vanrx Pharmasystems, Canadian aseptic filling innovator" by Cytiva (February 2021)
[2] "Filling in its drug product offering: Cytiva buys Vanrx Pharmasystems" by BioProcess Interntional (February 2021)
[3] "Pharmaceutical filling in aseptic manufacturing" by Cytiva
[4] "Top 10 Leading Companies in Cell and Gene Therapy Market Delivering Life-Changing Therapies to Improve Quality of Life" by Emergen Research (April 2023(
[5] "Cell & Gene Therapy Fill-Finish: Processes, Challenges, And Innovations" by Cell & Gene
[6] "Novartis begins construction of two new radioligand therapy facilities in the US, expanding its world-class RLT manufacturing and supply network" by Novartis (September 2024)

Regulatory and quality pressures

This growing ecosystem of equipment demands more than just automation — it requires **perfect orchestration**. Any change in product type, batch size or line configuration must be **rigorously validated, documented and compliant** with evolving regulatory expectations such as **EU GMP Annex 1**.

But the shift isn't only about compliance checklists. Increasingly, **regulators are asking manufacturers to adopt a risk-based mindset** — one that prioritizes anticipation and prevention rather than reaction and remediation.

In fill and finish, this shift is particularly significant. Why? Because no two fill and finish processes are ever exactly alike. **Modularity, multi-product capabilities** and **flexible batch configurations** mean that line conditions are **constantly changing**. Each format switch, container type or product strength introduces a **new set of risks** to sterility, traceability or performance.

As a result, risk management is becoming central not just to validation, but also to everyday decision-making:

- Can a new configuration maintain aseptic assurance?
- Will a new format trigger cleaning validation or airflow redesign?
- What is the impact of operator layout on error potential?

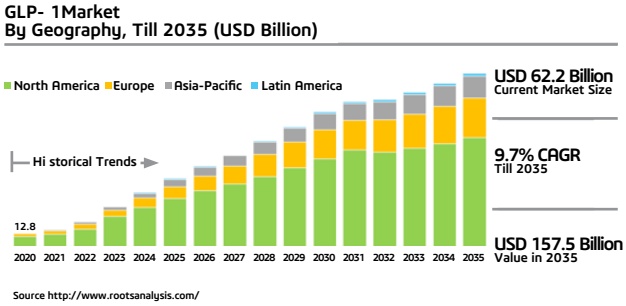
This level of scrutiny is not optional; it is the new standard for **regulatory readiness and quality assurance**.

WHEN FILL AND FINISH BECOMES A BARRIER TO CARE

As demand for biologics surges and drug delivery devices become more advanced, fill and finish is increasingly becoming the critical bottleneck between production and patient access.

In recent years, this bottleneck has become painfully visible.

- **Insulin shortages** have been a recurring issue globally. In both the U.S. and the EU, **backorders for analog insulin pens and cartridges have ranged from 30 to 60 days**,[7] despite sufficient supply of active pharmaceutical ingredients (APIs). The root cause? **Limited fill and finish capacity**; not a raw material issue, but a production one. These gaps directly endangered continuity of care for insulin-dependent patients.
- The **GLP-1 drug market** (used to treat diabetes and obesity) is expected to **double within the next 10 years**, growing at a compound annual growth rate of 9.7% and reaching **over $22 billion by 2035**.[8] These therapies are predominantly delivered via injection pens or autoinjectors, putting even more pressure on already constrained fill and finish infrastructure.



- Similarly, biologic treatments like **Dupixent (Sanofi/ Regeneron)**, used for asthma and atopic dermatitis, have seen skyrocketing demand. In 2023 alone, **global sales reached $10 billion**, with projections pushing higher in 2025.[9] [10] Supply challenges linked to fill and finish throughput have resulted in intermittent allocations.
- Other blockbuster therapies like **Keytruda (Merck)**, expected to **exceed $25 billion in global sales by 2026**, are also highly sensitive to any disruption at the fill and finish stage, especially as delivery formats and therapeutic indications expand.

Together, these examples illustrate a troubling pattern: **Even high-demand, high-value therapies can fail to reach patients** on time if fill and finish capacity or flexibility is lacking.

In a world where **demand is rising, therapies are evolving** and **delivery formats are multiplying**, the ability to scale, adapt and de-risk fill and finish operations is no longer optional — it is mission-critical.

