

**LIFE SCIENCES  
& HEALTHCARE**

# THE VIRTUAL TWIN EXPERIENCE FOR BIOPHARMACEUTICAL MANUFACTURING COMMISSIONING

Optimize commissioning and qualification processes  
with a virtual solution







## COMMISSIONING IN THE BIOPHARMACEUTICAL INDUSTRY




Commissioning and qualification (C&Q) are essential in the manufacturing of biotechnology and pharmaceutical therapies.

In the Life Sciences industry, mandatory C&Q processes ensure that the buildings and equipment involved in the manufacturing, processing, packaging, holding and storage of a therapeutic product are fit for their intended use and compliant with regulations from the relevant authorities such as Food and Drug Administration (FDA) and European Medicines Agency (EMA).

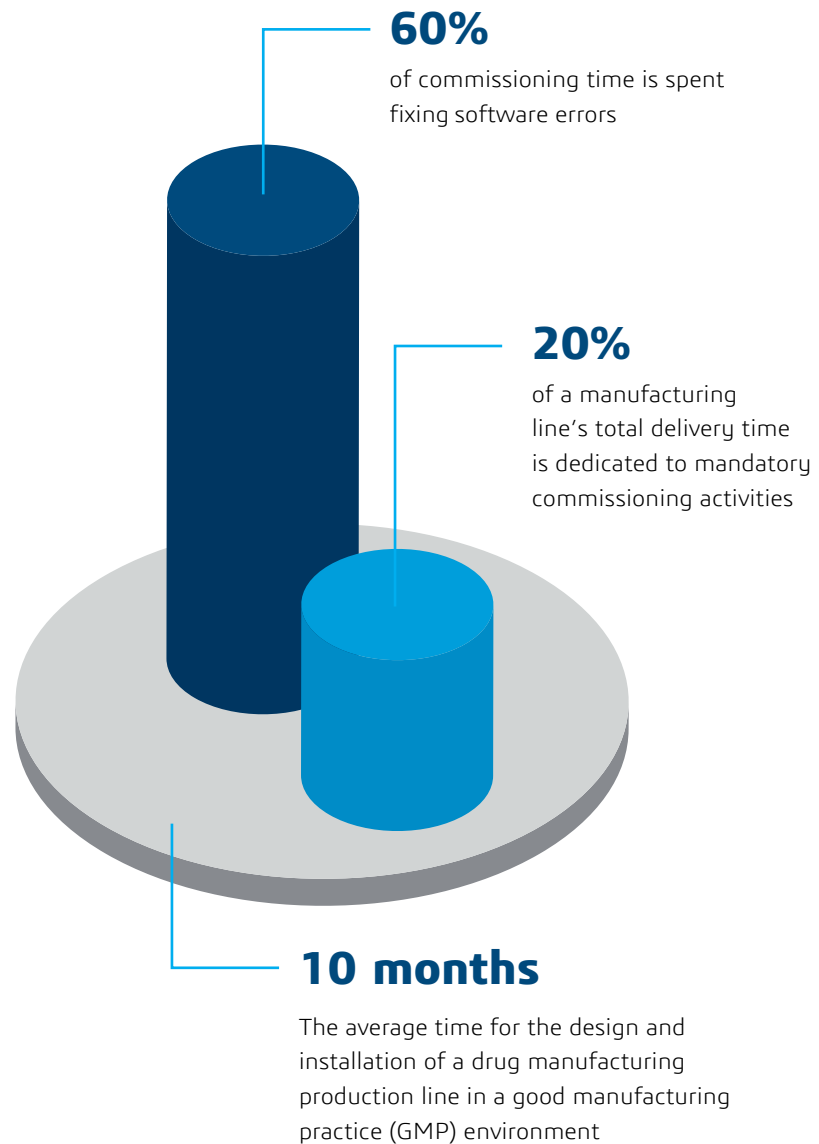
C&Q activities include:

-  Verification of operations, maintenance and training manuals
-  Design reviews
-  Factory and site acceptance tests
-  Functional testing

The C&Q process ensures:

-  Correct installation of specified equipment
-  Proper functioning of equipment as designed
-  Successful handover to the appropriately trained user

## COMMISSIONING IN NUMBERS



## KEY CHALLENGES IN COMMISSIONING

Biopharmaceutical GMP companies and contract manufacturing organizations (CMO) must strive for optimized C&Q processes. But first, they must address these challenges:

### 1. Third-party manufacturing equipment

Companies rely on industrial equipment providers that define, design and communicate control systems specifications using separate tools that limit collaboration.

