



THE VIRTUAL TWIN EXPERIENCE FOR LIFE SCIENCES

Connecting the real and virtual worlds of modern manufacturing to optimize operations

ACCELERATING INNOVATION FOR PATIENT-CENTRIC EXPERIENCES

KEY CHALLENGES IN LIFE SCIENCES MANUFACTURING

KEY TRENDS IN LIFE SCIENCES MANUFACTURING AND OPERATIONS

SEVEN ADVANTAGES OF THE VIRTUAL TWIN EXPERIENCE IN LIFE SCIENCES MANUFACTURING

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The Life Sciences industry is going through tremendous change, with a view to developing more affordable and equitable healthcare solutions based on novel science and technology breakthroughs. Life Sciences companies are under greater pressure to maximize revenue and stay ahead of the competition now more than ever. Taking into account that programs for innovative products are high risk/high reward, many companies continue to focus activities on developing first-in-class treatments and products. At the same time, companies looking to harness their investment in commercial products that are approaching the end of the patent life, are turning to novel formulation strategies and delivery systems that can vastly improve the patient experience and deliver value beyond patent expiration.

With the **market projected to reach over \$2 trillion by 2025**, Life Sciences will see more transformational changes towards patient-centric solutions—particularly personalized medicine, companion diagnostics, delivery and wearable devices. Pharmaceutical and Biotechnology as well as Medical Device sectors will look to address rapidly increasing product and process complexity, greater product customizations and changing regulatory landscapes. Urged on by regulators, such as the FDA, the industry is pressed to innovate; new manufacturing approaches for faster time to market and shorter time to patients, and drive more agile collaborations to manage ever-changing business demands. This extends to the transformation of operations and manufacturing to be more sustainable, an imperative that all companies must address not only to reduce their carbon footprint, but to ensure market competitiveness and relevancy as the mass of socially and environmentally responsible consumers continues to rise.

The explosion in demand for a wider variety of products catering to personalized patient and healthcare needs makes the ability of Life Sciences manufacturers to cater to shifting market demands even more crucial than ever. However, it is a major challenge for manufacturers to shift and deploy modern manufacturing systems rapidly with predictable quality and the regulatory compliance required to meet regulatory and patient demands while keeping operations within budget. Life Sciences manufacturers can overcome this gap by investing in technologies that connect systems, people and data, characterized by more predictive and adaptive facilities that leverage machine learning, 3D modeling, Industrial Internet of Things (IIoT) and—virtual twin technology: **the Virtual Twin Experience**. By leveraging such virtual solutions, manufacturers can continuously visualize and optimize their plans for new products, facilities and production processes and run optimized manufacturing operations that accelerate their time to market with total quality.

In this paper, you will learn about:



CHALLENGES AND KEY TRENDS IN LIFE SCIENCES MANUFACTURING



THE ADVANTAGES OF USING A VIRTUAL TWIN TO PLAN AND MANAGE OPERATIONS



WHAT THE VIRTUAL TWIN EXPERIENCE CAN ACHIEVE FOR LIFE SCIENCES MANUFACTURERS

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KEY CHALLENGES IN LIFE SCIENCES MANUFACTURING

Moving from being slow, risk averse and volume driven, the Life Sciences industry is entering a new era driven by a preventive and personalized approach. This, on top of the increasing need to manufacture and operate more sustainably, is accelerating the need for manufacturers to transform the way they invent, produce and deliver. Naturally, this also creates many challenges as a result:



HIGH PRODUCTION COSTS FOR NEW PRODUCTS AND FIRST-TO-MARKET PRESSURE

Competition from new players, such as technology companies with cutting-edge and efficient supply chain processes and capabilities is growing as the interest in virtual and home care as well as monitoring devices grow.¹ This pushes traditional Life Sciences companies to reimagine their operations in order to deliver at the same, or higher, rate to stay competitive.



