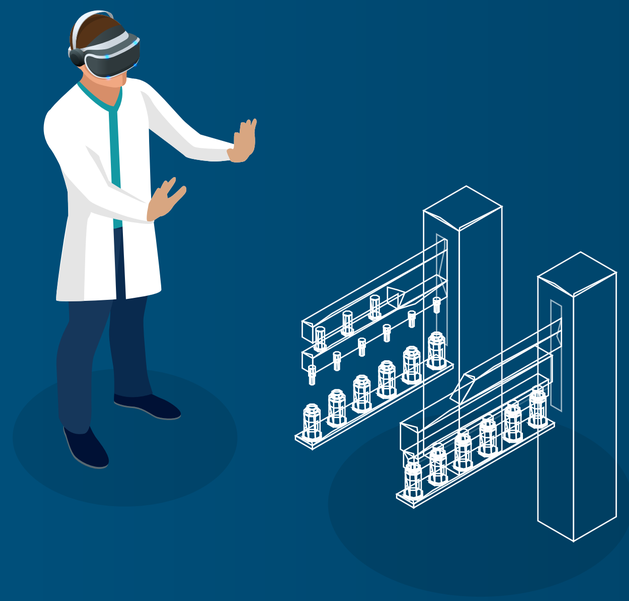

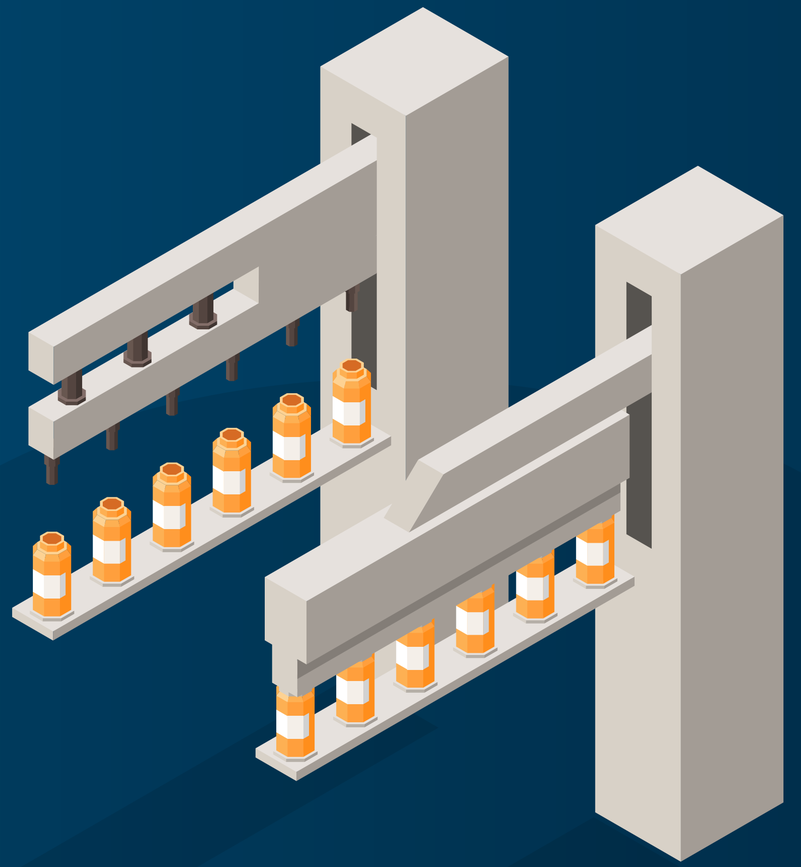

ARE YOU READY **FOR THE FUTURE OF MANUFACTURING?**

LIFE SCIENCES INDUSTRY

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UNDERSTAND THE FUTURE OF MANUFACTURING IN THE LIFE SCIENCES INDUSTRY
How digitalization transforms manufacturing

Today's Life Sciences Manufacturing Challenges
Managing Manufacturing Complexity in the Life Sciences Industry
The Future of Manufacturing
3 Success Pillars
3DEXPERIENCE: The platform approach to manufacturing

PART 2
EXPERIENCE THE FUTURE OF MANUFACTURING IN THE LIFE SCIENCES INDUSTRY
How the **3D**EXPERIENCE platform can disrupt Development and Manufacturing

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Experience 4 | IIoT and Manufacturing Analytics
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Are you ready for the Future of Manufacturing?

INTRODUCTION

The **Life Sciences industry** has changed significantly over the past 10 years. With a view to developing new, more effective treatments, industry leaders are exploring new therapeutic areas and approaches like biologics and precision medicine.

To address this shift, Pharmaceutical and Medical Device Manufacturers look to connect systems, people and data—characterized by more predictive and adaptive facilities that leverage machine learning, 3D Modeling, Industrial Internet of Things (IIoT), Digital Twin, Remove Control and Augmented Reality.

Indeed, the industry is poised to deliver breakthrough innovations and patient experiences at a rate and cost never thought possible.

IN THIS EBOOK, DASSAULT SYSTÈMES INVITES YOU TO:

#1 Understand the main challenges of the Future of Manufacturing in the Life Sciences industry.

#2 Discover 5 Manufacturing Experiences that disrupt the Life Sciences industry.

PART 1
UNDERSTAND THE FUTURE OF MANUFACTURING IN THE LIFE SCIENCES INDUSTRY

TODAY'S LIFE SCIENCES MANUFACTURING CHALLENGES

The Life Sciences industry is on the verge of a new era characterized by a preventive and personalized approach, rather than being prescriptive and volume-driven. Indeed, many manufacturers are realizing that they must reinvent themselves.

COMPANIES FACE A MYRIAD OF MANUFACTURING CHALLENGES...

PROBLEM	CAUSE(S)
High production cost for products	Low yield and efficiency, waste, time to test, batch switches, etc.
Drug shortages	65% from manufacturing and quality problems
Lack of improvements based on new technologies	Fear of changing validated manufacturing processes
Slowed development and access for investigational drugs	Inefficient transfer of new drugs into manufacturing and uncertain scale-up
Need for intensive regulatory oversight	Poor root cause analysis of manufacturing failures

Source: Modernizing Biopharmaceutical Manufacturing to Improve Drug Quality, FDA Voice Feb 1, 2016