A NEW LOGIC: SIMULATION-FIRST FILL AND FINISH

Given this complexity, biopharmaceutical manufacturers and CDMOs can no longer afford trial-and-error commissioning, layout mismatches or productivity bottlenecks. Every inefficiency in fill and finish delays time to patient and inflates cost. The growing use of advanced equipment and modular configurations means more revalidation, more integration points and more risk. Traditional strategies can't keep pace.

To navigate this landscape, manufacturers must move beyond static design and reactive planning. They need a **simulation-first mindset** — one that allows them to test, optimize and validate every decision before implementation. From equipment layout to airflow simulation, from operator workflow to container filling parameters, every variable must be modeled and understood in advance.

Virtualization is not just a digital convenience; it's becoming the foundation for **operational excellence**. As we'll explore in the next chapter, this is where **virtual twin technology** begins to show its full potential.

[7] "Citing 'capacity constraints,' Novo Nordisk plots global wind-down of human insulin pen production" by Fierce Pharma (November 2024)
[8] "GLP-1 Market" by Roots Analysis
[9] "The Global Drug sales of Dupixent (2020 - 2026, USD Millions)" by GlobalData
[10] "Dupixent sales continue to grow as Altuviiio set to become Sanofi's next blockbuster" by FirstWord Pharma (April 2025

CHAPTER 3:
OPTIMIZING BIOPHARMA MANUFACTURING WITH VIRTUAL TWINS

FROM STATIC MODELS TO DYNAMIC SYSTEM TWINS THAT GUIDE ACTIONS AND DECISIONS

Leaders in biopharmaceutical manufacturing are already embracing the industry's transformation and leveraging digital technologies to gain agility, speed and resilience. For manufacturers who haven't yet made the leap, the time to act is now.

Digital transformation in life sciences is evolving beyond digitized documents, dashboards and disconnected 3D assets. In today's complex and regulated environment, companies need more than visualization, they need the ability to anticipate, simulate, test and learn. This is where **the virtual twin** becomes a game changer.

Virtual twin technology refers to a dynamic digital replica of a physical system (such as a production line or an MRI scanner) that can be either non-existent, in development phase or existing with continuous optimization. It includes equipment and processes built from design geometry, real-time data, simulations and feedback loops. It enables multiple stakeholders to model operations, test scenarios, detect issues and optimize performance before committing changes in the real world.

Forty years ago, virtual twins were born as a way to design and develop a process or a product more efficiently. Today, virtual twins are a **system-of-systems replica**: A dynamic, data-driven model that fuses **design, simulation, operational data** and **real-time performance feedback** into one unified, actionable environment.

A closed-loop, simulation-first approach:
Design → Simulate → Test → Operate → Learn

Through the virtual twin, organizations can explore endless 'what-if' scenarios before making changes in the real world. It creates a **closed-loop cycle** where every design is tested, every simulation is validated and every learning is reintegrated into future decisions.

This loop becomes tangible through real-world applications. For example:

- **Design:** Reconfigure a filling line layout to handle two container formats without additional floor space
- **Simulate:** Test airflow and aseptic conditions across new isolator configurations
- **Test:** Validate a new cleaning cycle digitally to reduce downtime

A REALITY ALREADY TAKING SHAPE IN PHARMA

Long before it became a manufacturing imperative, **the 4P Medicine concept** was introduced by Dr. Elias Zerhouni during a 2011 conference at the Collège de France, describing the future of healthcare as **predictive, preventive, personalized and participatory**.[11] Today, virtual twins enable biopharmaceutical manufacturers to make this vision a reality.

Across the entire value chain, from early development to commercial manufacturing, virtual twin technology also enables a 4P concept built around **patients, products, processes** and **production plants**:

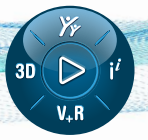
- **Patient virtual twin:** Models the patient's biological, clinical and behavioral context to inform more precise, personalized therapies. While more prevalent in R&D or late-stage development, its influence is growing in how manufacturing strategies are tailored to patient-specific needs.
- **Product virtual twin:** Represents the drug substance and drug product, including its physical, chemical and biological properties. It supports formulation development, stability testing, packaging compatibility and regulatory documentation — all connected in one digital thread.
- **Process virtual twin:** Simulates manufacturing steps — formulation, filling, inspection, labeling and more — allowing teams to test and validate every change, scale-up scenario and equipment configuration before implementation.
- **Plant virtual twin:** Digitally represents the production environment, including equipment, layouts, HVAC systems, operator flow, utilities and cleanroom behavior. It enables real-time monitoring, predictive maintenance and energy optimization across the physical facility.

