Life Sciences
& Healthcare

THE VIRTUAL TWIN EXPERIENCE OF THE PHARMACEUTICAL PROCESS

VIRTUALLY TEST AND UNDERSTAND SYSTEMS IN SPECIFIC ENVIRONMENTS RAPIDLY

Inceptra

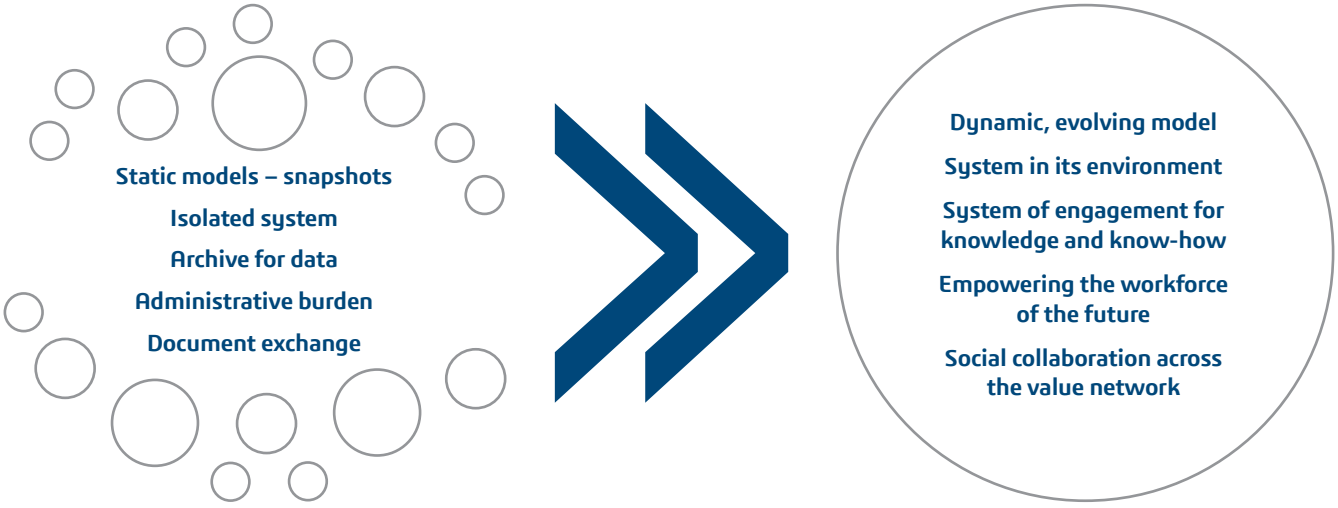
DASSAULT SYSTEMES

OUR MOTIVATION

We are proposing a comprehensive virtual twin experience of the pharmaceutical process.

Unlike digital twins, **virtual** is about **what is possible**. The value lies in the **potential for imagining the future**.

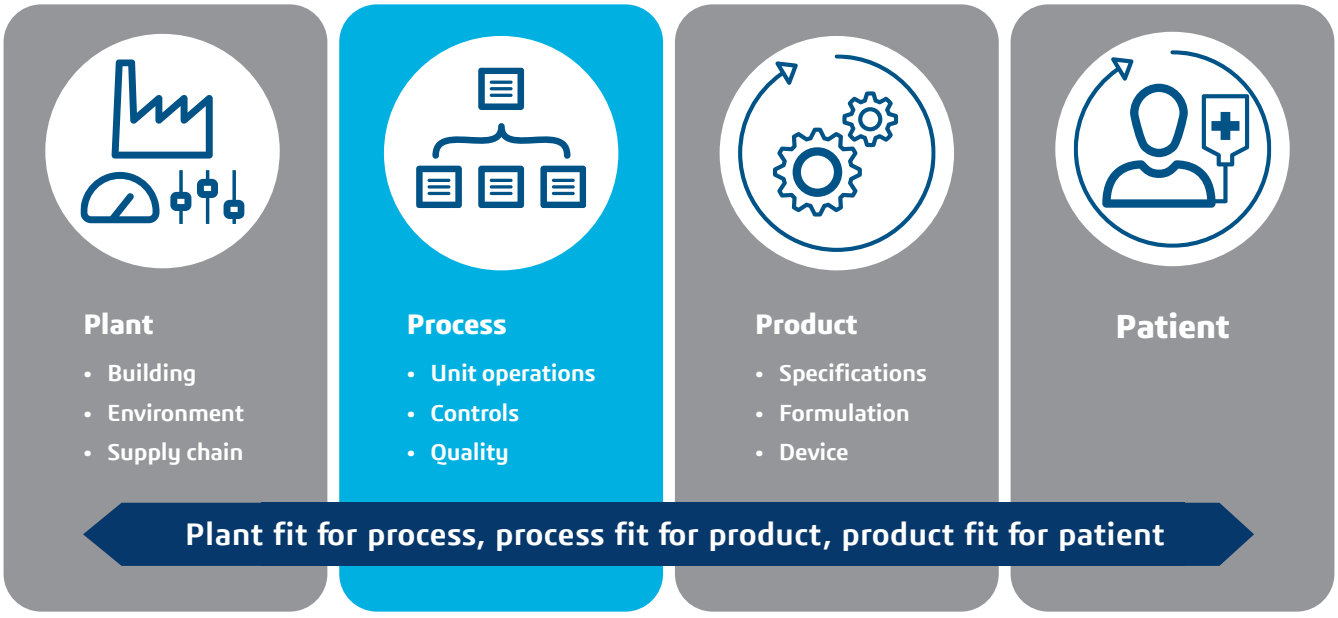
"**Experiences**" refer to the ability to model sophisticated systems, to run simulations, including "What If" scenario models to virtually test and understand systems and their use in a particular environment.