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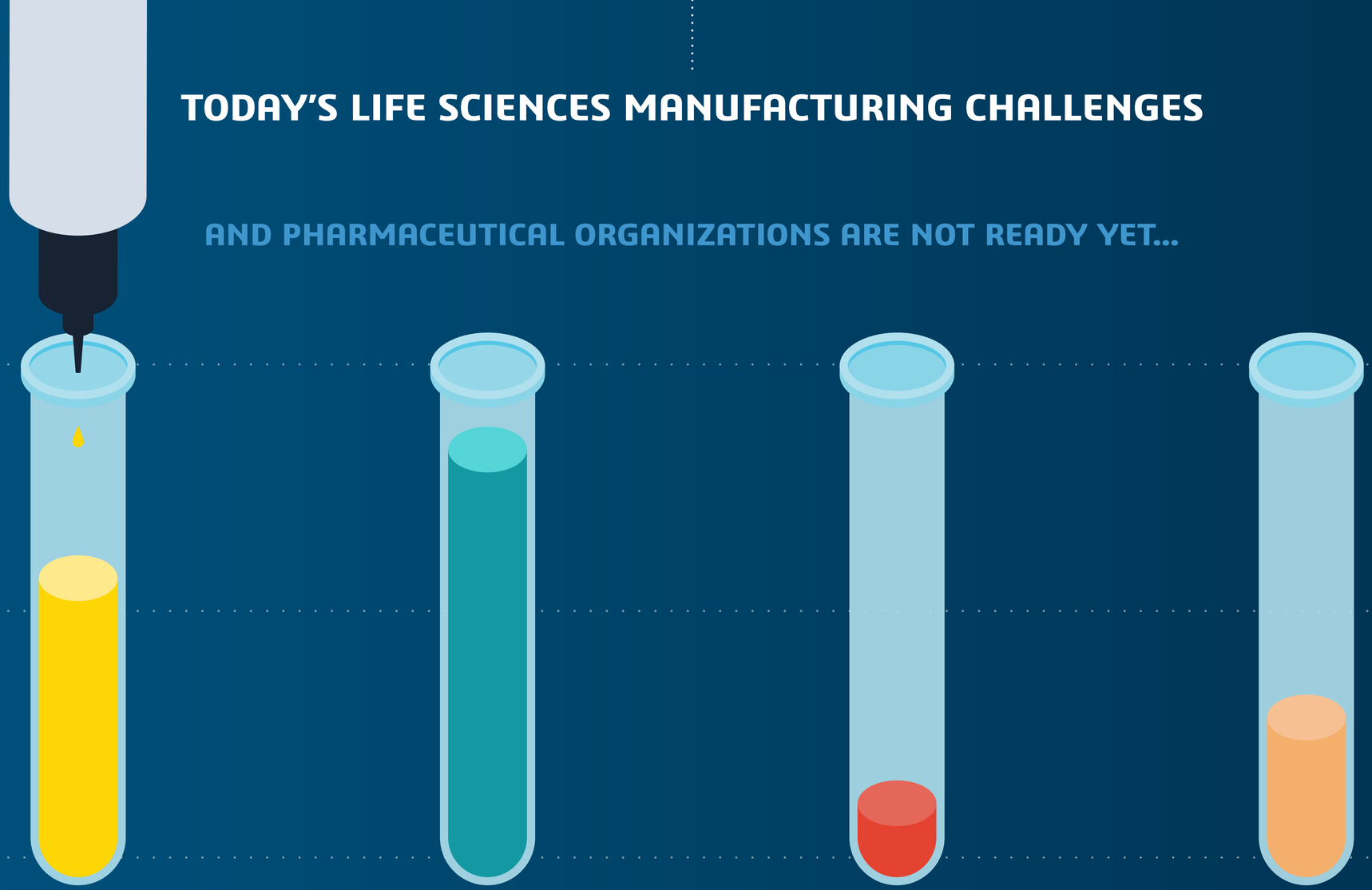
TODAY'S LIFE SCIENCES MANUFACTURING CHALLENGES

AND PHARMACEUTICAL ORGANIZATIONS ARE NOT READY YET...



OVER 50%
Are without process software

MORE THAN 90%
Need to connect siloed data

LESS THAN 16%
Analyze production in real time

ONLY 25%
Use collaboration software

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MANAGING MANUFACTURING COMPLEXITY IN THE LIFE SCIENCES INDUSTRY

Manufacturing in the Life Science industry is complex. Manufacturers must improve efficiency while being more agile and responsive.

Regulatory and validation requirements must be adhered to against new business models or product lines.
Manufacturers' growth in product lines now also blurs the lines of manufacturing styles and runs. This forces many manufacturers from mass production to mass personalization or a mix of process and discrete manufacturing methods.

All of which makes old methods and approaches insufficient and obsolete.

Business Drivers in Life Sciences	Pharmaceutical and Biotech	Medical Device
Transform Development and Manufacturing Operations	Pharmaceutical and Biotech companies are under significant pressure to lower costs and to deliver therapies to smaller populations. Leading companies are investing in more flexible infrastructure, leveraging disposable and modular equipment to be more adaptive, mainly driven by the acceleration of biologics.	Leaders in the Medical Device industry must continually evaluate how to improve manufacturing processes to drive efficiency, quality and performance. Leveraging digital design and production processes presents an opportunity to accelerate innovation and new product introduction.
Re-Invent the Value Chain	Pharmaceutical organizations that digitalize their businesses by embracing the principles and technology that deliver digital continuity across the entire innovation continuum will win in the marketplace. This will better serve the drive toward open innovation, discovery and research, manufacturing and the ultimate delivery of differentiated patient experiences.	As Medical Device companies look to leapfrog their competition by accelerating innovation, maximizing ROI and creating new, connected patient experiences, leaders will see significant growth in collaborative invention and new models will emerge throughout manufacturing and the value chain.