### 2. Poor visibility of processes

Control software that is manually developed and implemented for specific target hardware cannot be reused for other hardware, resulting in poor transparency across processes.

### 3. Lack of powerful testing platform

Integration and qualification tests are conducted late in the development process and require manual testing on-site using the physical plant. This increases the downtime before real batch production can begin.

### 4. Rigid systems

Companies have to stop the equipment line during commissioning activities, which leads to higher expenses and production costs. Companies also face increasing pressure to deliver agile systems ready for more products, smaller batches and quicker introduction of equipment lines.



## WHAT ARE INDUSTRY LEADERS ASKING?

In an increasingly competitive environment, companies must optimize C&Q processes for more efficient operations.

Industry leaders are asking:

How can commissioning activities be done without interrupting production?

How do I improve a plant's technical and operational efficiency?

How do I effectively train plant operators?

How can the equipment lifecycle be GMP compliant?

How can my company secure a risk reduction during commissioning?

How can my company deliver a flexible line with optimized performance?

**Virtual commissioning offers the solution.**

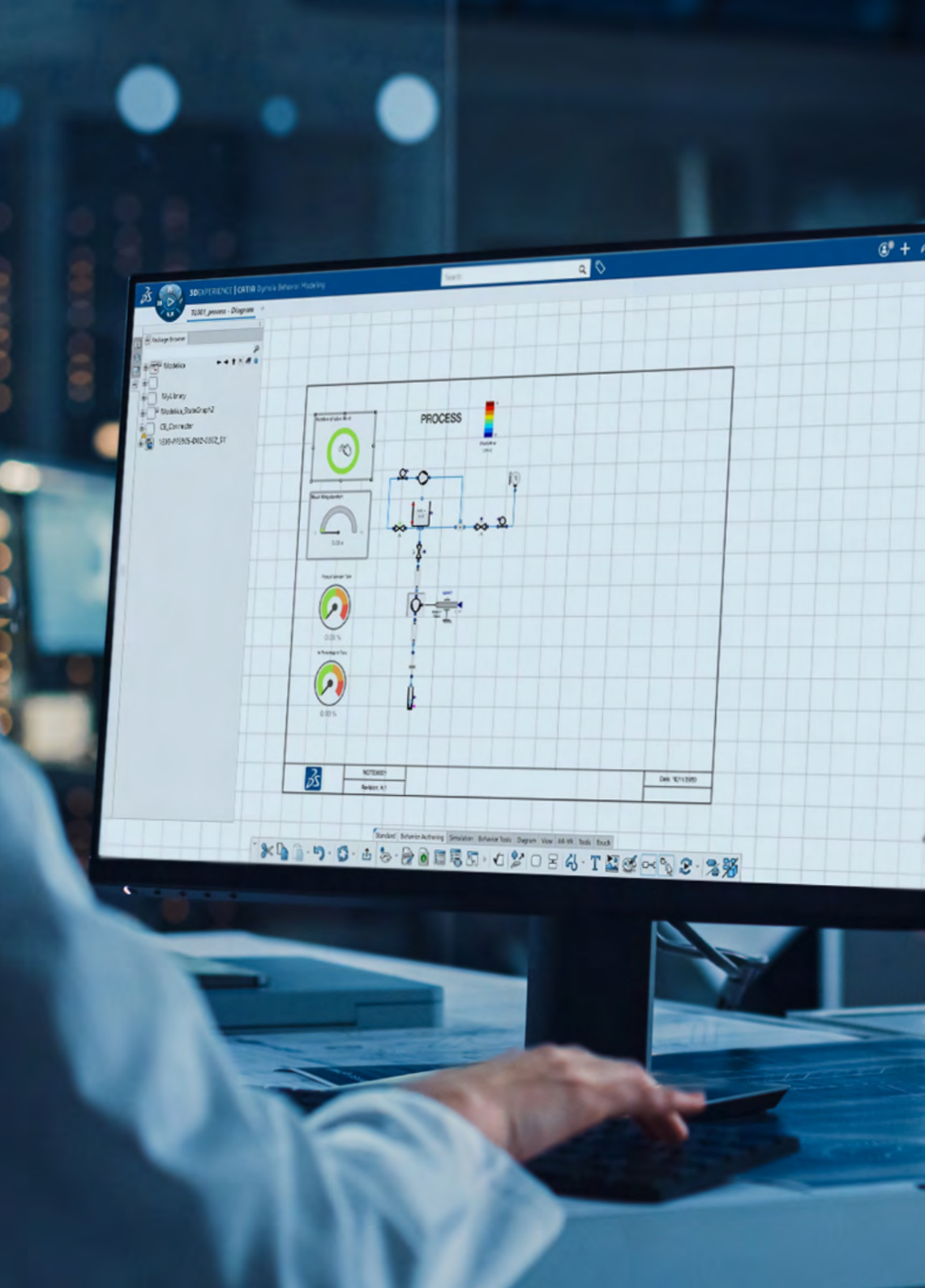
## VIRTUAL COMMISSIONING

Using the **3DEXPERIENCE®** platform and advanced virtual simulation, companies can create a virtual twin of operations for C&Q activities. The entire virtual system can be tested and validated before decisions are implemented in the physical plant. This enables an earlier production start that saves time and money.



# VIRTUAL COMMISSIONING PROCESS:





When companies leverage the **3DEXPERIENCE** platform and implement **line virtual commissioning**, they can reap these unique benefits:



Gain an **overview of the system** to virtually modify processes before real-world implementation



Create and manage dedicated **component libraries** for biopharmaceutical processes



Support high-level test processes and generate **good automated manufacturing practice (GAMP) compliance documentation** to develop simulation models



Reuse simulation models as **operator training systems (OTS)** to simulate stress situations and **quickly iterate** to find the best alternatives