Digital twins **Virtual twin experience**

Virtual twin experience connects the virtual with the real, thus enabling the understanding of the past to navigate the future. They provide real-time experiences with precision and accuracy by allowing multi-physics simulations of systems in the same referential of the collaborative experience.

According to NNE, Virtual twins in pharma can model and simulate data to describe and optimize patients, products, process and/or the plant. However, each of the 'P's are linked to one another by the requirements which propagate from patient to the plant.



The 4P model of the pharmaceutical value chain, adapted from NNE

- The product needs to deliver value to the patient
- The process delivers the product in the right quality and cost-effectively
- The plant is designed to accommodate the process

Just as indicated in the graphic above, we are concentrating on a virtual twin that structures and manages all data relevant to the process and its performance. Such a twin can be used to better understand and optimize processes against any number of requirements, including quality, cost and sustainability.

PROCESS DEVELOPMENT

Process development is critical to bringing new therapies to market. In many cases, it is on the critical path. For novel patient-specific therapies, it is also becoming the product itself.

Stakeholders from Therapeutic Area Leadership to Chemistry, Manufacturing and Controls (CMC), and Clinical can benefit from the virtual twin experience and be able to answer questions such as:

- Which process variant delivers quality medicinal products in a cost-effective and environmentally sustainable way?
- What does my organization know about my product and its manufacturing processes?
- What features and steps of the process have the biggest impact on my product?
- What requirements depend on a particular piece of equipment?
- Can I reuse this for another project or process?
- What risk does change pose to the process?
- What is the status of a particular piece of my equipment?
- What documents are associated with this equipment?
- What engineering changes have been made by whom, when and for what reason?
- What is the impact on the entire process behaviour, if I have to change a piece of equipment or some of its parameters?

Asking these questions will create a focus for your scientists and engineers to accelerate the product development process. It will improve quality and facilitate continuous improvement and learning for more agility, flexibility and speed in process development, manufacturing and operations.

Virtual twins can significantly accelerate:

- Process development
- Tech transfer
- Facility or site acceptance

All of this is included in the CMC (chemistry, manufacturing and control) process. Besides the product's description, such as the composition of the finished product and the materials for the primary packaging, the CMC process also governs the body of information that defines the manufacturing process itself.

That includes the quality control and release testing information, specifications and stability of the product and its manufacturing process and facility information as well as all of its support utilities, including design, qualification, operation and maintenance.

Modeling will significantly improve the ability to understand the process and assets, facilitate risk assessments and impact analysis to de-risk changes and improve quality.

WHY NOW?

Mastering complexity

As the molecular structures of active ingredients and their formulations become more complex, the processes to make these products also increase in complexity. Ultimately, for novel patient-specific therapies, the process becomes the product itself and thus core to drug development.

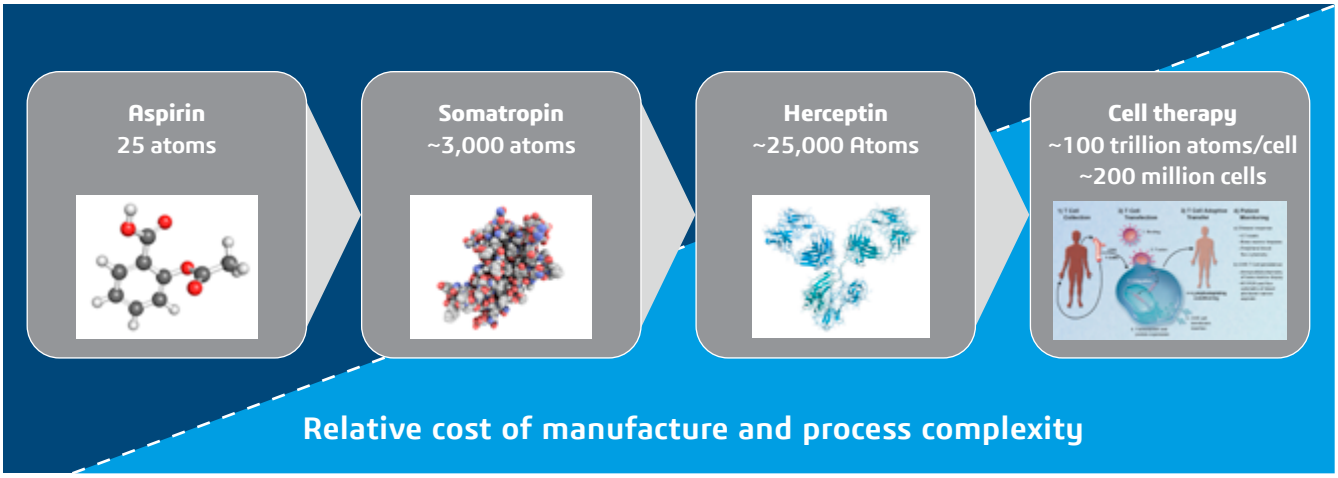
Accelerating time to market and improving success rates requires ***mastership*** over these increasingly complex manufacturing processes and a deep understanding of the technology. Only when the process is fully understood can we reliably predict how changing parameters will affect the manufacturing process and product quality, sustainability and yield.

Virtual twin experiences will become the standard enabler to facilitate process understanding and enable process optimization, process simplification through modularization, regulatory compliance and right-first-time (RFT) operations.

WHEN THE PROCESS BECOMES THE PRODUCT

The pharmaceutical industry is still lacking holistic propositions that detail what a process virtual twin experience will look like and what features it will contain.

Instead, the industry uses – haphazardly – partial and often isolated simulation capabilities. Such capabilities are often focused on certain process aspects and individual process steps rather than the process in its entirety.



Reference: "Science to Operations: Questions, Choices and Strategies for Success in Biopharma" by McKinsey & Company (December 2014)

The focus tends to be on simulation, especially artificial intelligence (AI) and machine learning (ML) as the answer. Still, it lacks core model lifecycle management, which is crucial if the industry moves to a virtual-first paradigm in process development.