EVER-CHANGING REGULATIONS AND NEED FOR DIGITAL EVIDENCE

As product experiences become more complex and integrated into our lives, Life Sciences manufacturers face greater regulatory and certification pressure to ensure these complex products provide safe and effective value to patients. Intensive regulatory oversight requires manufacturing to deliver traceability of all product aspects from patients to the raw materials and digital evidence of process compliance. At the same time, regulations continue to evolve as manufacturers are being urged to leverage simulation and virtual validation to further improve quality at lower cost.

¹ Arboleda, Pedro et al., Deloitte Insights. "Winning in the future of medtech: Novel partnerships with consumer tech to transform care delivery" (19 September 2019)

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RISING DEVELOPMENT COSTS AND TIME

The costs to create new drugs and devices is increasing, with the cost of developing a new prescription medicine that gains marketing approval amounting to around \$2.6 billion. Likewise, opportunity costs, or the expected returns that investors forego while drugs are in development, is also rising,² which pushes Life Sciences manufacturers to speed up production while improving success rates of launches.



MANAGEMENT OF PARTNERSHIPS

Manufacturers face greater expectations to create products through economically sound and socially responsible processes that strive to eliminate environmental impact.



PRICING PRESSURE

With price pressure from generics and shrinking margins, Life Sciences manufacturers are on a continuous quest to cut costs in all aspects of the business. More companies will shift towards value-added products and services across the board to protect against erosion and price wars, with the perception of pricing as a key decision driver for R&D support.³

² Sullivan, Thomas. Policy & Medicine. "A Tough Road: Cost To Develop One New Drug Is \$2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%" (21 March 2019)

³ Deloitte Switzerland. "Pricing in Life Sciences: Positioning value at the centre" (June 2015)



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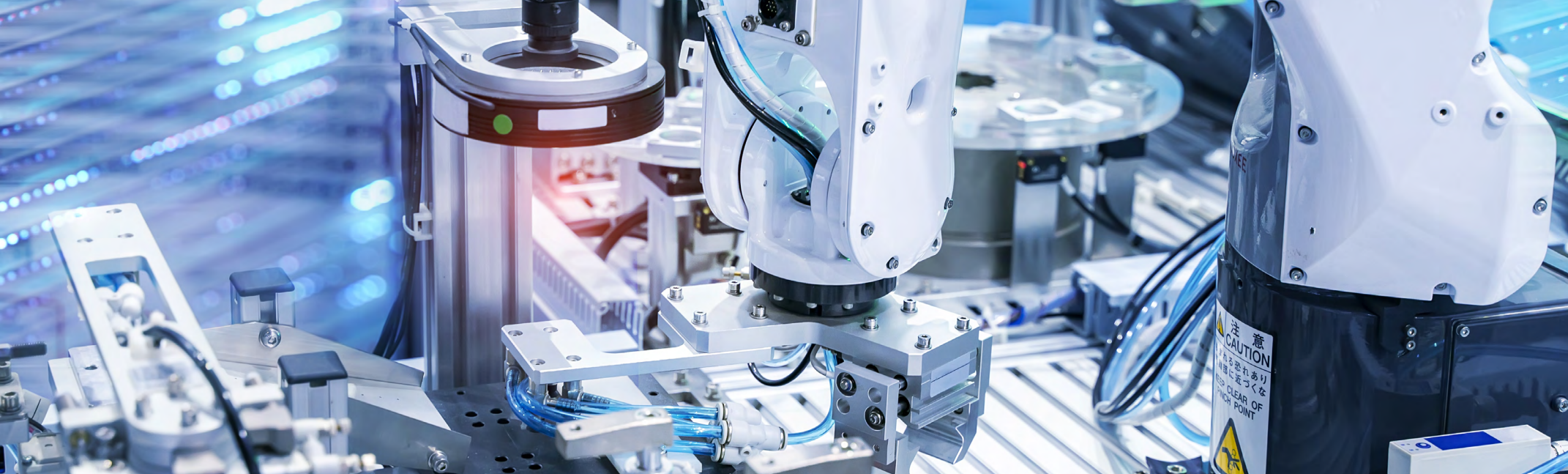
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The “next normal” for Life Sciences manufacturers due to technological disruptions has also amplified challenges that increase the urgency for companies to change and thus improve their business viability:



Prioritize re-skilling and safety

to reduce dependency on key skills



Automate more

to help employees multitask and cover skill gaps



Improve supply chain resiliency

to give companies the flexibility to optimize even during economically difficult situations



Maintain business continuity

to ensure that all operations are efficient



Increase flexibility and agility of manufacturing

to help companies adapt to new and unforeseen market dynamics

Discover the future of sustainable manufacturing and how you can make it happen by:

- Improving process performance and quality by connecting the virtual and real worlds to compare different scenarios
- Reducing energy use through digital operations optimization
- Making informed and data-driven decisions with real-time visibility of business and sustainability KPIs
- Reducing waste in resources and increasing productivity with lean manufacturing

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 PERSONALIZATION	 PRODUCT INNOVATION	 SUSTAINABILITY
<ul style="list-style-type: none"> • Today’s products are increasingly driven by the desire for personalized experiences and convenience. For Life Sciences, this means more complex product portfolios, including new medicines, new devices and apps and combinations thereof—all tailored to specific health needs. • With this complexity, manufacturers are developing a holistic approach to healthcare that encompasses genomics, diagnostics as well as behavior and the environment to provide precision medicine. 	<ul style="list-style-type: none"> • The current rate of patent expirations accelerates new product introductions and pushes Life Sciences manufacturers to adopt smarter technologies and leverage data and analytics to build future-proof innovation strategies. • More Life Sciences companies will seek to collaborate more across the value chain, with Biotech companies in particular expected to join forces with other health-related sciences organizations to push the boundaries for development.⁴ 	<ul style="list-style-type: none"> • Life Sciences manufacturing is one of the greatest contributors to CO2 emissions worldwide. Pharmaceutical companies in particular are looking at ways to make their operations much more sustainable, by optimizing energy use in processes and plants. • All manufacturers have a corporate and social responsibility to be sustainable, both in operations and product design. • Companies are moving towards a circular economy—recycling waste to reduce environmental impact, which will result in more sustainable innovation and profit. • More Life Sciences manufacturers will leverage virtual validation and simulation technology not just for product development but to evaluate everything from a value chain perspective, including manufacturing, sourcing and delivery.

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⁴ Linchpin SEO. "Trends Transforming the Life Sciences Industry Outlook in 2022" (10 October 2021)



SEVEN ADVANTAGES OF THE VIRTUAL TWIN EXPERIENCE IN LIFE SCIENCES MANUFACTURING



UNLIMITED SIMULATION

Life Sciences manufacturers are able to reduce time and cost of their development and manufacturing activities by deploying Virtual Twin Experiences that facilitate simulations to optimize processes and facility layouts. Optimal processes and operations can be found through virtual means rather than time consuming and costly real-world experimentation.



CONTINUOUS IMPROVEMENT

The Virtual Twin Experience enables a closed-loop connection between the virtual and real worlds, allowing simulated plans to be immediately and confidently executed. At the same time, real-time updates are captured from manufacturing to inform the Virtual Twin Experience, allowing it to continuously refine and optimize processes for a longer-term strategy.



IMPROVED WORKPLACE SAFETY

Workplace safety is important, but some unsafe working conditions may not be immediately apparent until an incident takes place. With real-world data input, the Virtual Twin Experience can simulate worker operations and facilities to address safety concerns, such as handling dangerous substances and navigating hazardous environments. Mobile and augmented reality capabilities in combination with collaborative tools significantly improve working conditions for operators and technicians.