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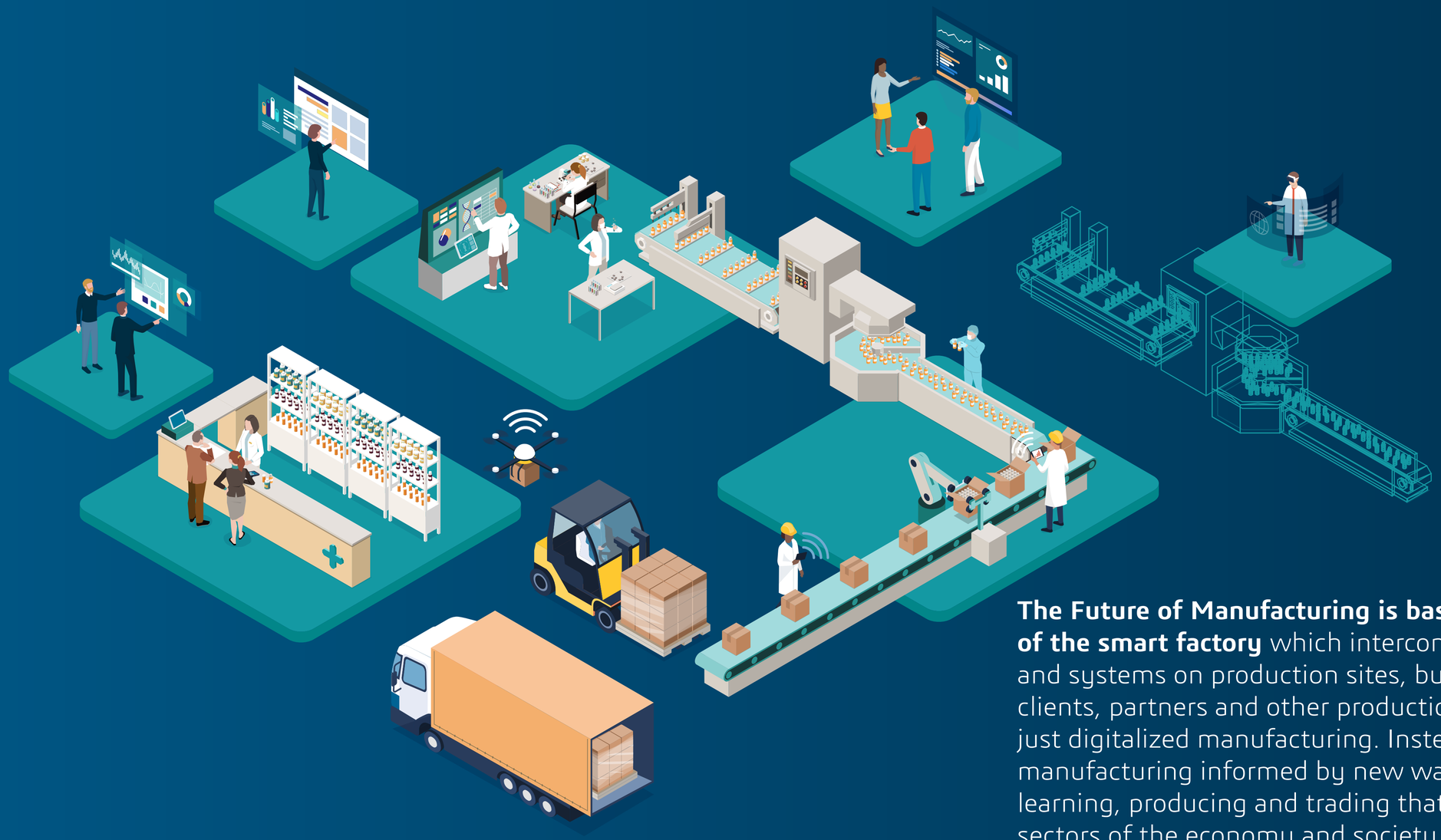
THE FUTURE OF MANUFACTURING



The Future of Manufacturing is based on the concept of the smart factory which interconnects machinery and systems on production sites, but also outside to clients, partners and other production sites. It is not just digitalized manufacturing. Instead, it is digitalized manufacturing informed by new ways of inventing, learning, producing and trading that are shaking all sectors of the economy and society.

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3 SUCCESS PILLARS

Manufacturing is a critical element in a process of value creation, not just a way of producing goods and services. In the Experience Economy and specifically in Life Sciences, value resides in the knowledge and know-how used to create the solution, and in the patient experience the solution enables, rather than in the solution itself.

Life Sciences businesses now look to implement digital value networks using virtual experience platforms where multiple resources are connected and the real and virtual merge to enable new business models.

THE PLATFORM MANUFACTURERS USE TO DELIVER VALUE IS CHANGING...

#1 VALUE NETWORKS

Transform supply chains into **value networks** by removing barriers between potential business partners and enabling **new business models** for delivering **sustainable innovation** to customers.

#2 SUSTAINABLE INNOVATION AND EXCELLENCE

Reduce risk, improve and predict **operational performance** by combining the power of **virtual and real worlds** where people and machines come together to **transform manufacturing.**

#3 WORKFORCE OF THE FUTURE

Reveal the **workforce talents** to train the workforce of tomorrow by **combining experience and know-how.**

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3DEXPERIENCE:
THE VIRTUAL EXPERIENCE PLATFORM APPROACH TO MANUFACTURING

Dassault Systèmes' **3DEXPERIENCE®** platform offers technologies and solutions to pursue discoveries, nurture them and bring the results to business and people throughout the world. Sophisticated modeling and simulation, data acquisition, analysis and reporting, and breakthroughs in imaging and manufacturing come together for organizations to achieve what was once thought "impossible": balancing product, nature and life for sustainable innovation.

The **3DEXPERIENCE** platform provides a global operations management cockpit that supports knowledgeable decision making to keep operations running smoothly. This helps companies optimize production for greater efficiency and output, while reducing costs and time-to-market.

Social and Collaborative Apps

Information Intelligence Apps

3D Modeling Apps

Real-time **3D**EXPERIENCE

Content and Simulation Apps

3DEXPERIENCE®

3DEXPERIENCE IN FOUR MINUTES, TOPS ! - WATCH THE VIDEO

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3DEXPERIENCE:
THE VIRTUAL EXPERIENCE PLATFORM APPROACH TO MANUFACTURING

DID YOU KNOW?

The Dassault Systèmes solution for manufacturing provides visibility across the enterprise and data-driven decision making for therapeutics design, development and commercialization. Infusing virtualization and simulation into manufacturing planning and operations helps ensure therapies are produced as designed and as registered in the most cost-effective and high-quality manner.