Together, these four Ps provide a comprehensive, closed-loop model of pharmaceutical operations that **unifies design, execution, compliance and learning**. By connecting virtual design with physical execution, companies can **break silos, accelerate time to market** and **improve quality** — without increasing risk.

By connecting these four dimensions, the virtual twin experience empowers life sciences leaders to design with precision, manufacture with confidence, and adapt with speed — all while maintaining patient safety, compliance and sustainability.

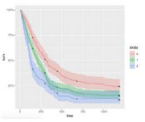
VIRTUAL TWIN EXPERIENCES FOR SUSTAINABLE INNOVATION

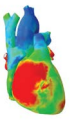
COMBINE REAL WORLD DATA with MODELS to deliver OUTCOMES



Patient Virtual Twin

Clinical Trial | Cohort
Organ | Tissue

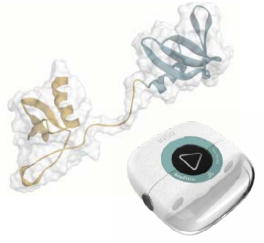




The Living Heart Project

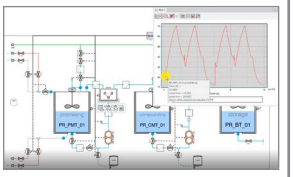
Product Virtual Twin

Molecule | Formulation
Device | System Architecture



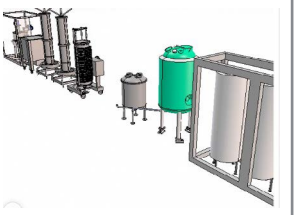
Process Virtual Twin

Recipe | Method | Operations
Process Parameters | Controls



Plant Virtual Twin

Building | Environment
Equipment | Resources



[11] "La médecine des «4P»: une prophétie en trompe l'œil" by Journal International de Médecine (March 2024)

VIRTUAL TWIN AS A PERFORMANCE ENGINE

Every virtual twin is a performance engine in disguise. It captures and contextualizes KPIs such as:

- Throughput and yield
- Changeover time
- OEE (Overall Equipment Effectiveness)
- Energy and resource usage
- Batch release timelines
- Contamination risks and sterility assurance levels
- Ergonomics and operator workload
- Training time and deviation rate

With these KPIs tracked in both simulation and execution, manufacturers can compare expected versus actual performance, identify drift and proactively resolve root causes. This isn't just operational insight, it's decision intelligence.

WHY THE VIRTUAL TWIN IS UNIQUELY SUITED TO BIOPHARMACEUTICAL FILL AND FINISH

Biopharma is a domain where precision, traceability and repeatability are non-negotiable. The combination of high regulatory scrutiny, product complexity and rapidly evolving modalities makes it one of the most demanding manufacturing environments in the world.

Nowhere is this more evident than in fill and finish operations. Every line reconfiguration, every packaging switch and every batch variation introduces a new level of complexity. Traditional methods are no longer sufficient to manage this safely, efficiently and at scale.

The virtual twin is not just an enabler, it is a necessity for bringing together the right expertise, data and systems to meet today's expectations and tomorrow's opportunities.

CHAPTER 4:
FIVE STRATEGIC USE CASES FOR FILL AND FINISH

WHERE VIRTUAL TWINS DELIVER MEASURABLE VALUE, FAST

The complexity of modern fill and finish operations demands more than reactive troubleshooting; it requires proactive, simulation-driven decision-making. Whether the goal is to optimize a new facility or adapt an existing production line, virtual twin technology offers actionable insights to improve sterility, safety, efficiency and compliance.

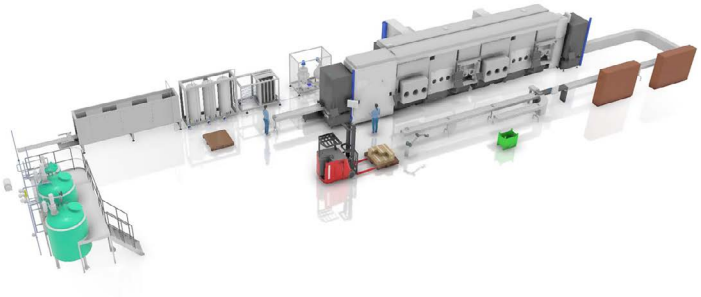
Here are five proven use cases where virtual twins make an immediate difference:

Layout and process flow optimization

Virtually test and validate multiple layout options for your fill and finish line before anything is built or reconfigured. Simulate flows of materials, operators, equipment and waste to eliminate bottlenecks and improve space utilization. Benefit from reuse by capitalizing virtual twin models and continuously improve your manufacturing process.