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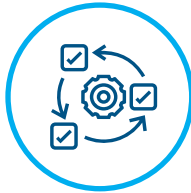
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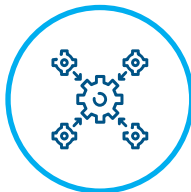
ADDED AGILITY

Life Sciences manufacturers struggle to reduce costs as well as adapt to shorter production runs for more personalized solutions, increasing the need to improve Overall Equipment Effectiveness (OEE) swiftly and sustainably. The Virtual Twin Experience helps Life Sciences manufacturers be more flexible by simulating changeovers ahead of time and identifying the quickest and most cost-efficient way to do so, minimizing downtime whilst improving quality and sustainability indices.



GLOBAL COLLABORATION

There are often digital “divides” between engineering and manufacturing departments that result in lost time and reduced quality. The cloud-based Virtual Twin Experience enables stakeholders to share detailed information and animated 3D models that boost collaboration and input from all departments for optimal operations. Simulations utilizing the Virtual Twin Experience can extend across the value network to include external factors and how those affect the production process, thus improving predictive accuracy.



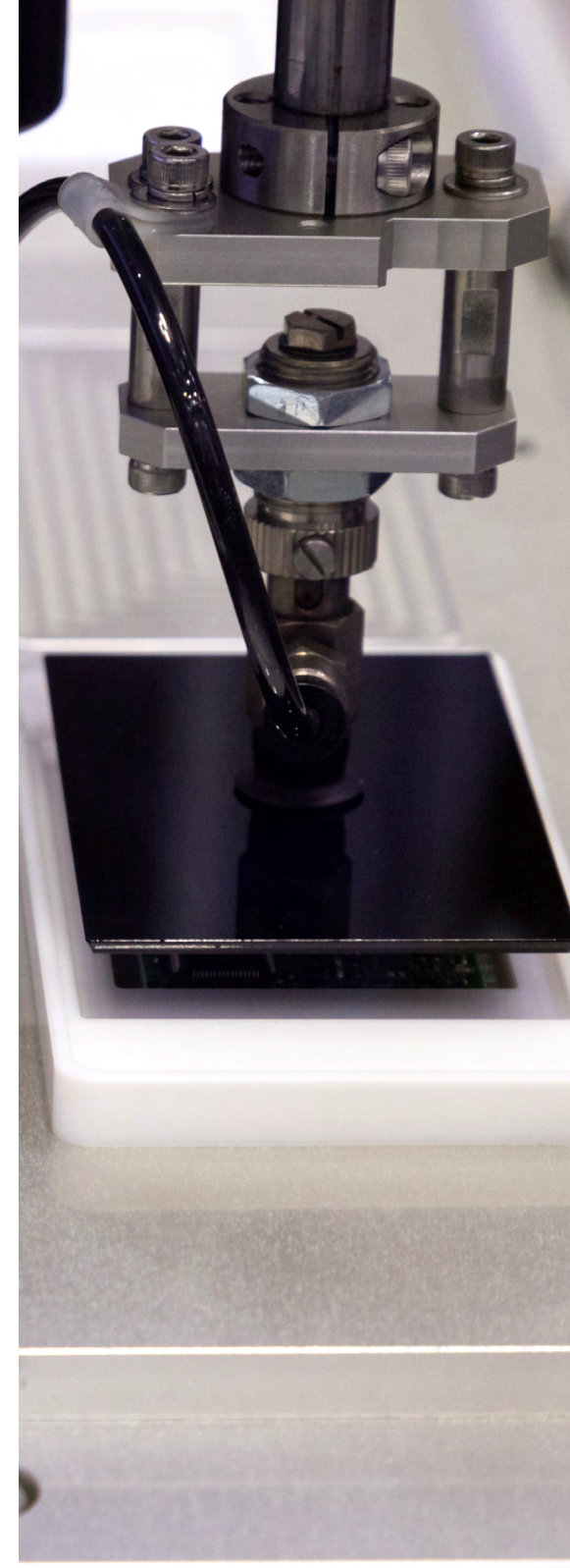
IIoT INTEGRATION

Much of Life Sciences production equipment is sensor-driven and generates large quantities of real-time data—which is used for quality control and production monitoring. The level of integration (between resources/equipment and manufacturing systems) that is now possible with the Virtual Twin Experience makes modern factory operations fully transparent to engineers and managers, allowing greater optimization.



