Digital Innovation & Transformation in the Pharma & Life Science Industry

Andrew Whytock
Head of Digitalization, Pharma Segment

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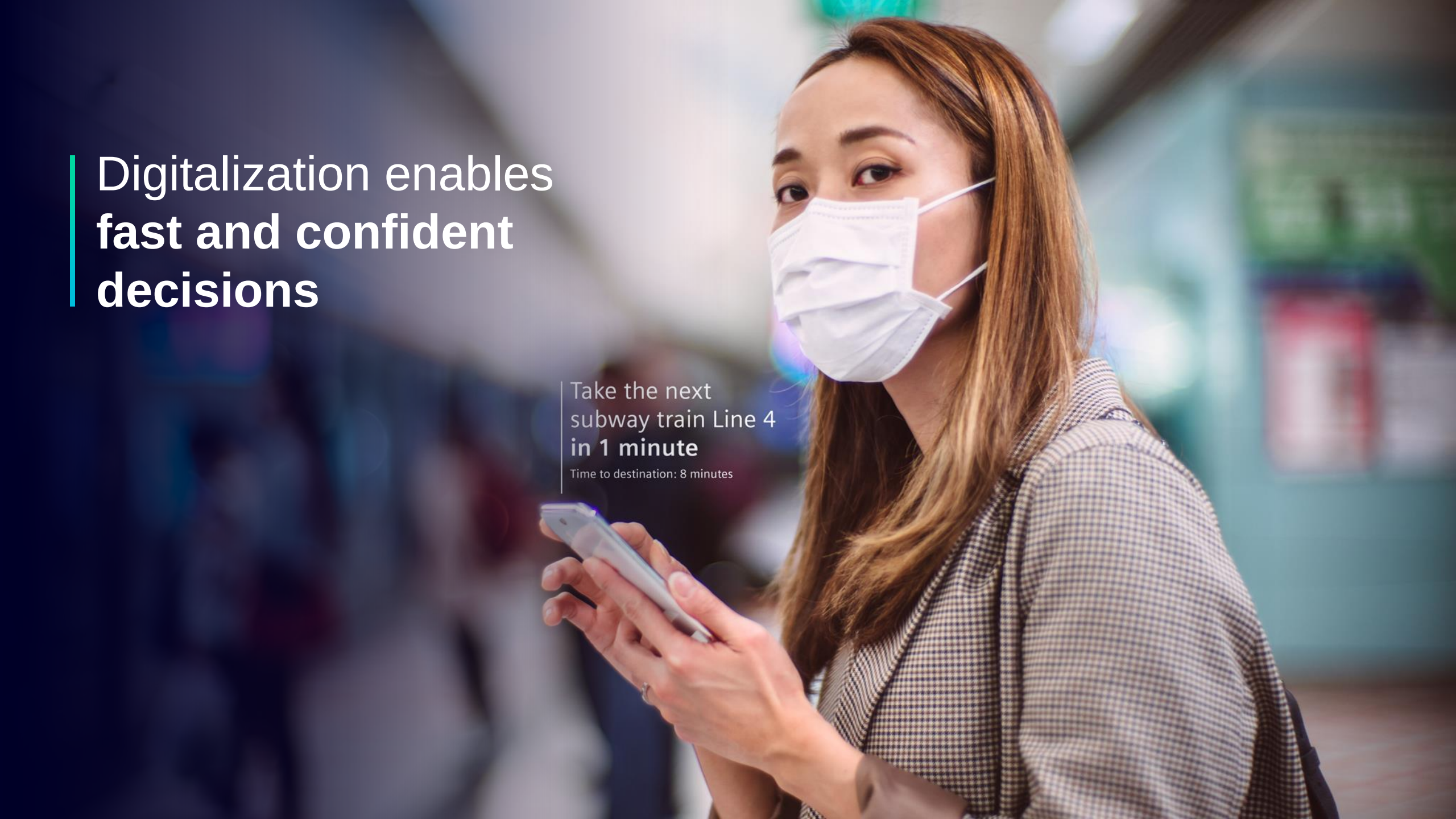
Digitalization enables **fast and confident decisions**