Democratizing predictive tools for virtual-first modeling and simulation strategies requires managing both the model and the simulation capabilities.

Predictive tools utilize versions of the system model under investigation. Simulation context, such as input, parameters, and model version and success metrics, needs to be managed to achieve the ultimate goal of deep process understanding and robust and accurate predictions of behavior and outcomes.

A Holistic and Multi-Dimensional Virtual Twin Experience

We propose a holistic and multi-dimensional virtual twin experience of the process, which includes the process requirements, the recipe and its procedures, the physical assets, documents, and data and information related to regulatory compliance and performance.

The virtual twin will be managed through the entire lifecycle of the process and its maturity stages.

This managed virtual twin experience becomes the launchpad for:

- A multitude of simulation capabilities and drives
- Democratized predictive capabilities
- Virtual-first through the entire organization

Predictions and right the first time will become the norm rather than the exception.

Throughout the process development, companies can seamlessly manage optimization and operation, changes and compliance.

Project gates and decisions will be integrated and contextualized with the right version of the twin, delivering the right information to the right person in the right format and at the right time.

Just as the FDA on the basis of the ICH Q8 (R2), Q9, and Q10 recommends, such holistic knowledge management enabled by a virtual twin experience will start with the requirements.

The quality target product profile (QTPP) describes the design criteria for the product as a basis for the development of the process, specifically the critical quality attributes (CQAs), critical process parameters (CPPs), and the control strategy. All information will be traceable and managed in order to:

- Develop control strategy
- Ensure quality of the product throughout the product lifecycle
- Increase product and process knowledge
- Increase transparency and understanding for regulators and industry
- Evaluate changes

"In terms of critical quality attributes, the greater the interdependency of the key process parameters, the more complex the procedure and the more important it is to explore how each one affects the others."

— Matt Harrison, GSK

Learn more: Manufacturing Vaccines, Digital Twins and Lessons Learned: Part I

IS SOFTWARE EATING THE WORLD?

This question was asked by Marc Andreessen, co-founder and general partner of venture capital firm Andreessen Horowitz in 2011. And, it is clear today that software dominates the functions and processes of all industries. For the pharmaceutical industry, software can accelerate the delivery of patient-centric systems, facilitate the exchange of scientific results and increase manufacturing efficiency and yield.

LEARNING FROM OTHER INDUSTRIES

Virtual twin experiences have revolutionized the way products are designed, engineered and manufactured. Concurrent engineering is standard in discrete manufacturing such as automotive and aerospace.

Product manufacturing processes are developed and optimized while the product goes through design and engineering concurrently.

This has significantly reduced times to market, improved quality and reduced costs. Engineering changes are immediately available to all engineers so that issues and risks are collaboratively reviewed and resolved.

In addition to concurrent engineering, discrete manufacturers deploy simulations to test the product and manufacturing line behaviors virtually.

Discrete manufacturing

Physical crash testing of a new car model is performed when the first cars roll off the final production line. The crash behavior is accurately predicted using simulations, thus removing the need for costly prototypes before building the manufacturing line. This reduces time to market by months if not years.

Process industry

Similarly, most companies in the fast-moving consumer goods (FMCG) sector, such as Unilever and P&G, are establishing virtual-first strategies to reduce time and effort of product development. These strategies significantly improve agility and reactivity to changing market demands without compromising quality and reducing cost and environmental footprint.

Pharmaceutical industry

The development of manufacturing processes is unviable due to the high attrition rates of products during pharmaceutical development.

However, the COVID-19 crisis and the extreme acceleration caused by the global need for vaccines have upended the traditional development processes and pushed process development and manufacturing to the forefront. All successful vaccine launches were delivered by simultaneously developing the product and the manufacturing process.

LEARNING FROM THE COVID-19 CRISIS

Digital collaboration

The COVID-19 vaccine launches gave us a glimpse of the future. Enabled by digital collaboration, regulators can:

- Share accurate, contextualized, compliant, and up-to-date data in near real time during rolling reviews
- Rapidly scale manufacturing capacity through a complex network of partners, where each partner delivers data, regulatory information and documents with its high quality products – intermediate and final – globally

Flexible manufacturing

The COVID-19 crisis has merely accelerated changes, which have been underway for some time. Due to the changing nature of healthcare to become much more personalized, the industry needs to reduce cost, accelerate times to market, and move to agile and flexible manufacturing processes.

The maturation of new technologies such as process analytical technology (PAT) and IIoT, as well as continuous processing, will make quality by design (QbD) and real-time-release (RTR) possible in the near future.

Just this year, the FDA announced an expansion of its commitment to advanced manufacturing technologies because it aimed to prepare the U.S. to face the rest of the 21st century with a modern and resilient system for pharmaceuticals, biopharmaceuticals, medical devices and vaccines.

THE FUTURE OF PROCESS ENGINEERING

"As the pharma industry strives to achieve increasing efficiency in response to global economic challenges, new capabilities such as product and process data manage-ment, collaboration and analytics are needed. Increasingly, pharma companies are turning to PLM to address these challenges, but they should be thoughtful about its design and implementation, as the 'right' architecture for pharma may look familiar in places but very different in others, when compared to other industries."

Learn more: PLM for Pharma: Applying an Old Tool in New Ways

FROM QUALITY-BY-TESTING TO QUALITY-BY-DESIGN

The European Medicines Agency (EMA) said, "One of the goals of quality by design is to ensure that all sources of variability affecting a process are identified, explained and managed by appropriate measures. This enables the finished medicine to consistently meet its predefined characteristics from the start — so that it is 'right first time'."

Quality by design and right first time require process control. However, without identification and explanation of all sources of process variability, this cannot be achieved, even if the technology exists in principle. Technology such as sensors and control units only deliver value if we can achieve full process understanding and accurately model the process and its behaviour and outcome.