KNOWLEDGE RETENTION

Losing key personnel with extensive knowledge of a manufacturer’s processes or the need to translate code from obsolete legacy equipment for newer systems have traditionally hindered older manufacturing operations from migrating to lower cost, higher quality processes. These problems no longer trouble manufacturers who rely on the cloud-based Virtual Twin Experience, which integrates all information on the cloud and ensures data continuity and complete knowledge retention through the lifecycle of the manufacturing asset.



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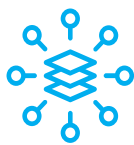
The **3DEXPERIENCE** platform is the foundation for model-based data-driven design, planning and execution. This cloud-based platform provides what we call the **Virtual Twin Experience**.

In the Virtual Twin Experience, the **virtual** world enables users to see what they want to accomplish through modeling, simulation and visualization, which can then be implemented and executed in the **real world**. At the same time, experience and data collected in the real world is used to update the virtual twin model and maintain it as a perfect twin that can be used to improve all aspects of real-world operations.

This **convergence of the virtual and real worlds** and the continuous cycle of information between the two achieves a closed-loop capability that enables optimization of virtually any scenario.



Achieve Sustainable Innovation and Excellence



Support Creation of Value Network



Empower the Workforce of the Future



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What the Virtual Twin Experience enables for Life Sciences manufacturers:	How this is achieved:	Where the solution applies:
<ul style="list-style-type: none"> Assess new products and evaluate potential changes in production as well as optimize processes Assess manufacturing strategies and capacity to mitigate shortcomings and to make informed decisions Synchronize planning and execution to drive continuous improvement Ensure compliance with regulatory and validation requirements when introducing new business models or product lines 	<ul style="list-style-type: none"> By creating a virtual model to design, optimize, control, operate and improve real-world systems By ensuring layout efficiency for operator safety Through simulation as a lever for continuous improvement By using facility flow simulation to increase flexibility and productivity By optimizing layouts, work centers and process plans 	<ul style="list-style-type: none"> Value networks, which include suppliers, contract manufacturers, original equipment manufacturers (OEMs), line builders and service providers, EPC (Engineering, Procurement and Construction) partners, robotic vendors and system integrators Facilities, warehouses and construction projects



INNOVATION TIME HORIZONS

The **3DEXPERIENCE** platform features solutions that help Life Sciences manufacturers at every stage of a product’s lifecycle, from the initial planning phase all the way down to manufacturing execution and delivery. The platform keeps manufacturers informed in their strategic decision-making—which involves planning in the virtual world—as well in their tactical decision-making when it comes to execution in the real world.

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FACILITY PLANNING

How to optimize physical space and assembly lines to manufacture new products?



Capabilities of the Virtual Twin Experience

- Create 3D virtual models (BIM & CAD) from any available 2D documentation or drawing
- Conduct mobile or fixed-point scans of facilities to convert into a 3D point cloud
- Position and manipulate resource positions in 3D
- Validate and define facility floor with resources
- Connect recipe and quality control to manufacturing equipment and facility



Goals & benefits

- Validate use of equipment, workstations and tools in context
- Minimize potential for design-induced risks to health, personal or environmental performance
- Avoid costly layout redesigns by enabling users to collaborate and share 3D layouts
- Efficient collaboration with suppliers and other partners in the value chain

PROCESS PLANNING

How to optimize production process to maximize efficiency, cost, quality & safety?