Digitalization enables **fast and confident decisions**

Multiple factors are bringing urgent challenges in the pharma industry

Patients

Market Growth

Changing demographics

Affordable products

Patient data

Patient centric healthcare

Products

New Therapies

New drug delivery methods

New manufacturing techniques

Tech transfer

Pace of Change

Uncertainty

Technology development

Supply Chain complexity

Uncertain success

Performance

Pressure to Deliver

Operational excellence

Cost pressure

Outsourcing

International collaboration

Source : www.biophorum.com

BioPhorum

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Multiple factors are bringing urgent challenges in the pharma industry

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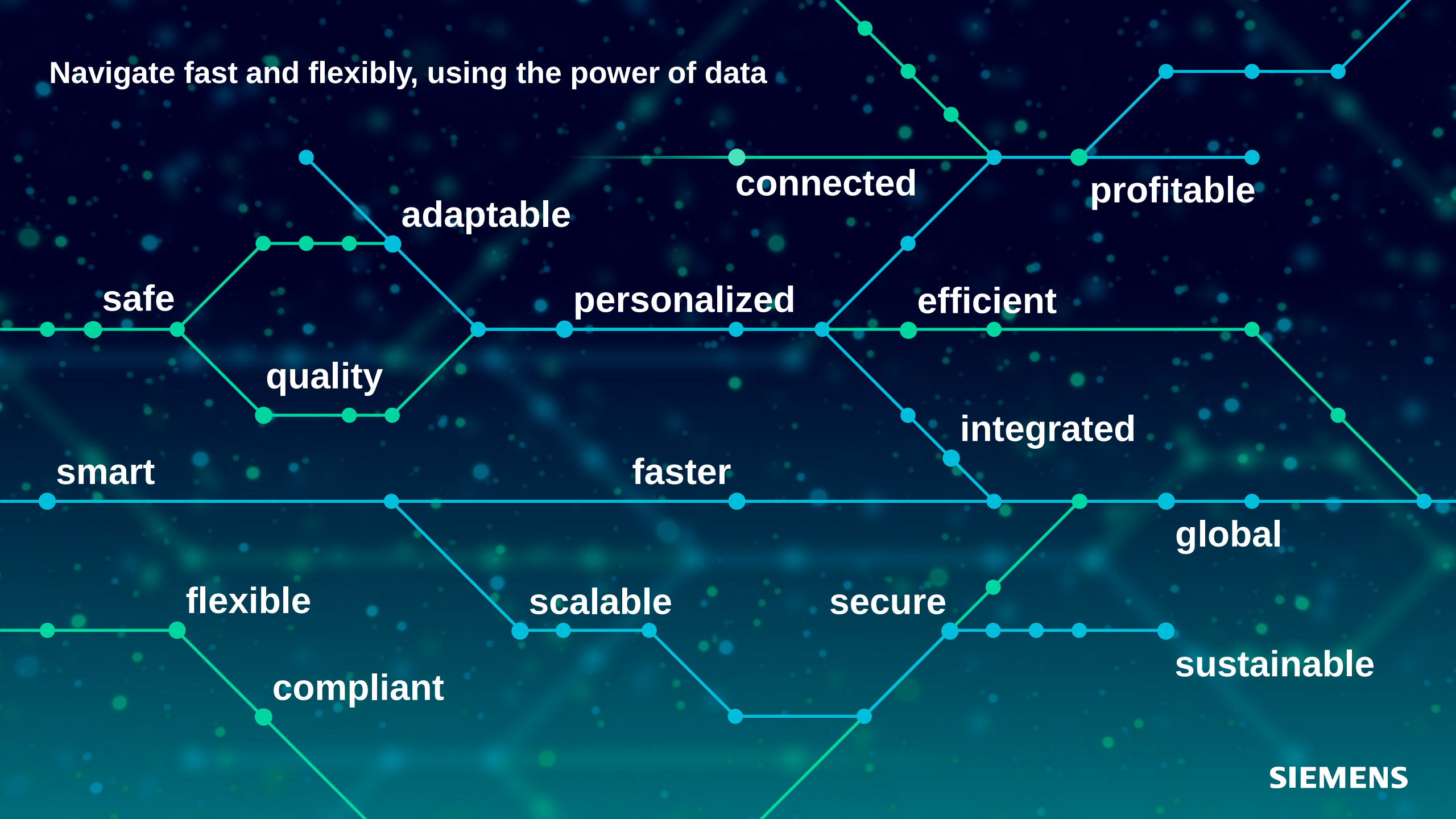
Navigate fast and flexibly, using the power of data
connected
profitable
adaptable
safe
personalized
efficient
quality
integrated
smart
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global
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sustainable
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Five key business drivers in the pharmaceutical industry