Such process models will map the design space of the process, which is a multi-dimensional space that is spanned by all process parameters, including quality attributes of raw and intermediate materials. Only then can sensors and control technology bring the process back to a state of control should it diverge from the design space.

The benefits are immense:

- Clear definition of the quality control key parameters and related criteria
- Lower cost of manufacturing
  - Shorter cycle times
  - Lower material and energy use
- Fewer or no failed batches
- Reduced and ultimately no quality control (QC) testing
- Improved product quality
- Anticipate design errors long before the physical implementation

But there is more: Complexity, as discussed above, is compounding the efforts to deliver quality by design. With more and more complex drugs being developed, we are actually further from process understanding than before.

As a result, the control strategies for product quality are rigid and often overly restrictive. This makes therapies more expensive, the release processes long and costly and altogether leading to longer times to market at higher prices.

The lack of full process and product understanding also impacts the regulatory approval process and — in the worst cases — can lead to too many lost batches, even though the product may well be safe and effective. Novartis lost 10% of its Kymriah batches due to being out-of-specification yet effective and used to treat patients successfully.

Digitalization and digital twin technology have promised to improve process understanding. However, we hear from the pharmaceutical industry that we are still a long way from seeing a holistic approach to virtual twins; modeling and simulation are still the exception rather than the standard.

Definitions

Quality by design (QbD)

A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.

Design space

The multidimensional combination and interaction of input variables (such as material attributes) and process parameters that have been demonstrated to provide assurance of quality.

See also ICH Q8 (R2)

DIGITAL TWINS: WHAT'S HOLDING US BACK?

So far, digital twins are often reduced to only mean simulations to answer specific questions. Due to advances in IIoT and machine learning or artificial intelligence, simulation often means data analytics today.

There is hope that somehow if we collect enough data and have enough processing power, we can create an AI model that correctly predicts the behavior of the process under development or in operation.

So far, that promise has not been delivered; in response, process scientists and engineers revert to mechanistic simulations of process steps, which may or may not be accurate enough. The task is made harder by the vast diversity of processes, process behaviors and outcomes – in other words, the complexity of the processes.

Experts typically run the digital twin simulation and manage the results locally without any association to the process as a whole. Results and insights are locked in documents and rarely used consistently to learn and improve process understanding for future projects.

There is mistrust as to the validity of simulation results and the value to the development projects is difficult to ascertain: Is development effort reduced or quality and success of projects improved?

Exceptions to this are strategic and holistic modeling and simulation approaches, such as reported by AstraZeneca in "An Industrial Approach Towards Solid Dosage Development for First-Inhuman Studies: Application of Predictive Science and Lean Principles" by Dhaval R. Kalaria, Keith Parker, Gavin K. Reynolds and Johanna Laru in Drug Discovery Today (Volume 25, Number 3, March 2020). But even there, the emphasis is on simulations to predict particular behaviors, such as flow and mixing. A review of approaches and tools can be found here.

To move to a true virtual-first paradigm, which will enable quality by design and deliver its benefits, companies need to fix the basis for the simulation. They need a model that:

- Is truly virtual and describes the process from start to end
- Is managed through the lifecycle
- Facilitates change and impact analysis
- Is trusted to be a true twin of the process and equipment

Such a model can then act as the catalyst for predictive science and lean principles in process engineering and manufacturing.

We are also proposing that such a model can be accessible to all scientists, engineers and technicians, leaving experts to focus on the most intricate problems and the development of new simulation methods.

This paper elaborates on the model of the process rather than describing in detail how the model will change process engineering by facilitating model-based systems engineering (MBSE). That topic will be covered in detail in a subsequent paper.

LAUNCHPAD FOR SIMULATIONS: THE VIRTUAL TWIN EXPERIENCE

The virtual twin experience that we are proposing manages all knowledge related to the process and will be available to engineers, scientists, managers or technicians to move from document-based to data-driven model-based ways of working.

The holistic virtual twin experience relies on a high level of abstraction, which describes the requirements, the functional and logical and the physical make-up of the process and its assets. This level of abstraction models the process by:

1. Its requirements – this includes but is not limited to specifications and critical quality attributes and is most often the quality target product profile.
2. The functions it supports, which are typically the unit operations.
3. The logical structure of the process: The flowsheet, process flow diagrams (PFD) and/or piping and instrumentation diagrams (P&ID).
4. The physical instantiation of the process, including 3D CAD models, if available and identifiable by name, number, location and any other details, such as the supplier and calibration records.

Each of these aspects describes the process or its steps fully and can be used by different stakeholders to navigate or interrogate the process model in the virtual twin experience. Such a data-driven model enables analytics, visualizations, automated reporting and object-based engineering.

This virtual twin experience model differs significantly from the digital twins discussed in the last section. Unlike the digital twins that focus on simulation capabilities, we apply a model-based systems engineering approach, which has shown to reduce development efforts and improve quality in discrete manufacturing.

Such a consistent model of the process system and its requirements facilitate lifecycle management, information traceability, risk and change impact analyses. This is crucial in addition to predictive simulations. Simulations – authored by various experts and vendors – can utilize this model and be launched from the model to answer questions and deliver predictions.