Some concrete examples:

- **Simulate and optimize fill processes** as well as operator and automated guided vehicle (AGV) workflows to minimize errors and improve productivity by **up to 15%.**
- **Model the entire fill and finish and packaging line**, test automation strategies, and predict machine uptime for better overall equipment effectiveness (OEE), reducing plant engineering cost by **up to 20%.**
- **Simulating and predicting optimal changeover sequences** from a configuration A (drug A) to a configuration B (drug B); from equipment disassembly and cleaning workflows, operator movements and task coordination to material flow and automation adjustments.



Result: Faster commissioning, fewer redesigns and more efficient good manufacturing practice (GMP) zoning.

Virtual commissioning

Simulate automation logic, equipment interactions and batch sequences in a risk-free environment. Identify integration issues early and reduce the time needed for installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). Improve process and equipment standardization from one line to another and capitalize knowledge.

Some concrete examples:

- **Virtual verification and validation tests** for full manufacturing lines or single equipment.
- **Virtual operational qualification** to test automated process cycles such as filling, capping, clean-in-place (CIP) and steam-in-place (SIP) as well as alarm activation and system responses to reduce overall qualification time by **up to 20%.**
- **Digital simulation** of the entire plant layout, automation sequences and operator training before actual deployment.

Result: Months saved on deployment and increased right-first-time performance.

Airflow and aseptic zone simulation

Visualize and optimize airflow, pressure differentials and contamination risk using computational fluid dynamics (CFD) simulation. Ensure cleanroom compliance and adapt heating, ventilation and air conditioning (HVAC) configurations without disrupting operations.

Some concrete examples:

- **HVAC design optimization:** Simulate airflow, personnel movement and particle dispersion to optimize HVAC designs, reduce risks and divide by three clean room validation time.
- **Biosafety cabinet and isolator design:** Simulate airflow interactions with operator movements, optimize exhaust rates and directional flow, and validate containment effectiveness before implementation.
- **Contamination prevention in open processing areas:** Simulate particle migration and containment effectiveness, optimize local ventilation and air curtains, and improve airflow zoning strategies.

Result: Enhanced sterility assurance and faster validation of environmental controls.

Operator optimization and virtual training

Use ergonomic simulations and virtual human models to improve workstation design and reduce human error. Train operators in virtual environments with realistic scenarios before they step into the cleanroom.

Some concrete examples:

- **Fill and finish line operator efficiency:** Simulate hand-eye coordination and reachability in high-speed filling lines, optimize layout and human-machine interfaces for faster interventions, and test automated versus manual workflows for efficiency.
- **Optimize and reduce maintenance difficulty:** Simulate maintenance tasks before execution to identify accessibility challenges in advance.
- **High-speed packaging and assembly line optimization:** Simulate repetitive tasks to identify high-risk movements, recommend automation or ergonomic redesigns (e.g. adjustable workstations and exoskeleton support) and reduce unnecessary reaching, twisting and lifting.

Result: Safer, faster onboarding and more consistent performance on the line.

Line, AGV and robotic programming

Digitally program and test robotic systems, AGVs and line synchronization. Optimize motion paths, changeovers and line efficiency in advance without stopping production.

Some concrete examples:

- **Fill and finish process optimization:** Simulate and optimize robotic arm movements to minimize errors and improve productivity.
- **Human-robot collaboration optimization:** Simulate and test different human-robot task distributions to enhance ergonomics and reduce physical strain on operators.
- **Robotic depalletization and material handling:** Simulate robotic pick-and-place operations to optimize material flow and reduce handling errors.

Result: Improved throughput, fewer interruptions and seamless tech integration.

Together, these use cases demonstrate how virtual twins can turn fill and finish into a predictable, scalable and future-ready operation — from design to daily execution.

CHAPTER 5: FROM SIMULATION TO REAL-WORLD PERFORMANCE

The power of virtual twin technology lies not just in what it simulates, but in what it delivers: Faster commissioning, safer operations, better productivity and fewer surprises. Whether through a full-scale digital transformation or a targeted deployment, real-world implementations in fill and finish are showing measurable gains.