Patients
Market Growth

Products
New Modalities

Pace of Change
Uncertainty

Performance
Pressure to Deliver

Flexibility
- Faster capacity expansion
- Flexible, modular operations
- Multiproduct facilities

Speed
- Faster approvals
- Faster batch release
- Smart modular standards

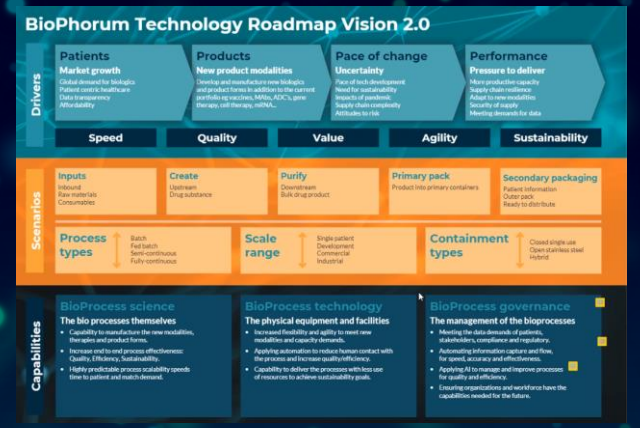
Quality
- More effective compliance
- Better process control
- Data integrity & consistency

Sustainability
- Increase energy efficiency
- Reduce carbon emissions
- Reduce water consumption

Efficiency
- Lower waste
- Improved productivity
- Improve equipment utilization

efficient

faster



BioPhorum

sustainable

Source : www.biophorum.com

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Driving our Focus Topics with our key customers through co-creation

- Flexibility
- Speed
- Quality
- Sustainability
- Efficiency

Digital Twin & Simulation

Paperless Manufacturing

Smart Biopharma

Continuous Manufacturing

Cell / Gene Therapy & Personalized

Integrated Engineering

Integrated OEM & Secondary Lines

IIOT, Cloud & Edge

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Baxter
BAYER
CSL
BIONTECH
Boehringer Ingelheim
GSK
Johnson & Johnson
MERCK
MERCK
NOVARTIS
Pfizer
Roche
SARTORIUS
sanofi
Takeda

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DIGITAL TWIN AND SIMULATION

Digital twins to **win the race against time**

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Digital Enterprise
The comprehensive Digital Twin approach

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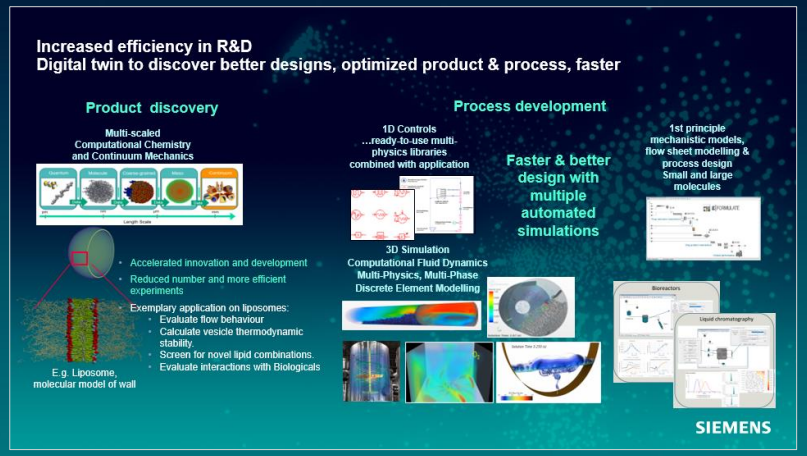
END TO END DIGITAL TWIN

Leveraging the different Digital Twins across the entire Manufacturing Value Chain