As production planning shifts from engineering design to manufacturing execution, manufacturing companies face a challenge in translating designs into real-world plans as both sides traditionally use different sets of tools that do not connect with each other. The lack of information flow and collaboration across the digital divide has real consequences for production:



The solution lies in asking if we can manufacture what we have designed or developed—to do it efficiently and in a way that eliminates costly and time-consuming manual prototypes and technical batches. The first step in achieving this is by using the development recipe or engineering bill of materials (EBOM) to build up a general recipe or manufacturing bill of materials (MBOM) through the **3DEXPERIENCE** platform.



Engineering bill of materials (EBOM) to build up a manufacturing bill of materials (MBOM)

Once this is done, the next steps involve looking at the ‘how’ and ‘where’ to manufacture the product. The **3DEXPERIENCE** platform enables Life Sciences manufacturers to **virtually simulate their process** in order to identify potential issues ahead of execution, which avoids many of the risks associated with real-world testing and also reduces product launch times.

They can then create a complete **virtual build** that incorporates the recipes, the MBOM and process plan and identifies the resources needed, how to improve resource utilization and potential quality issues in order to reduce work and scrap. Doing this virtually helps Life Sciences manufacturers save time and money that is otherwise spent on technical batches and manual prototypes—shortening the time needed to bring products to market while improving quality and validating the process steps across the time horizon.

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Planning for worker safety on the facility floor has always been a focus for Life Sciences companies. The Virtual Twin Experience can now be deployed to create safe and ergonomic work conditions, e.g., by simulating social distancing in facilities, calculating the new productivity rate and optimizing within any applicable constraints.

Now that the Virtual Twin Experience has both the model and process set up, Life Sciences manufacturers have a clearer picture of how their product will be manufactured in their facility. The simulation can then be used as a lever for continuous improvement in manufacturing flexibility and agility.

Capabilities:

- **Design factory layouts and analyze multiple production scenarios**
- **Optimize process performance with alternate product routings**
- **Natively integrate robot, NC machine programs and human tasks into model**

Goals & benefits:

- **Workforce safety**
- **Agile manufacturing**
- **Optimized production performance**



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MANUFACTURING PLANNING

How to optimize production while managing constraints?

This stage of the time horizon is where manufacturers apply data on demand and supply to the model to simulate how the system performs and how operations can be optimized while managing constraints in manufacturing, assembly and distribution.

The time horizon for this stage may still be quite varied. At the highest level, Sales & Operations Planning (S&OP) might be performed monthly or quarterly and look up to several quarters out. This allows organizations to help analyze global supply chain constraints and possible “what-if” plans to deal with fluctuating supply and demand scenarios or any other issues which impact product supply.

The time horizon could also be more tactical—for example, generating a more detailed Master Production Schedule that considers more granular constraints of resources, materials and bottlenecks in production. Life Sciences companies are particularly constrained by regulations, which vary depending on the location of sites and suppliers. Such constraints, of which CGMPs are the most important, can be included in all planning.

There are numerous opportunities in this area and the various optimization engines that leverage machine learning and artificial intelligence are significant drivers of agility and planning in the face of both certain and uncertain future elements. For example, infusing virtualization and simulation into manufacturing planning and operations helps ensure therapies are produced “as-designed” and “as-registered” in the most high-quality and cost-effective manner. But with so many possible scenarios to consider, it is sometimes difficult to develop any single feasible plan, let alone an optimal plan.

When developing strategic plans, it is important to represent the business KPIs that are critical to success in multiple scenarios so that Life Sciences manufacturers will have a sustainable plan in place yet are able to respond quickly to sudden changes in factors, both internal and external.

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MANUFACTURING EXECUTION

How to execute flawlessly and deliver products on time with superior quality?