FOR MORE INFORMATION ON THE 3DEXPERIENCE PLATFORM, CLICK HERE >

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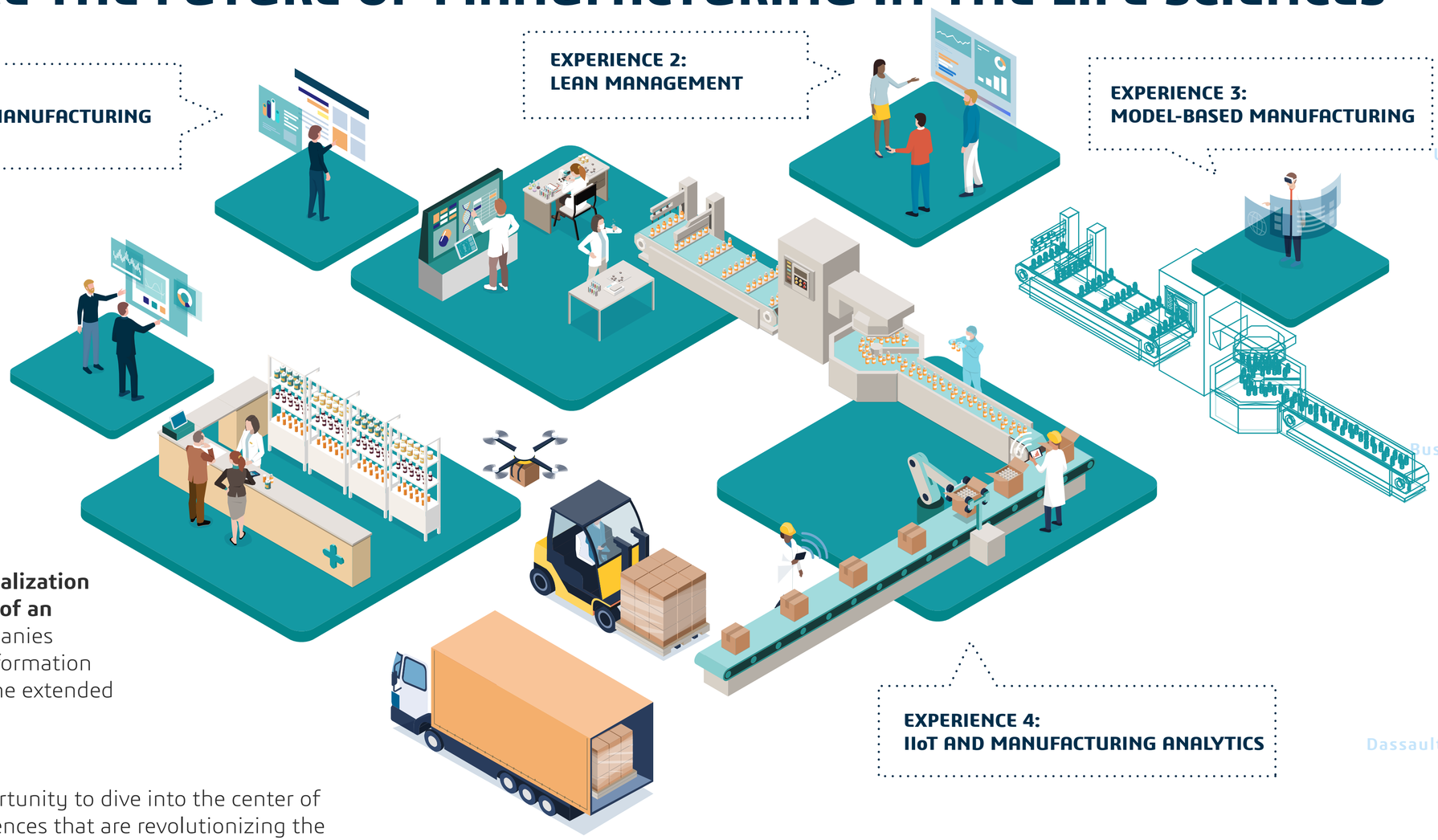
PART 2

EXPERIENCE THE FUTURE OF MANUFACTURING IN THE LIFE SCIENCES



Disruptive technologies will drive digitalization in Life Sciences manufacturing as part of an ecosystem-wide transformation. Companies worldwide are engaging in digital transformation that creates substantial impact across the extended value network.

Dassault Systèmes offers you the opportunity to dive into the center of a smart factory and discover five experiences that are revolutionizing the future of manufacturing in the Life Sciences Industry.

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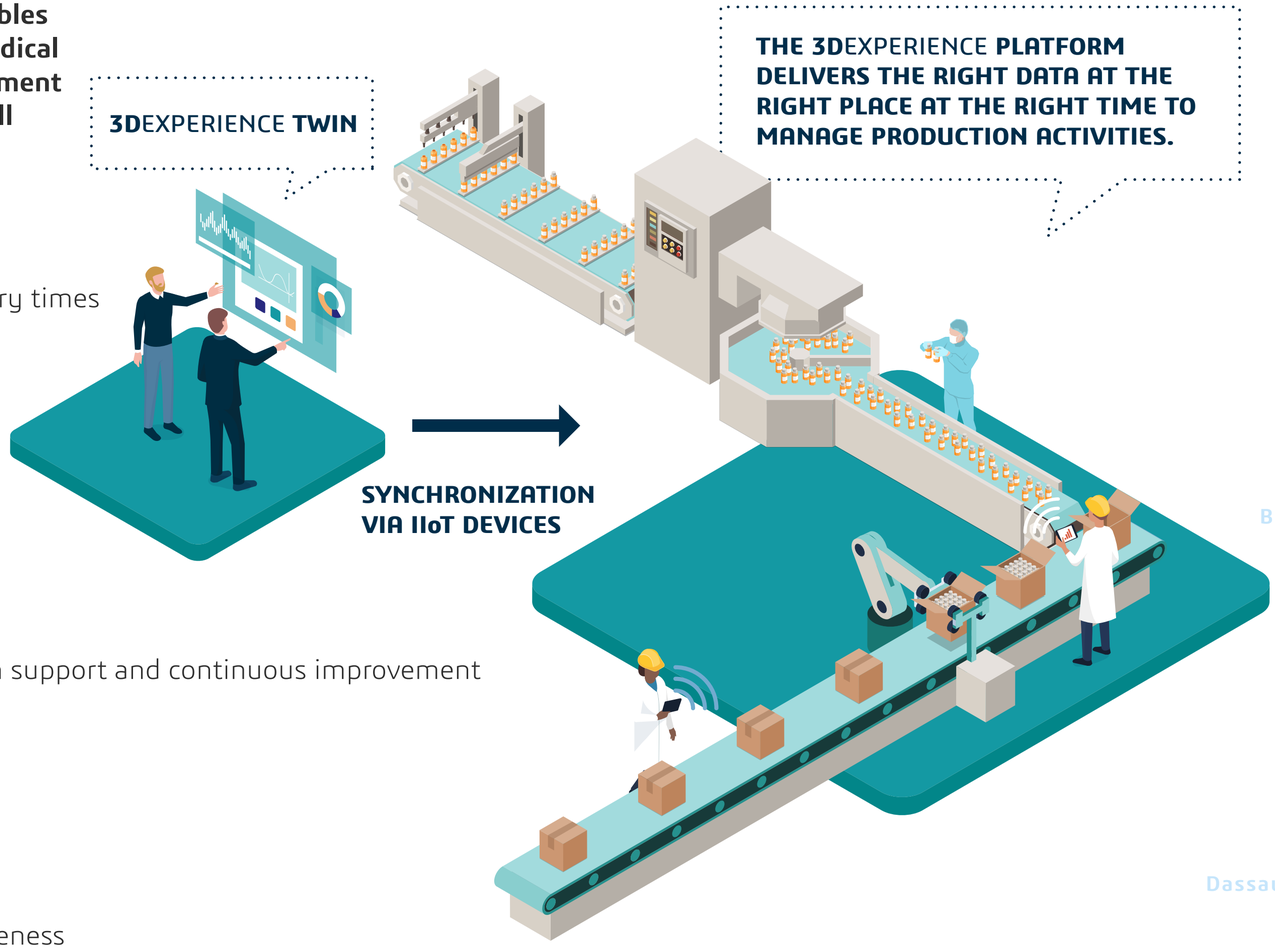
EXPERIENCE 1 | 3DEXPERIENCE MANUFACTURING IN OPERATION

Manufacturing Operations Management Workflow

Business success is driven to a great extent by the creation of new revenue streams and operational excellence. To manage this, the 3DEXPERIENCE platform enables Life Sciences companies to create experiences to satisfy previously unmet medical needs and improve patient outcomes in global markets in one virtual environment (exploration, discovery, development, testing and commercialization) with full visibility across their internal and external ecosystems.