...to discover better designs, optimizing products & processes

...to engineer faster, reducing commissioning time

...to optimize Plant Operations

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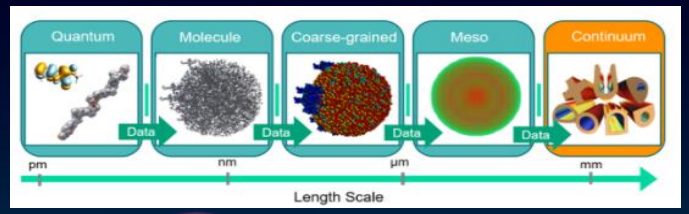
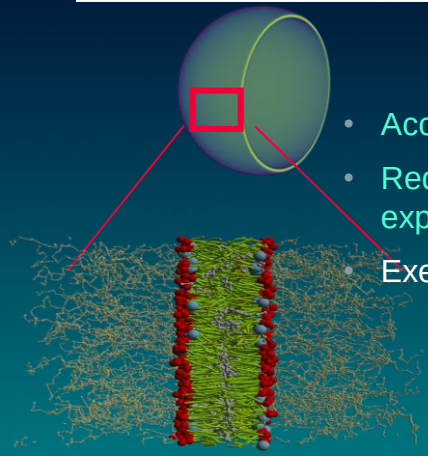
Increased efficiency in R&D
Digital twin to discover better designs, optimized product & process, faster

Product discovery

Multi-scaled Computational Chemistry and Continuum Mechanics



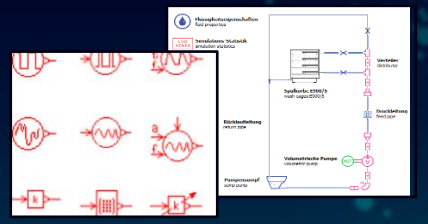


- Accelerated innovation and development
- Reduced number and more efficient experiments
- Exemplary application on liposomes:
  - Evaluate flow behaviour
  - Calculate vesicle thermodynamic stability.
  - Screen for novel lipid combinations.
  - Evaluate interactions with Biologicals

E.g. Liposome, molecular model of wall

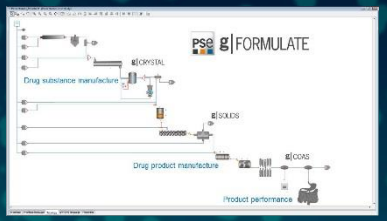
Process development

1D Controls …ready-to-use multi-physics libraries combined with application

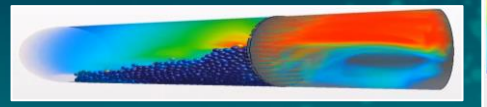


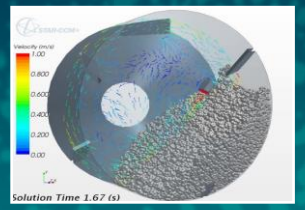
Faster & better design with multiple automated simulations

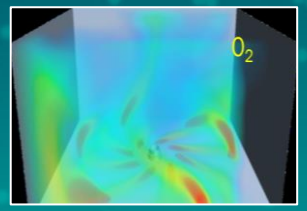
1st principle mechanistic models, flow sheet modelling & process design Small and large molecules

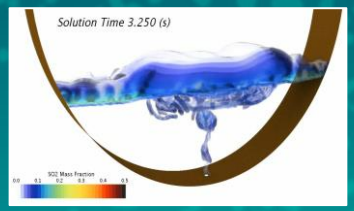


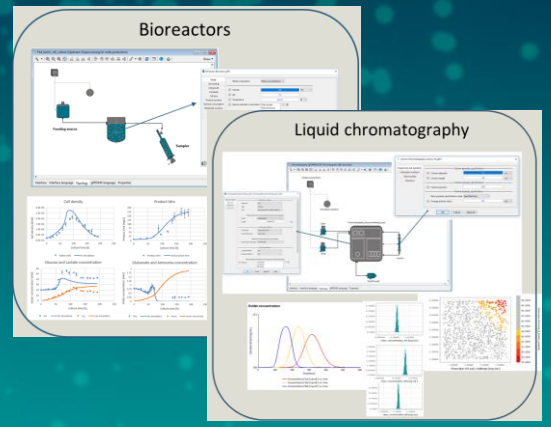
3D Simulation Computational Fluid Dynamics Multi-Physics, Multi-Phase Discrete Element Modelling