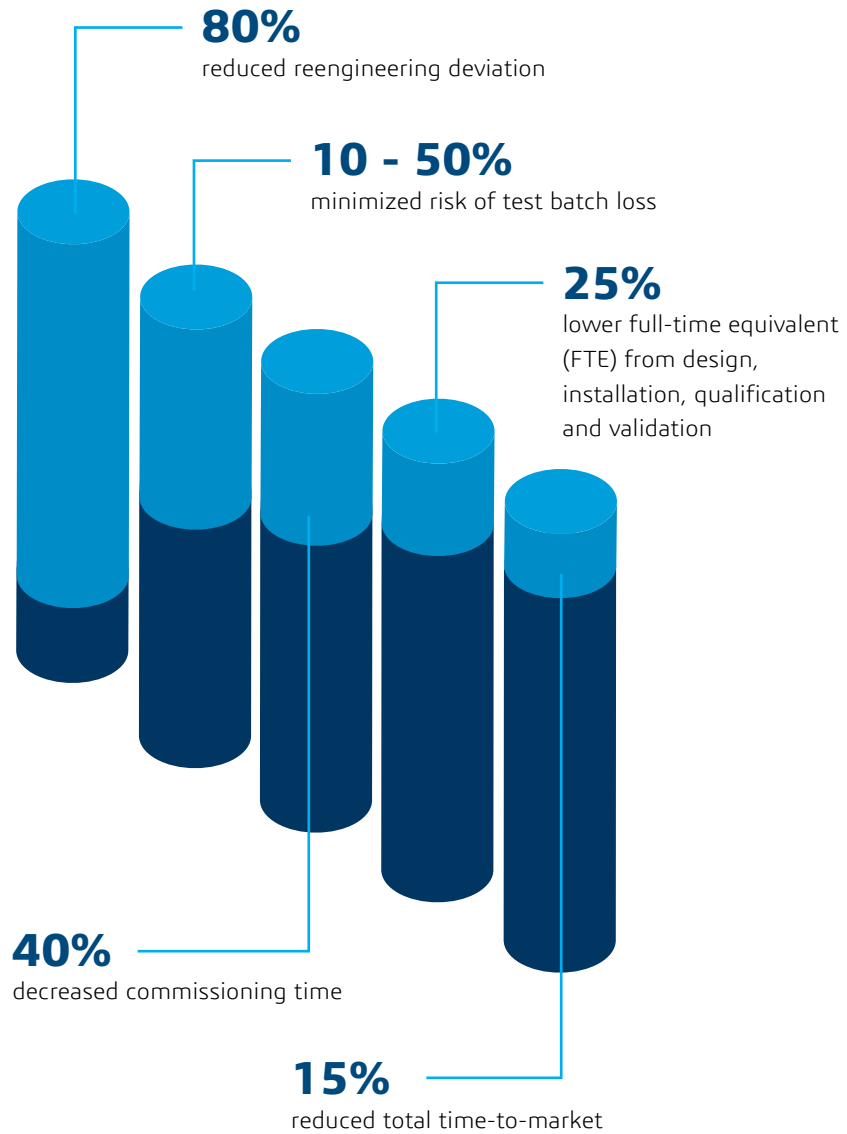


Test and validate the **control system** of production lines



Virtually simulate **plant behavior and equipment** in automatic and manual mode

## THE VALUE OF VIRTUAL COMMISSIONING







## VIRTUAL COMMISSIONING: CUSTOMER STORY

With the **3DEXPERIENCE** platform, many companies have experienced great success in optimizing the commissioning process. Here is one success story from a **leading pharmaceutical company**.

### **Challenge:**

- No appropriate tools to support factory acceptance tests, including the generation of GAMP compliant documentation
- Lack of dedicated component libraries for pharmaceutical processes
- Unable to measure and improve the quality of the development process of system integrators

### **Solution:**

Line virtual commissioning on Dassault Systèmes' **3DEXPERIENCE** platform.

### **Results:**

- For new systems, on-site test time is reduced by a factor of three
- For system modifications, on-site test time decreased from one week to one day
- Simulation models are effectively reused as OTS to simulate stress situations

## REAL-TIME PLANT SIMULATION WITH VIRTUAL COMMISSIONING

The transition to virtual commissioning may be challenging for companies. That is why Dassault Systèmes can do it for you.

Our experts can build a virtual twin of your facility and equipment line from 3D scans and 2D drawings or pictures. Results can be directly applied within your projects to secure benefits and value in a short timeframe.

When you are ready to operate our software solutions, you will have access to a ready-to-use environment with the virtual twin experience on the **3DEXPERIENCE** platform.

Dassault Systèmes' outcome-based services help you to create and profit from the virtual twin experience. Our experts also address activities related to simulation and optimization to propose 'what-if' scenarios for customer decisions and the integration of technologies such as data analytics, virtual reality or augmented reality.









## VIRTUAL COMMISSIONING IS ESSENTIAL FOR OPTIMIZED PROCESSES

The Dassault Systèmes' **3DEXPERIENCE** platform and advanced simulation technology enable companies to create a virtual twin of manufacturing operations for virtual C&Q. With virtual commissioning, C&Q activities can be completed before connecting to the real plant and delivers the benefit of an earlier production start.

Experience the following advantages:

-  Accelerated time for industrialization, scale-up and technology transfer
-  Reduced immobilization of assets and equipment
-  Minimized quality risk
-  Increased flexibility and modularity of production line for small multi-batch therapies



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[Inceptra.com](http://Inceptra.com)

### Our 3DEXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the 3DEXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our 3DEXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production.

Dassault Systèmes' 20,000 employees are bringing value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit [3ds.com](http://3ds.com).