CHALLENGE

OVERALL

- Manage new patient demands, highly customized solutions and shorter delivery times
- Optimize costs to improve margins

MANUFACTURING POINT OF VIEW

- Facilitate better synchronization across all manufacturing activities
- Improve manufacturing assets efficiency
- Capitalize, share and develop operator skills

BUSINESS VALUE STATEMENT

INCREASE EFFICIENCY

- Visibility, control, orchestration and automation of operational activities
- Business process activities and exhaustive data collection for informed decision support and continuous improvement
- Comprehensive performance monitoring

IMPROVE QUALITY

- Comprehensive and real-time quality management across the enterprise
- Quality, traceability and genealogy across parts, processes and resources
- Corrective actions to resolve problems and quality issues

IMPROVE SPEED AND AGILITY

- Business process-driven tasks and exception handling for agility and responsiveness
- Real-time digital continuity across engineering and manufacturing
- Visibility and synchronization of operations across departments improves speed and reduces risk

EXPERIENCE 1 | 3DEXPERIENCE MANUFACTURING IN OPERATION

3DEXPERIENCE ELEMENTS

#1 3D WORK INSTRUCTIONS

The **3D**EXPERIENCE platform ensures **digital continuity from engineering to manufacturing** and provides the ability to interface with IIoT devices installed on the production line.

#2 MANAGING NON-CONFORMANCE

Synchronization among all departments to manage operations efficiently.
Collaboration simplified by **consolidating all information in a single platform** and making it available in the context of each team.

#3 SYNCHRONIZING MATERIAL FLOW

Delivering **the right materials to the right place at the right time**, plus recording of detailed genealogy on components for traceability.

#4 REAL-TIME PERFORMANCE MONITORING

Ready access to production-activity information:
Line Monitoring Cockpit and team information with list of actions and issues. All information made available for more collaborative work and stronger team involvement.

DASSAULT SYSTÈMES IMPROVES OVERALL PRODUCTIVITY WITH MANUFACTURING OPERATIONS MANAGEMENT
WATCH THE VIDEO

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EXPERIENCE 2 | LEAN MANAGEMENT

Key routines in operational management are mainly coming from Lean principles which involve the team to continuously improve overall performance.
The **3D**EXPERIENCE platform supports Lean practices, continuous improvement and traceability in organizations by enabling production efficiency, visibility, required regulatory compliance and end-to-end quality management.

3DLEAN ON THE 3DEXPERIENCE **PLATFORM COMBINES LEAN BEST PRACTICES AND OPERATIONAL METRICS ON A COLLABORATIVE DIGITAL PLATFORM.**

CHALLENGES

- Enable faster and better reaction to manufacturing issues
- Enable stronger collaboration within and between teams
- Reduce number of non-added-value tasks for team members

BUSINESS VALUE ELEMENTS

INCREASE EFFICIENCY WITH 3DLEAN
- Digitalize Lean and facilitate Lean practices across organizations for continuous improvement
- Manage operational performance and Lean Key Performance Indicators (KPIs).

DIGITALIZE SUSTAINABLE CONTINUOUS IMPROVEMENT
- Best-practice benchmarking and sharing for operational processes
- Cross-functional and cross-organizational collaboration for greater awareness

IMPROVE TEAM INTELLIGENCE
- Collaborative worker interaction and creativity within and across peer groups
- Capitalized know-how of the company for better collective intelligence

- **COLLABORATIVE PROBLEM-SOLVING**
- **INTERACTIVE SHOP FLOOR MANAGEMENT**

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EXPERIENCE 2 | LEAN MANAGEMENT

3DEXPERIENCE **ELEMENTS**

#1 FLASH 5 MEETING

From the 3DLean board of the maintenance team, the Facilitator prepares and animates the Flash5 meeting:
- Select and review key topics
- Take actions
- Review action log

#2 PROBLEM-SOLVING MEETING

Facilitator, Maintenance Technician and Operator are reviewing the 3D Work Instruction on the 3DLean board and analyze issue root cause through a problem-solving session.

#3 MANAGEMENT MEETING

Project management team reviews specific tasks linked to project in the **3DEXPERIENCE** platform and monitors operational performance.

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EXPERIENCE 3 | MODEL-BASED MANUFACTURING

The Dassault Systèmes' 3DEXPERIENCE **Twin allows Life Sciences manufacturers to model, simulate, visualize and experience biological medical processes in a virtual environment ('in silico').** A fusion of technologies blurs the lines between the physical and digital domains, collectively referred to as a cyber-physical system.

Digital twins provide synchronization between the virtual and real world.
Digital twins enable manufacturers to develop and validate different scenarios in the work cell before implementing them in the real world.

CHALLENGES

OVERALL

- Limit risk when investing in new manufacturing assets or existing facility change, thanks to virtual simulation and validation

MODELIZATION POINT OF VIEW

- Reduce cost and time to digitalize existing resources to generate models for simulation
- Manage large numbers of product variants having a high frequency of product changes
- Simulate manufacturing processes and validate asset capability in context of real organizational conditions