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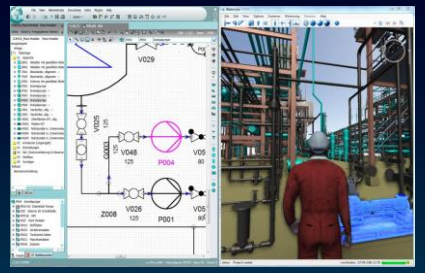
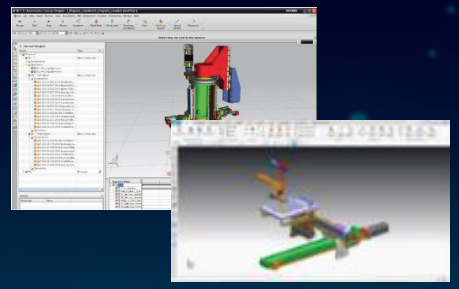
…to engineer faster, reduce commissioning time
Digital twins for virtual commissioning and Operator Training.

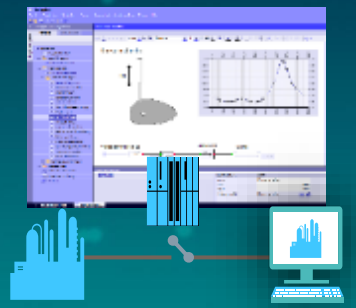
Digital twin process plant and Operator Training System



Mechatronic Concept Designer for machine building and virtual commissioning



Process Simulation & virtual controller



- **Speed up the commissioning of plant operation**
- **Mitigate risks and reduce costs**
- **Avoid unplanned process/machine behavior**
- **Identify mechanical or software failures at an early stage**

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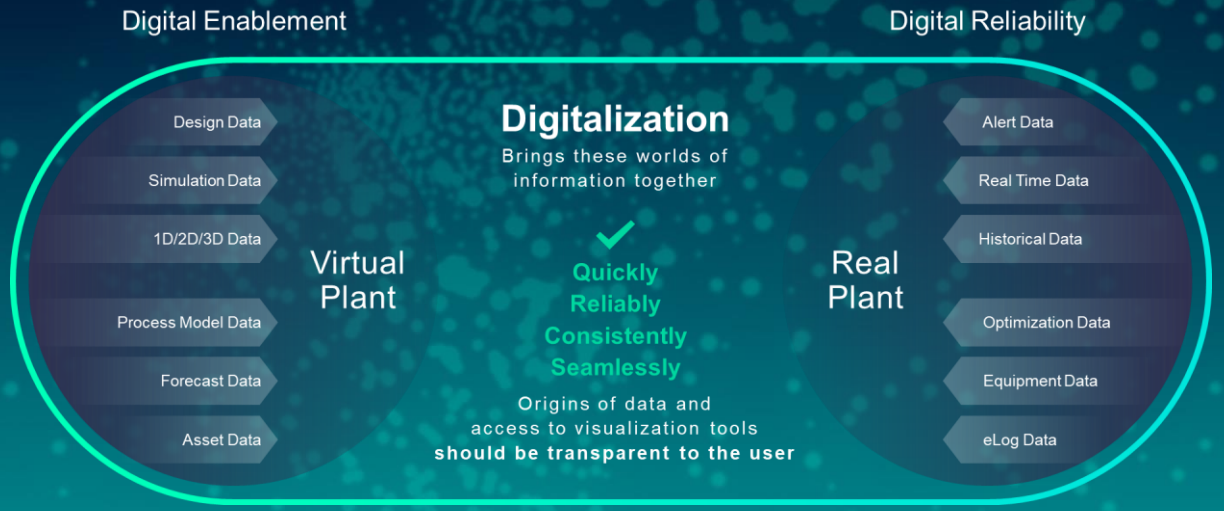
…to optimize Plant Operations
Optimized Plant design, flow of materials and resources, production capacity, …

Simulate material and logistics flow in operational factory to optimize plant operations design prior to build
Identify bottlenecks
Perform FMEA studies

Use virtual operational factory model in combination with advanced planning and scheduling to optimize production capacity

Optimize Production Cells Cobots simulation,
Perform Ergonomy studies to optimize operator labor

To optimize Asset Performance
To predict downtime and reduce maintenance cost



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Accelerating Vaccine Development