Process System Model

Any system can be described by its requirements, its functions, its logic and its physical form. For pharmaceutical processes these include, but are not limited to:

Requirements

- Quality target product profile (QTPP)
- Drug specifications
- Sustainability targets

Functions

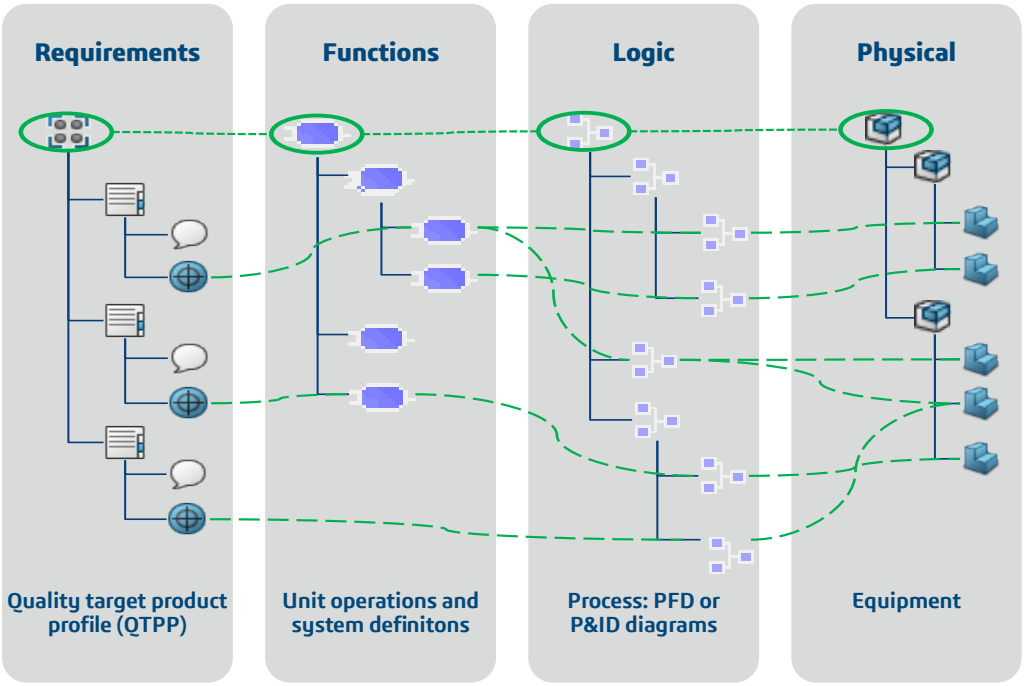
- Unit operations
- Process steps

Logic

- Recipe
- Flowsheet
- PFD
- P&IDs

Physical instantiation

- Equipment
- Tubing
- Sensors
- Valves



MAKING THE MOST OF THE VIRTUAL TWIN EXPERIENCE

The virtual twin of the process is beneficial to change the way we work. To justify the investment, the twin must enable new ways of working, which will significantly improve product and process development in terms of quality, cost and cycle times.

So, how will a virtual twin experience change the way business is done?

The virtual twin experience enables a closed-loop connection between the virtual and real worlds. Stakeholders continuously experiment, derive knowledge and optimize it by exploring all possibilities and scenarios.

Learn more: The Virtual Twin Experience

DOING THE RIGHT THINGS RIGHT IN ALL DEVELOPMENT PROJECTS

Pharmaceutical development is urgently required to reduce its historical lead times of 7 to 10 years. Clinical trial innovation is also putting pressure on process development, quality and clinical manufacturing.

New technology and changes in response to clinical trial results need to be implemented rapidly and robustly. At the same time, documentation requirements are rising and regulators are prepared to fast-track or even roll reviews. This depends on timely, accurate and high quality data and automation of analysis and authoring, which will be delivered by the virtual twin experiences.

The project team and other collaborators can analyze and retrieve information, enable transparent decision-making and easily navigate tasks. No more remembering and searching for document names; information will be linked to the engineering asset and will be searchable through an easy-to-use and secure explorer function.

COLLABORATE TO UNDERSTAND THE PROCESS, ITS RISKS AND IMPACTS OF CHANGE

ICH Q8 (R2) and Q9 recommendations delivered a risk-based approach to pharmaceutical product and manufacturing process development. Model-based systems engineers have long embraced and used risk-based methodologies, which underpin the virtual twin experience we propose.

The proposed model delivers full traceability from requirements, which include but are not limited to the QTPP and facilitates visual analysis of risks and assessments of change impact.

Rather than relying on email or other communication and the experience of individual scientists and engineers, the virtual twin experience can be used to investigate the impact of a proposed supplier change for a piece of equipment.

This change can be traced to:

- The procedure or flow diagram
- The process logic or to the availability of one or more process functions
- Which equipment the change facilitates
- The impact on the requirements

Issues can be flagged early and before any physical change has been made, and project tasks can be assigned referring to the change. The relationship between tasks and issues is retained. Internal and external experts can collaborate to resolve issues rather than ascertain the status of the object undergoing change.