Here are key performance metrics observed across recent deployments:

Cycle time reduction

By modeling equipment, layouts, operator workflows and cleanroom behaviors before deployment, virtual twins dramatically reduce project timelines:

- **Up to six months saved** per facility or line becoming operational
- Between **20% and 30% faster** tech transfer and commissioning timelines
- **Faster validation**, smoother inspections and fewer surprises at startup

Productivity improvements

Simulation of changeovers, automation logic and resource allocation translates directly into operational efficiency:

- **Between 30% and 40% less downtime** during physical testing and batch changeovers
- **Between 5% and 20% OEE improvement**, driven by optimized layout, sequencing and manpower utilization
- More **flexibility** in managing multi-format and multi-product lines

Waste reduction and sustainability gains

Virtual testing minimizes unnecessary trial batches and rework:

- **Significant reduction** in material waste from failed changeovers
- **Less energy and water consumption** thanks to optimized cleanroom airflow and equipment usage
- Increased readiness for **sustainability audits** and Scope 3 reporting

Human-centric gains

Operator efficiency and safety also benefit from virtual training and ergonomic modeling:

- **Faster onboarding** through immersive virtual training
- **Reduced risk** of human error in aseptic environments
- Ergonomically validated workstations for **lower injury risk and higher consistency**

CHAPTER 6:
VIRTUAL TWIN AS A SERVICE (VTAAS) AS A SHORTCUT TO VALUE

Today, virtual twin technology provides value fast, without risk or budget overruns. A new approach, based on online managed services (OMS) and available through cloud applications, is helping manufacturers tackle the latest industry challenges.

VTaaS is a **yearly cloud subscription service** that combines virtual twin technology with Dassault Systèmes' expertise and apps on the **3DEXPERIENCE®** platform to continuously optimize operations and improve outcomes. Our experts build, deliver, operate and maintain the entire experience for your success at the speed of your business needs.

Standardize and capitalize manufacturing know-how

With VTaaS, companies don't just digitize — they industrialize. Processes, layouts, best practices and equipment configurations are captured in reusable templates that can be shared across sites. This enables **global standardization**, accelerates tech transfer and builds **digital continuity**.

Start fast and stay agile

VTaaS allows you to **start small, scale fast and pivot as needed**, without committing to full internal deployment upfront. You can launch a simulation in one facility, replicate it elsewhere or sunset the model once the goal is met. This flexibility supports both **innovation and control**.

Scalable to all, regardless of size

Whether you're a global manufacturer or a CDMO, VTaaS is built to scale. Its cloud-based model makes cutting-edge simulation and optimization accessible even to organizations with limited IT infrastructure or resources.

A shortcut to value, a bespoke online application

VTaaS is **outcome-driven**. Engagements are governed by clear **service-level agreements (SLAs)** and performance is measured against tangible KPIs such as reduced time to commission, faster changeovers or better OEE.

Simple, transparent licensing on a GxP cloud platform

Say goodbye to opaque software bundles and unpredictable upgrade paths. VTaaS offers a **clear, modular licensing model** delivered via a **GxP-ready cloud infrastructure**. No complex installation. No surprise costs. Just a simplified customer experience designed for compliance and scalability.

Built on generative design and data intelligence

Every simulation creates data. And every data point builds intelligence. VTaaS integrates **generative design, AI** and **machine learning** to continuously improve recommendations, equipment layout and process parameters, turning each deployment into a smarter one.

From complexity to clarity

In the face of fragmented systems, talent shortages and global pressures, biopharma manufacturers are seeking **speed, standardization and scalability** — without compromising quality or compliance. **VTaaS delivers exactly that**.

By virtualizing key fill and finish processes with VTaaS, companies can unlock faster time to market, de-risk investment and build a future-ready manufacturing model — without the overhead of traditional IT-heavy deployments.

CONCLUSION

Biopharmaceutical manufacturing is entering a new era defined by personalized therapies, modular production, real-time decision-making and rising expectations for speed, precision and compliance. Nowhere is this transformation more visible than in **fill and finish**, where every drop counts and every delay matters.

As we've explored throughout this white paper, the combination of complex product portfolios, next-generation therapies, advanced equipment and regulatory pressures demands a smarter way to operate — one that goes beyond trial-and-error, static layouts or disconnected tools.

The **virtual twin**, delivered "**as a service**," offers that smarter way. It empowers companies to anticipate instead of react, simulate instead of speculate, and optimize before executing, unlocking measurable gains in speed, quality, safety and scalability.

Whether you're equipping a facility with new manufacturing lines, adapting to a novel modality or simply seeking to standardize best practices across sites, **VTaaS turns digital ambition into operational reality without risk, on time and on budget**.

Now is the time to turn complexity into clarity, to transform fill and finish from a constraint into a competitive advantage — to move from insight to impact.

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Dassault Systèmes is a catalyst for human progress. Since 1981, the company has pioneered virtual worlds to improve real life for consumers, patients and citizens.

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