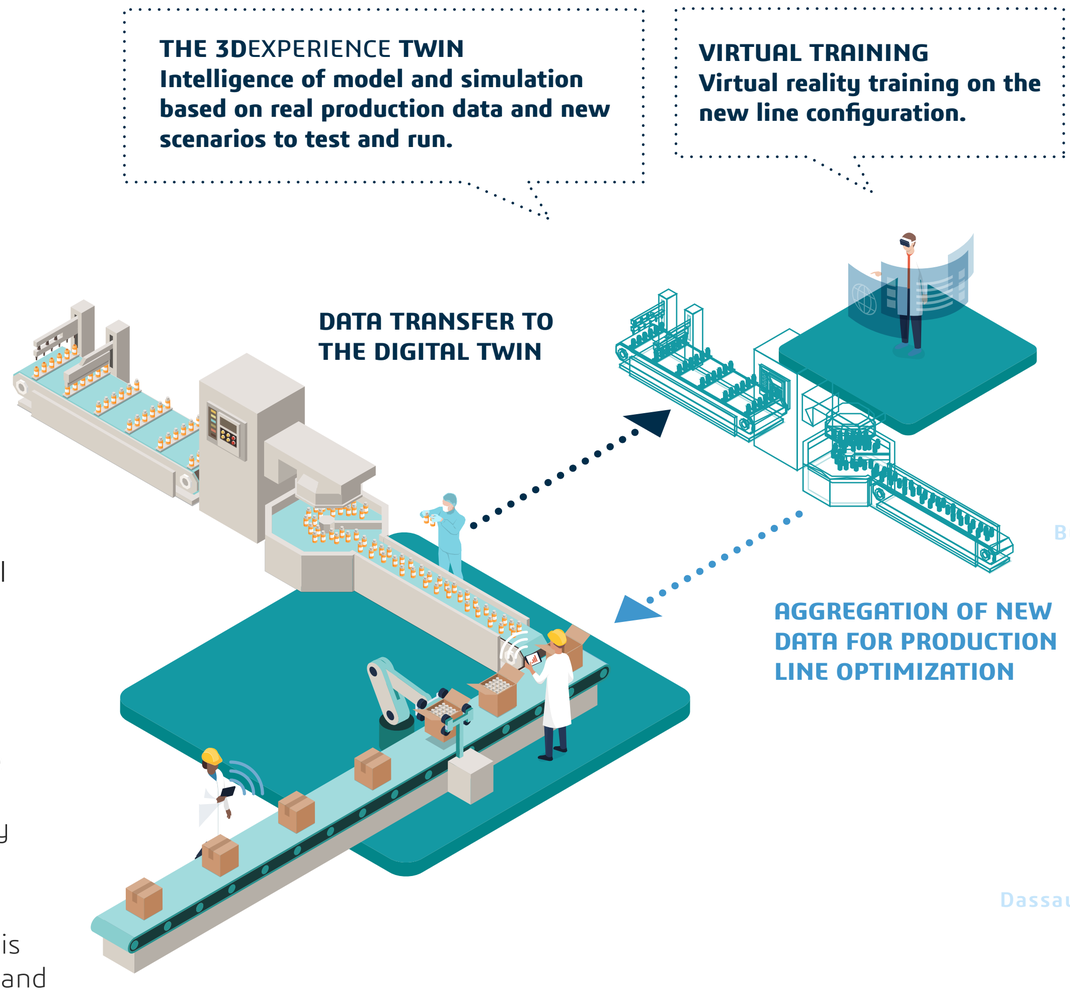
BUSINESS VALUE STATEMENT

INCREASE SPEED AND EFFICIENCY

- Validate and test manufacturing strategies, processes and throughput to understand enterprise behavior
- Reduce time and cost by simulating the impact of product introductions and changes or factory configuration changes

INCREASE RESPONSIVENESS AND AGILITY

- Identify and reduce the risk of interdependencies and bottlenecks with what-if scenario analysis
- Achieve real-time digital continuity between product engineering, manufacturing engineering and manufacturing operations
- Virtually model manufacturing processes based on real production constraints and data



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EXPERIENCE 3 | MODEL-BASED MANUFACTURING

3DEXPERIENCE **ELEMENTS**

#1

Immersive Shop Floor Experience with Dassault Systèmes' 3DEXPERIENCE Twin

Leveraging the latest 3D scanners and analytics technology, the **3D**EXPERIENCE platform identifies the **manufacturing situation** to quickly visualize the current state of the shop floor and maintain digital continuity from product ideation to shop floor activities.

#2

MBOM, Process Plan and 3D work instructions definition

The Manufacturing Bill of Material (MBOM), process plan and 3D work instructions **can be shared directly with the shop floor.** In the event of changes, the entire process will update automatically thanks to digital continuity.

#3

Factory Flow Simulation

The flow simulation **analyzes the utilization rate of an asset**. (Imagine the difficulty and the cost of doing what-if scenarios in the real world!)

#4

Ergonomic Workplace Design

Simulate and validate operator tasks on the Dassault Systèmes' 3DEXPERIENCE platform. Using simulation, quickly understand which part of the process is risky for the operator. The intelligence engine automatically sets up the posture of the virtual manikin based on the task to be performed.

#5

Virtual Training For Assembly Station

With virtual training, gradually **teach** the operator using a typical "**show me"**, "**help me**" and "**let me**" scaffold methodology.

MODEL YOUR MANUFACTURING ASSETS WITH DASSAULT SYSTÈMES' 3DEXPERIENCE TWIN
WATCH THE VIDEO

EXPERIENCE 4 | IIoT AND MANUFACTURING ANALYTICS

Increasingly, connected devices are used on the shop floor to manage Life Sciences manufacturing operations. Those devices can be connected to machines, tools, sensors, Radio-Frequency Identification (RFID) tags and Automated Guided Vehicles (AGVs). They all contribute to a higher level of visibility into operations, higher levels of safety for the operator, better control of product quality and a more detailed level of traceability.

CHALLENGES

- Connect and aggregate data from disparate sources in a unified way
- Achieve high volume and velocity of manufacturing data from sensors

BUSINESS VALUE STATEMENT

INCREASE PRODUCTIVITY

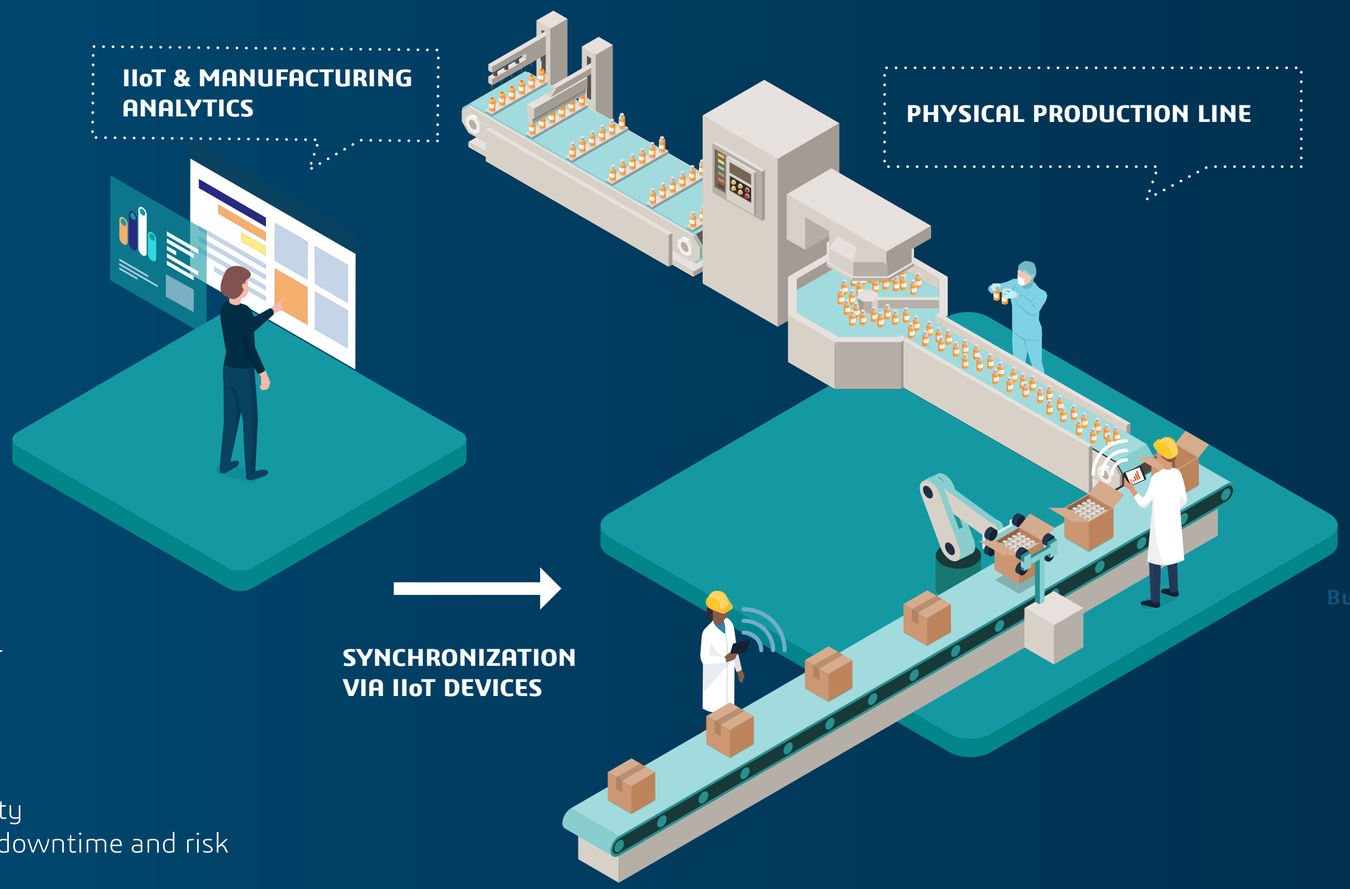
- Business context of production and machine data for decision support
- Real-time monitoring and performance of manufacturing assets with IIoT
- Machine-learning and analytics to optimize asset utilization