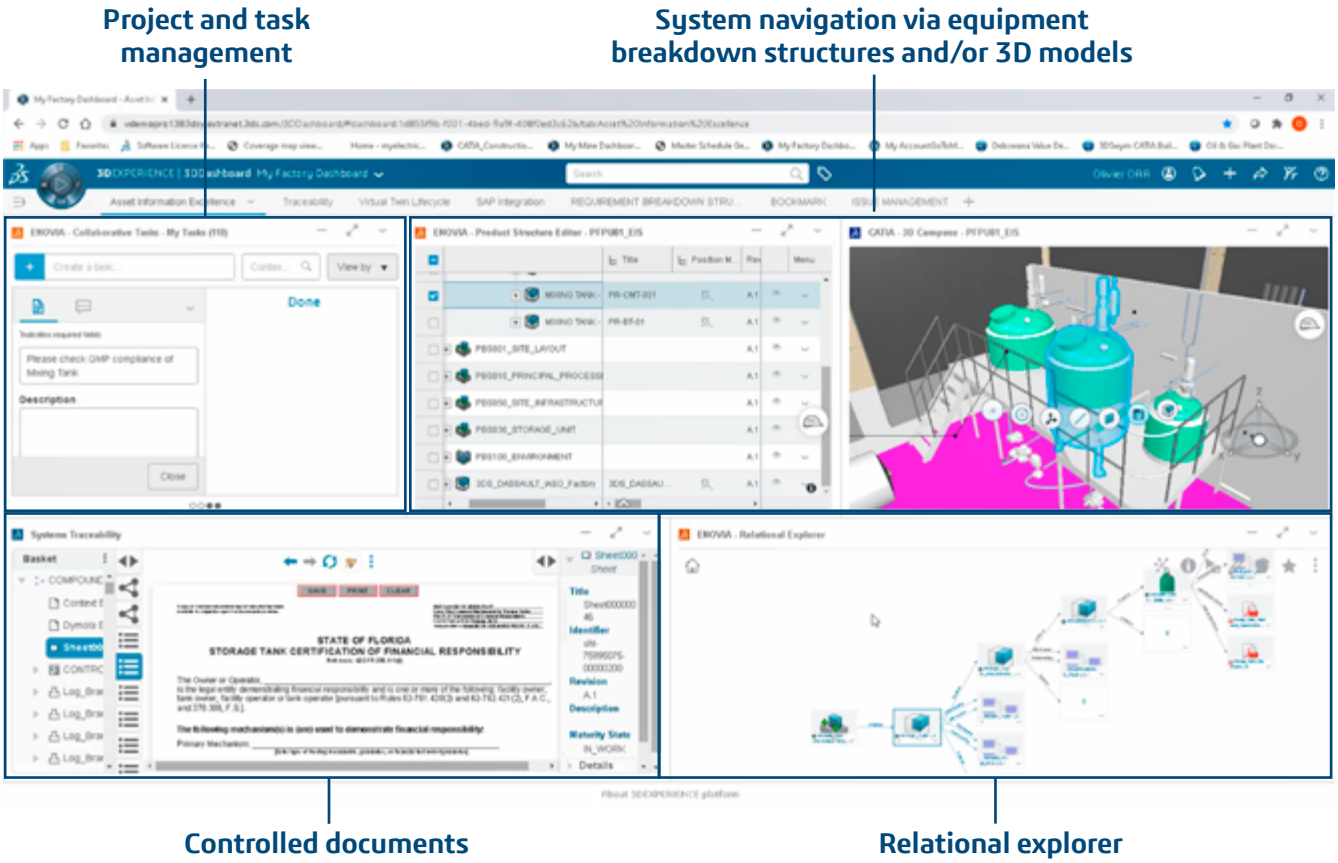
LEARNING AND IMPROVING ALONG THE PROCESS LIFECYCLE

ICH Q12 recommends the definition of established conditions in pharmaceutical development and the management of post-approval CMC changes. Ultimately the goal is to make changes more predictable.

The virtual twin experience provides a way to deliver such predictability across the entire process lifecycle, from the development of the QTPP in early development to the decommissioning of the process. Various maturity levels are available to provide the right version of the process model. The body of knowledge around the process and its twin model changes and increases in detail as it moves across these stages: 'As designed', 'as commissioned', 'as approved', and 'as serviced.'

These model versions are then available to trace the process evolution and understand the risks and impacts of change as the process moves through its lifecycle.

Knowledge will be available in the right context and decisions can be understood retrospectively. Organizations can reuse information and learn for future projects.



Typical dashboard to navigate virtual twin experiences

IMPROVE PROCESS DEVELOPMENT AGILITY AND FLEXIBILITY WITH MODULAR MANUFACTURING

Speed, agility and flexibility in process engineering and manufacturing are improved considerably by moving to a modular approach.

By defining, pre-fabricating and reusing modules, processes can be assembled rather than built from scratch. Other industries such as semiconductor manufacturing have long utilized modular approaches to "copy exactly" and thus ramp up production rapidly at a lower cost without compromising quality. Pfizer has now used such a modular approach to scale out its COVID-19 manufacturing capacity rapidly.

Managing such a plug-and-play approach will require robust models or digital assets of the physical process modules to reduce the burden of change control and revalidation. The new processes can be designed virtual-first using such modules.

When utilizing the RFLP data model, requirements, physical, process logic and functions are covered – as discussed above – to ensure the process is designed using the right modules in the right way to perform optimally against the requirements.

PREDICT PROCESS PERFORMANCE, RISKS AND BEHAVIOR

This virtual twin model can be used to simulate to predict the behavior of the process and unit operations using various simulation tools and algorithms. Simulations are used to understand and map the design space, the influence of all parameters and the risks around the process. Ultimately the virtual twin will be the entry point for all kinds of what-if questions from the process to the plant.

There is a vast amount of literature on simulation methods, which is why we stress the importance of an open virtual twin model, which allows the inclusion of all simulations tools and algorithms that have been proven to aid engineers and scientists during process development.

A good overview of available simulation methods can be found here and here. AstraZeneca has recently published a comprehensive review of applying risk-based and predictive techniques to solid dosage drug development.

Crucially our twin will facilitate the consistent and reproducible application of those diverse collections of predictive tools, which are currently — in most cases — not used systematically.

To achieve the move to virtual-first and predictive process development that facilitates right first time, the virtual twin experiences that we are proposing will standardize, automate and ultimately democratize simulations.