Manufacturing operations management (MOM) has a broader scope than manufacturing execution systems (MES) as it involves automating, executing and managing the performance of all business processes relevant to manufacturing execution, which includes manufacturing production, quality, warehousing, the workforce and maintenance. The ability to manage all of this on a single platform provides many advantages:

- ✔ **Visibility for production operations to promptly carry out unplanned maintenance**
- ✔ **Quality events can trigger maintenance alerts and move work in progress**
- ✔ **Can immediately identify a need to requisition materials or replace components**
- ✔ **Visibility that allows management to respond faster to unplanned events**
- ✔ **Eliminates silos and rogue applications**
- ✔ **Reduces risks and increases operational flexibility**



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LIFE SCIENCES
MANUFACTURING

A LEADING EDGE IN
LIFE SCIENCES WITH
THE VIRTUAL TWIN
EXPERIENCE



MANAGE AND CONNECT ALL ELEMENTS OF MANUFACTURING OPERATIONS

Machine integration enables the MOM solution to connect to all machines and devices in the physical world through IIoT. Open standards for connectivity—both directly and through partner hardware and software—empowers the MOM solution to work across all operations. This drives better compliance with regulatory requirements, enforces best practices and enables lean operations.

Creating that IIoT connection between the physical world and MOM solutions can be challenging for companies, but it makes up a key part of the Virtual Twin Experience philosophy. The connectivity enables closed-loop synchronization of the virtual and real worlds, which drives productivity, provides complete real-time visibility, enables predictive maintenance and improves product quality.

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Manufacturers typically find it a challenge to realize this connectivity as the array of software and technology they rely on often use different communication standards that do not translate well between systems. There is no single medium that is universally accepted as the industry standard. Incompatibility between legacy machines and newer systems makes this even more difficult.

DELMIA adopts an open and agnostic approach to these challenges. With no stake in the hardware game, our approach is to adopt widespread industry standards and utilize a one-size-fits-all solution that can work with all forms of hardware; working with partners to ensure that all systems are able to connect with the **3DEXPERIENCE** platform.

With the arrival of 5G, new connectivity standards have created powerful new possibilities for manufacturers through the Virtual Twin Experience. Low latency enables instant response for time critical applications while the drastically improved data rate enables everything from augmented reality to virtual reality and 4K streaming at 10 times the speed. This increased capacity for connections will enable bigger and more complex operations, making 5G the true enabler of the smart factory.



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CUSTOMER STORY: LEVERAGING THE VIRTUAL TWIN EXPERIENCE TO OPTIMIZE OPERATIONS

Here is a real-life example of a Life Sciences company that has turned to the **3DEXPERIENCE** platform in search of a way to optimize their operations and change over to new production processes:

THE CHALLENGE	STRATEGY	RESULTS
<ul style="list-style-type: none"> The manufacturer needed to evaluate if a new line could be put in that would change over production from batch to continuous process. It required improved production flexibility, reduced changeover times and process changes that could improve flexibility with new equipment for new products. The manufacturer also needed to empower its workforce with new equipment and methods as well as enhance employee safety and ensure regulatory compliance. 	<p>The manufacturer leveraged the DELMIA and the 3DEXPERIENCE platform to:</p> <ul style="list-style-type: none"> Automate a 3D model design developed from a combination of factory scanning, 2D and 3D design sources. Validate steps required for installation and commissioning of new equipment. Evaluate operational improvements gained in the changeover from new processes and equipment within plant constraints through virtual “what if” scenario analysis. Evaluate worker productivity and safety through various “what if” scenarios and workflows. 	<ul style="list-style-type: none"> Commissioned new line, Right First Time. Reduced risks to budget and capital project schedule. Ability to make informed decisions faster. Trained operations team using virtual model and shortened learning curve for existing and new employees. Change Over Time optimization, increased operational flexibility and agility.

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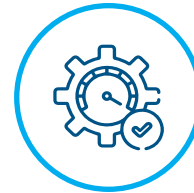
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Transitioning to a Virtual Twin Experience represents a profound shift in manufacturing decision-making. Dassault Systèmes Strategic Business Development Director, **Adrian Wood** breaks down the Virtual Twin Experience into four distinct parts:



COLLABORATION

is where organization stakeholders determine the needs, wants and goals of the project. Design engineering, manufacturing engineering, quality assurance, sales, procurement and management all contribute to the creation of a unified system in manufacturing operations for any industry.