IMPROVE EFFICIENCY

- Benchmark performance across multiple factories through analytics
- Automate data collection and eliminate mundane non-value-added activity
- Enable data-driven alert and exception handling to minimize operational downtime and risk

INCREASE QUALITY

- Contextualize quality resolution by leveraging a comprehensive set of data types and sources
- Provide intuitive and powerful visualization to understand complex problems impacting quality
- Provide AI-based decision support for a wide range of process and product quality issues



- **REAL-TIME MACHINE PERFORMANCE MOITORING**
- **PREDICTIVE ANALYTICS AND SELF-LEARNING**
- **PREVENTIVE MAINTENANCE**

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EXPERIENCE 4 | IIoT AND MANUFACTURING ANALYTICS

3DEXPERIENCE **ELEMENTS:**

#1 IIoT – EQUIPMENT INTEGRATION CAPABILITIES

The **3D**EXPERIENCE platform **allows operators to connect directly to IIoT devices** and to contextualize the information in a data model.

#2 REAL-TIME MACHINE PERFORMANCE MONITORING

Operators can interact from their stations with other teams to address any unexpected issue or send requests. **Communication among departments is faster and more efficient** thanks to the information that is automatically contextualized.

#3 PLAN PREVENTIVE MAINTENANCE

Supports operators in finding the best time to implement scheduled maintenance on a machine: before an issue occurs thus with the lowest impact.

#4 EXECUTE PREVENTIVE MAINTENANCE

Via a mobile device, maintenance technicians automatically receive details of maintenance orders.

IIoT – Industrial Internet Of Things
IIoT refers to the extension and use of the Internet of Things (IoT) in manufacturing sectors and applications. The IIoT enables better efficiency and reliability within industrial operations.

DASSAULT SYSTÈMES IIoT AND MANUFACTURING ANALYTICS IMPROVE MANUFACTURING PERFORMANCE
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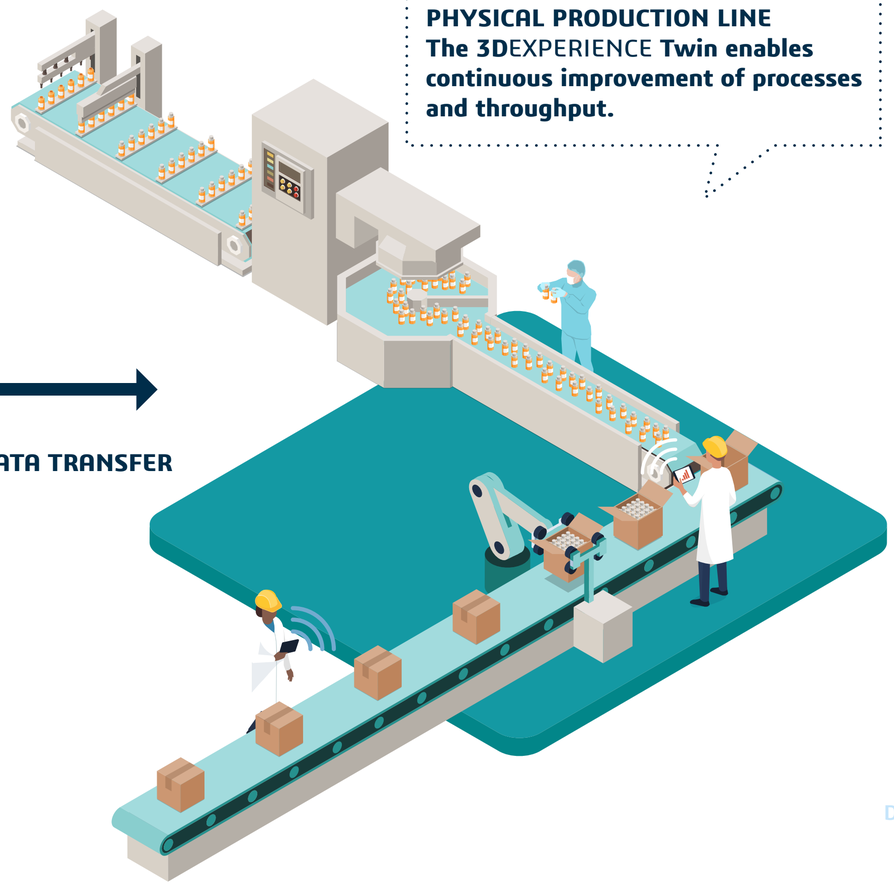
EXPERIENCE 5 | VALUE NETWORK OPTIMIZATION

Good manufacturing requires good planning. Value Network Optimization shows you how to resolve challenges, optimize supply chain planning and enhance transparency and efficiency.