ACCELERATE TIME TO PRODUCTION BY VIRTUAL MEANS

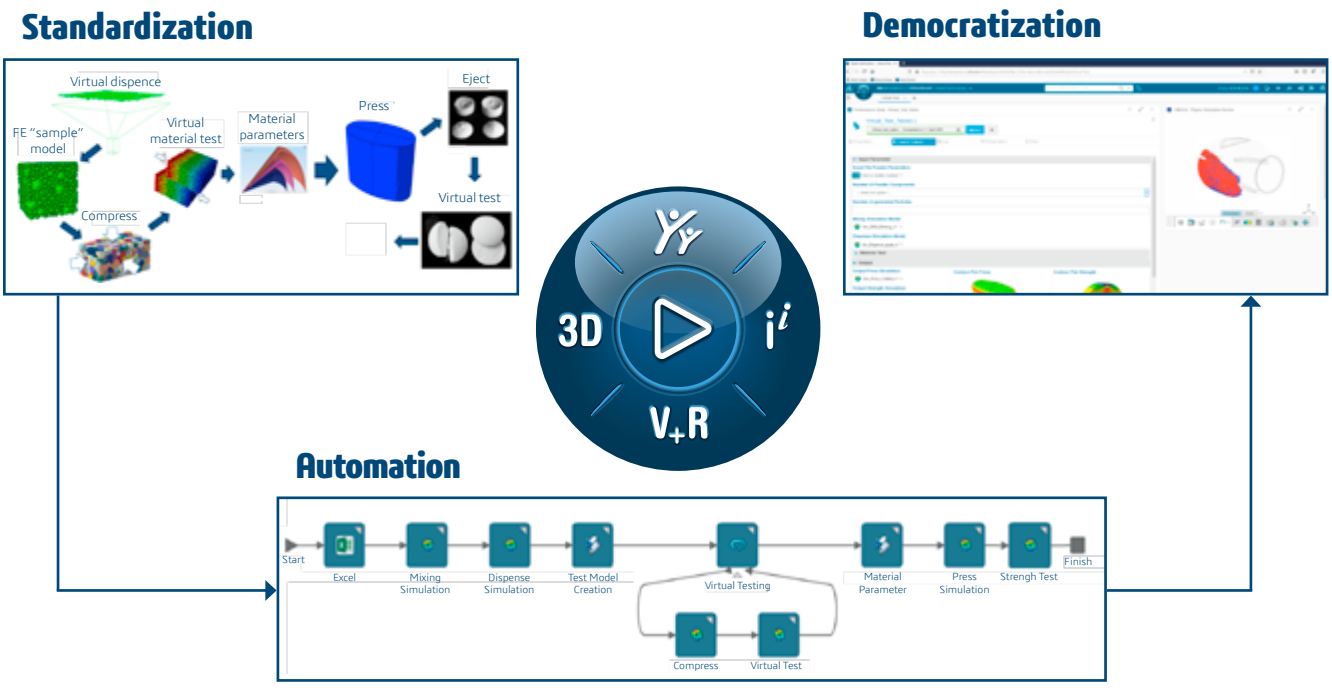
Just as in other industries, pharmaceutical manufacturing is increasingly automated. The virtual twin experiences can significantly accelerate and improve the quality during the commissioning of such automated process lines.

The twin offers the ability to model, simulate, test, validate and deploy critical control applications. A large part of the tests that are traditionally carried out on-site can now be simulated very early in the project in a virtual FAT environment.

Additionally, debugging during the commissioning and qualification phases is also considerably reduced. Eli Lilly saved three months to deliver projects whilst also increasing production quality.

The significant regulatory burden in pharmaceutical manufacturing, especially during validation is the reason that pharmaceutical manufacturers see very low capacity utilization of 30 to 35% compared to 85% in the consumer goods industry.

Virtual twin experiences will be crucial to address this problem, which is set to increase when batch sizes become smaller and therapies become personalized, making processes more complex and revalidations more frequent.



MEASURING WHAT 'BETTER' LOOKS LIKE IN THE PHARMA INDUSTRY

Improvements in process development and optimization are driven by the increasing demand for better and more versatile products and their corresponding need for flexible and smart manufacturing processes.

The COVID-19 crisis and the previously unimaginable response by the pharmaceutical industry in supplying tests and vaccines at record volumes and in record times has opened the eyes to what is possible.

Innovation and new technologies like mRNA enable cheaper and faster manufacturing. Process and equipment innovation is evolving at a rapid pace. Digitalization using virtual twin experiences will now be needed to bring such advances in manufacturing to every product that contributes to the health of patients everywhere.

We have been able to measure improvements that were enabled by virtual twin experiences, specifically during a single technology transfer project. The following data was reported:

- 25% FTE reduction (17 weeks reduction out of 70 from design, installation, qualification and validation)
- Deviation reduction (reengineering) by 80%
- Risk reduction of test batch loss from 50% to 10%
- Earlier Go Live for production (6 weeks in advance)
- Decrease CMO cost

Utilizing virtual twin experiences to develop pharmaceutical processes and manufacturing delivers substantial improvements in quality, cost and cycle times. This allows innovative therapies for unmet patient needs to be affordable and accessible globally.

Manufacturing plant optimization for pharmaceutical products with process virtual twins:

- USD $106 billion incremental OPEX savings
- 61 Mt of CO2 emission reductions

Learn more: The Critical Role of Virtual Twins in Accelerating Sustainability

Pharmaceutical manufacturing is one of the most energy-intensive processes and contributes significantly to the environmental footprint of healthcare as a whole.

Accelerating innovation in process development will benefit healthcare in terms of creating more innovative products faster. It will also help pharmaceutical customers deliver on their climate commitments, such as:

- Enabling businesses to meet their ambitions for 1.5°C
- Meeting science-based emission reduction targets

Accenture and Dassault Systèmes have recently published a study that outlines the benefits of virtual twin experiences under "Use of factory virtual twins in the pharma industry." The study was conducted to identify process improvements leading to efficiencies across businesses and sustainability drivers, such as increased existing asset capacity, lower raw materials and energy usage, improved product quality, and reduced waste and rework.

JOIN THE VIRTUAL TWIN EXPERIENCE

Virtual twin experience of the manufacturing process will add considerable value to any pharmaceutical or biotech organization by facilitating collaboration, risk analyses, change assessments, predictive simulations and support for many more activities.