OPTIMIZATION

is the payoff from the Virtual Twin Experience, where changes are tested virtually to eliminate bottlenecks and improve efficiency. This is where planning changes become true “what if” experimentation—on everything from equipment cycles to worker time and motion study.



MODELING

is the starting point for digitalization, creating an accurate representation of machines, processes and workflows. Accuracy must be maintained throughout the project; ad hoc or emergency changes to equipment or processes must be reflected in the models, which helps managers test solutions before implementation.



PERFORMANCE

is the goal; the actual implementation of new processes and procedures tested in the virtual factory. With a successful Virtual Twin Experience, production changes are swift and trouble-free, and downtime is minimized. Equipment with sensors then feed real-time data back to the twin to confirm outcomes and establish a new baseline for the next series of experiments and improvements.

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Shortened production cycles enable Life Sciences manufacturers to keep up with accelerating market demands for products made with the latest innovations. Manufacturers can also plan within changing regulatory constraints and create optimal facility layouts that allow them to keep up with the proliferation of product variants while working with limited assembly lines and resources.

Flawless execution allows Life Sciences manufacturers to get it right the first time in manufacturing new products without wasting precious time and money on multiple test batches and physical prototypes, which also reduces waste and enables sustainable manufacturing. Further optimization can make operations and supply chains resilient to disruption from resource scarcity.

Manufacturers, whether in Biotech, Pharmaceuticals or Medical Devices, have an opportunity to optimize manufacturing output and overall operations, drive down costs and maximize returns as well as bring products faster to market by leveraging the endless possibilities of the Virtual Twin Experience, powered by the **3DEXPERIENCE** platform. Through enhancing processes and the cohesion between design, engineering and manufacturing, Life Sciences manufacturers can achieve the agility and synchronization necessary to make their business more competitive, agile and sustainable.

>> [Learn more about our solutions for manufacturing here](#) <<

>> [Continue the conversation at DELMIA Communities](#) <<



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North America Headquarters

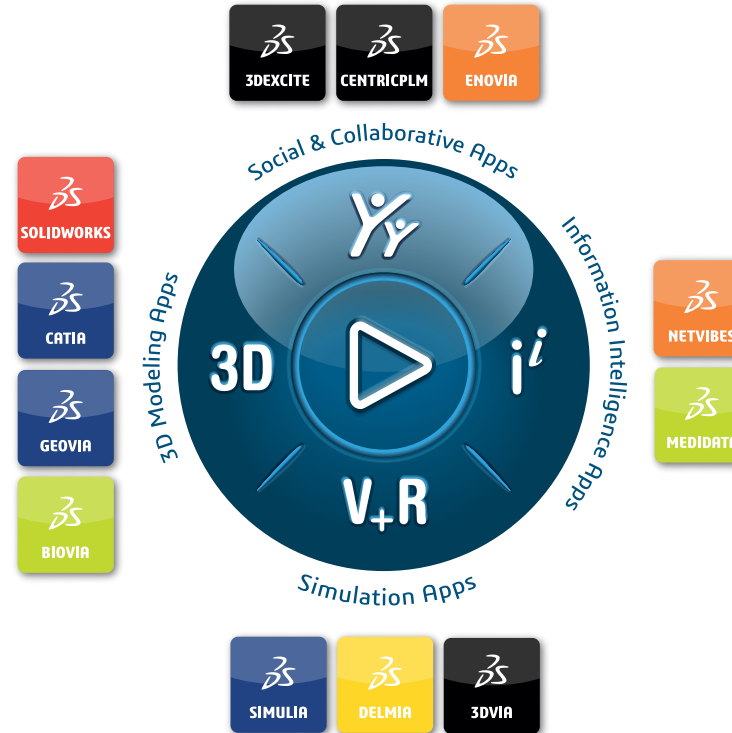
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Our 3DEXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

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.



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