- **REVIEWS**
- **DEDUCTIONS**
- **VISUALIZATION AND KPIs**
- **OPTIMIZED PLANS**
- **PLANNER IN CONTROL**

DATA TRANSFER



PHYSICAL PRODUCTION LINE
The 3DEXPERIENCE **Twin enables continuous improvement of processes and throughput.**

CHALLENGES

- Maintain and exceed production rates
- Maximize asset utilization
- Minimize operation, employee and maintenance costs

BUSINESS VALUE STATEMENT

IMPROVE CUSTOMER SERVICE

- Optimize throughput to meet or exceed customer service level commitments
- Continuously balance production variables for optimal outcomes based on business objectives
- Improve available-to-promise accuracy based on a true reflection of value network constraints

REDUCE COSTS

- Enable dynamic rescheduling to reduce the impact of costly production disruptions
- Lower inventory without impacting production
- Improve transportation and delivery costs through optimized routing

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EXPERIENCE 5 | VALUE NETWORK OPTIMIZATION

3DEXPERIENCE ELEMENTS

#1

REVIEW

The factory traffic manager reviews the **production schedule and traffic requirements**. The **3D**EXPERIENCE platform ensures work cells are utilized at maximum capacity and avoids locked work cells.

#2

ANALYSIS

The **3D**EXPERIENCE platform provides **immediate feedback on the schedule to proactively avoid potential conflicts**.

#3

VISUALIZATION AND KPIs

Unlimited scenario capability gives ability to explore **various alternate options** and understand **impact on KPIs before publishing the plan**.

#4

OPTIMIZATION

The **3D**EXPERIENCE platform allows **continuous improvement of assumptions based on data collected from execution**.

#5

PLANNER IN CONTROL

Real-time communication with execution and feedback for adherence tracking.

DASSAULT SYSTÈMES AUTOMATION SIMULATION ALLOWS FOR FLEXIBLE PRODUCTION AND INCREASED EFFICIENCY
WATCH THE VIDEO

PART 3

BUSINESS CASE: HOW BIOGEN EMBRACES THE FUTURE OF MANUFACTURING

Context

- Founded in 1978, Biogen® is the world's oldest independent biotechnology company.
- The company discovers, develops and delivers to innovative therapies to patients worldwide for serious neurodegenerative diseases, autoimmune disorders and hematologic conditions.
- Inherent to Biogen and all biotechnological and pharmaceutical manufacturing facilities is a constant cycle of change, as well as the need for utmost control over the changes. Biogen assessed their paper-based Standard Operating Procedure (SOP) delivery system and determined it was inefficient and costly which was the basis for their transition to an electronic management solution from Dassault Systèmes.

Challenge

Improve the delivery of critical documentation to employees working in a clean environment.

Solution

After selecting the iPad®, Biogen relied on their compliance and quality management partner, BIOVIA®, to provide the interface that would allow them to make their documentation available on the iPad in a way that is faster and less costly.

Benefits

- Saved time – over 1,575 hours per year
- Reduced labor costs by USD$110,000 per year
- Eliminated materials costs of over USD$3,300 per year
- Freed up counter space in manufacturing areas

LEARN MORE ABOUT BIOVIA

READ THE FULL CUSTOMER STORY

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To achieve Development and Manufacturing excellence in Life Sciences, a company must find the answer to the following question: "How do we create more agile manufacturing and production operations to meet market demands?"

LIFE SCIENCE ORGANIZATIONS CAN LEAPFROG THE COMPETITION BY 4-7 YEARS AND TAKE THE LEAD IN DEVELOPING HIGH-GROWTH, INNOVATIVE THERAPEUTICS AND DEVICES BY STRATEGICALLY PARTNERING WITH DASSAULT SYSTÈMES TO:

Achieve Sustainable Innovation and Excellence
Reduce risk, improve and predict operational performance by combining the power of virtual and real worlds where people and machines come together to transform manufacturing.

Create Value Networks
Transform supply chains into value networks by removing barriers between business partners to deliver sustainable innovation to consumers.

Empower the Workforce of the Future
Reveal the workforce talents of today to train the workforce of tomorrow by combining experience and know-how.

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CONCLUSION

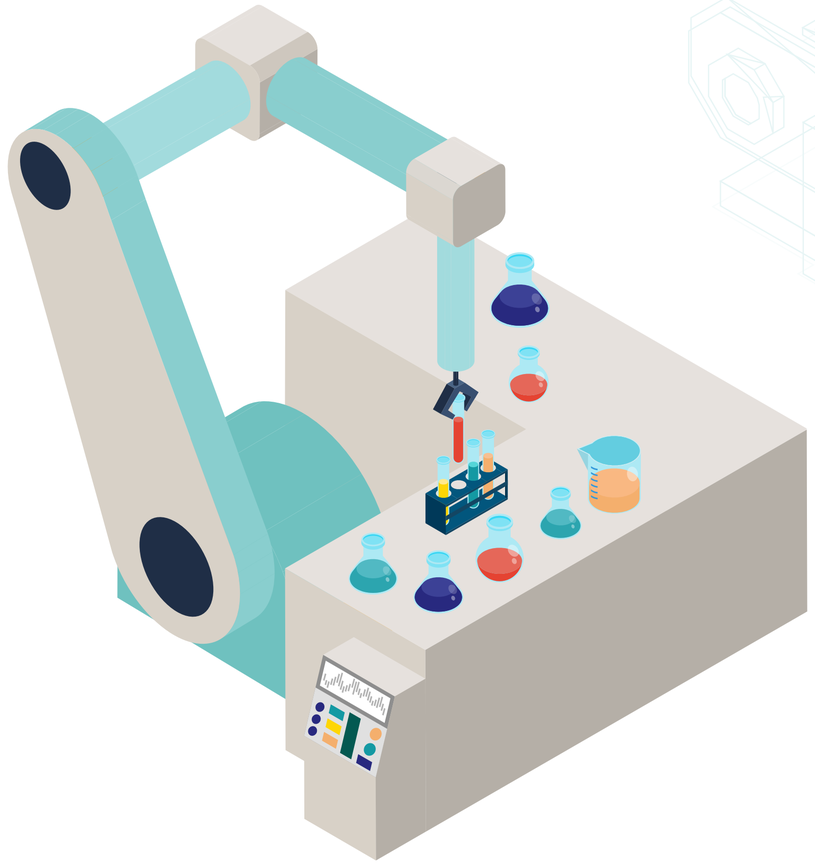
ARE YOU READY FOR THE FUTURE OF MANUFACTURING?

THE BENEFITS OF DIGITALLY TRANSFORMING MANUFACTURING

Reduce risk of late-stage attrition

Harmonize information, modeling/simulation and knowledge

Accelerate pipeline through better science and enhanced cross-functional collaboration



Achieve end-to-end innovation productivity

Unify intellectual property protection efforts

Ensure quality and regulatory compliance through data security, integrity and traceability "Right First Time"

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PART 5

ARE YOU READY FOR THE FUTURE OF MANUFACTURING IN THE LIFE SCIENCES INDUSTRY?

LEARN MORE ABOUT Dassault Systèmes Manufacturing
ifwe.3ds.com/life-sciences/

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