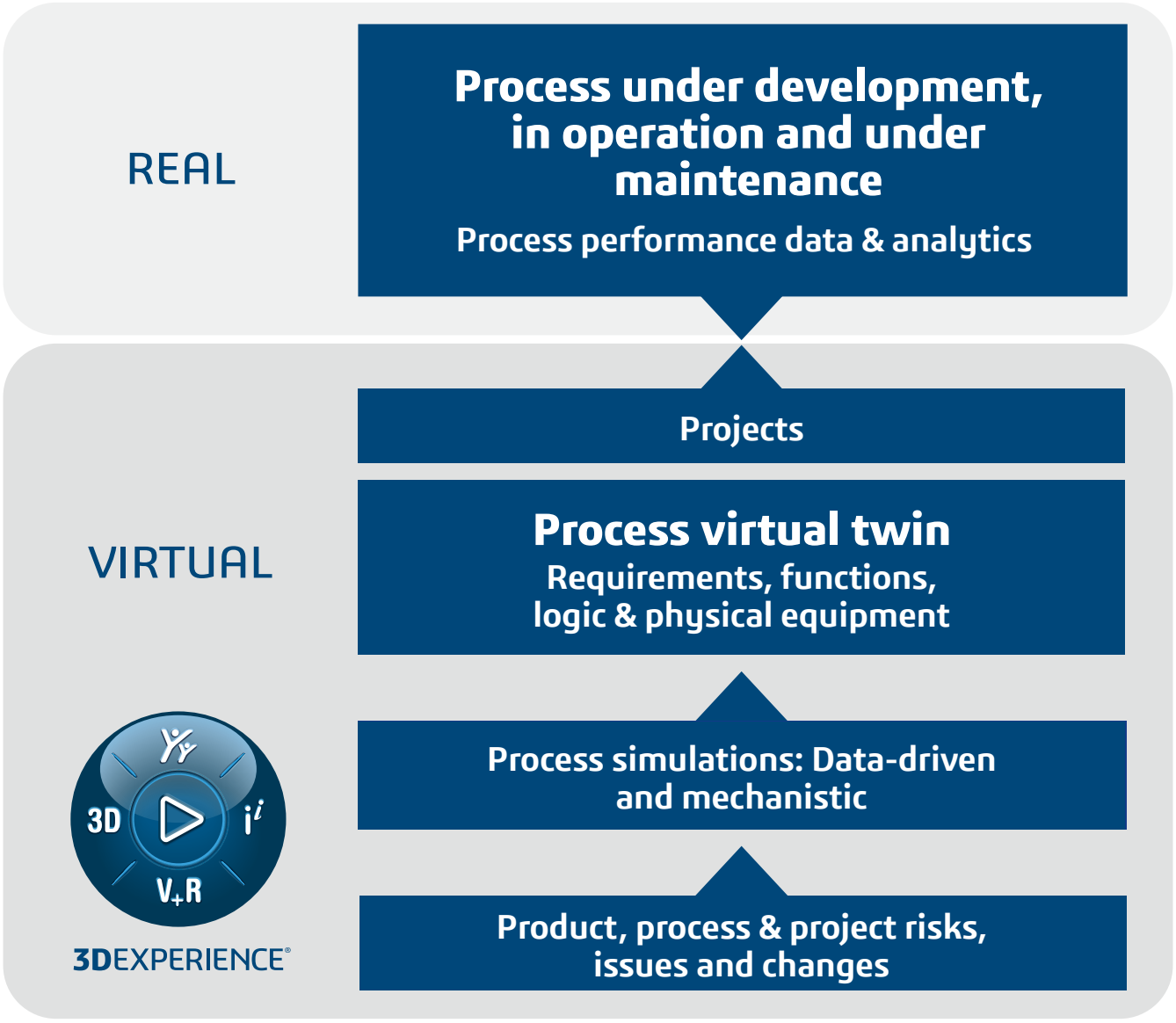
The value of the virtual twin in discrete manufacturing has been shown to include significant benefits such as:

- 34% product quality improvements
- 30% reduced manufacturing costs
- 28% reduced unplanned downtime
- 25% increased throughput

The virtual twin experience, which we are proposing, is characterized by a holistic data model that's supported with a comprehensive model lifecycle management, openness to any data sources, analysis tools and methods, and the ability to manage decisions and projects based on project deliverables.

The virtual twin will deliver the right experience for all scientists, engineers and technicians, from process research to pilot development and from tech transfer to manufacturing.

We can help you deliver very similar benefits in process development, engineering and manufacturing.



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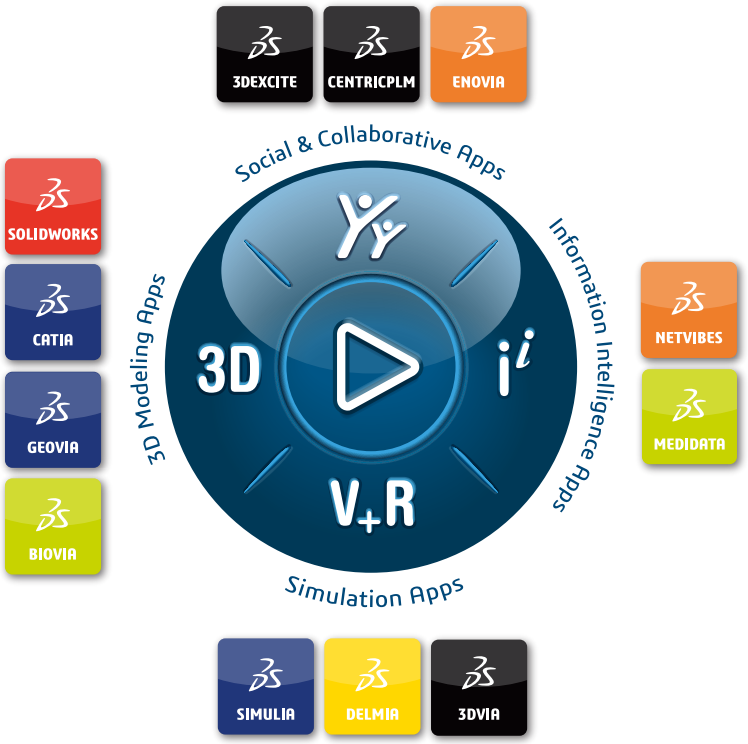

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