Digital twins for process understanding and control

Shorter vaccine development process

Less waste of raw materials

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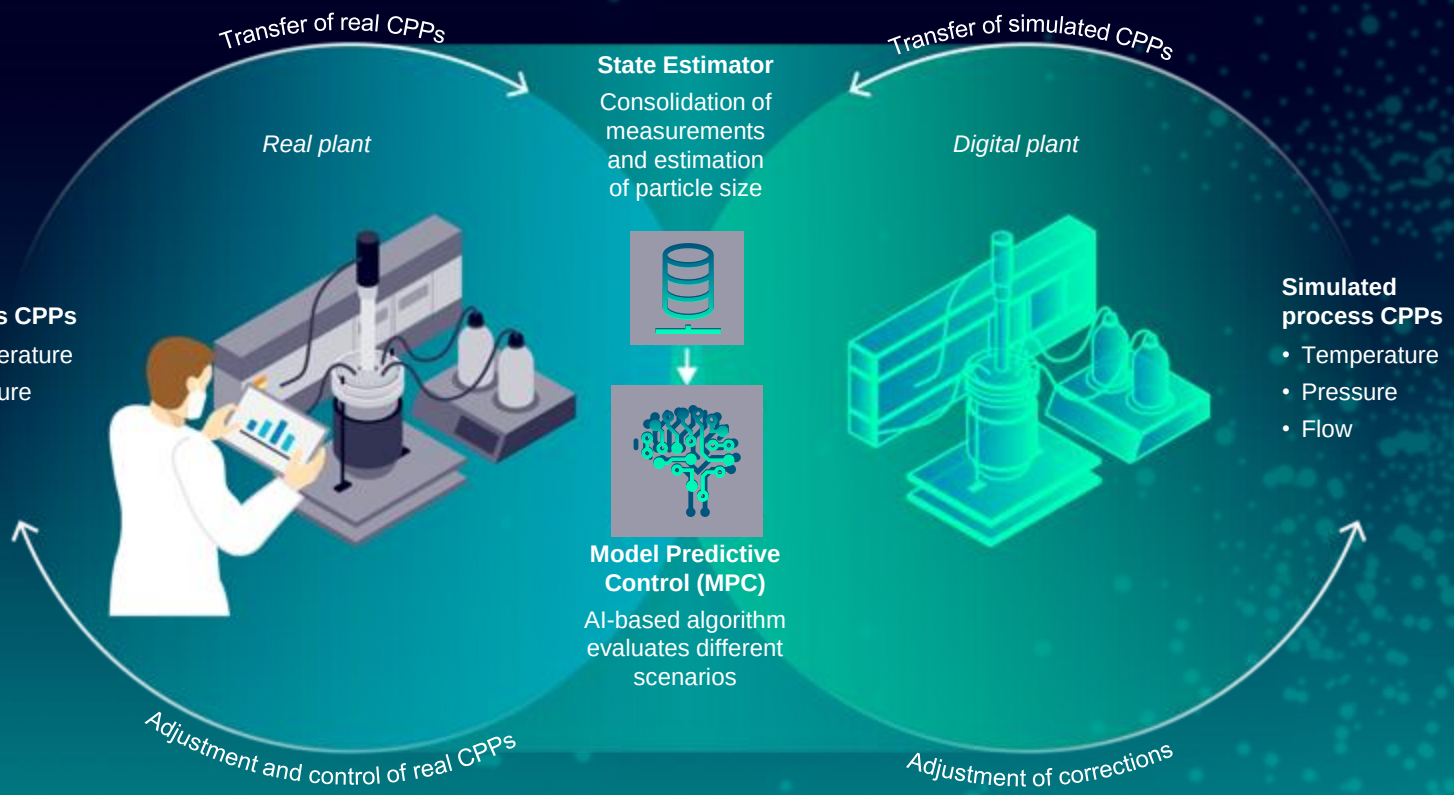
EXAMPLE: DIGITAL PROCESS TWIN

Enable faster, more effective development and better quality management with a digital twin of a manufacturing process



CPP Critical Process Parameter

Simulate & optimize the production process by creating a virtual plant based on data from the real plant.

Provide new insights for development and better control over the production process

Send predictions and control measures back to the real plant

Reduce waste and speed up development

SIEMENS + Atos

Modelling and control expertise

Data science & UX knowledge

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PAPERLESS MANUFACTURING

The platform to **win the race against time**

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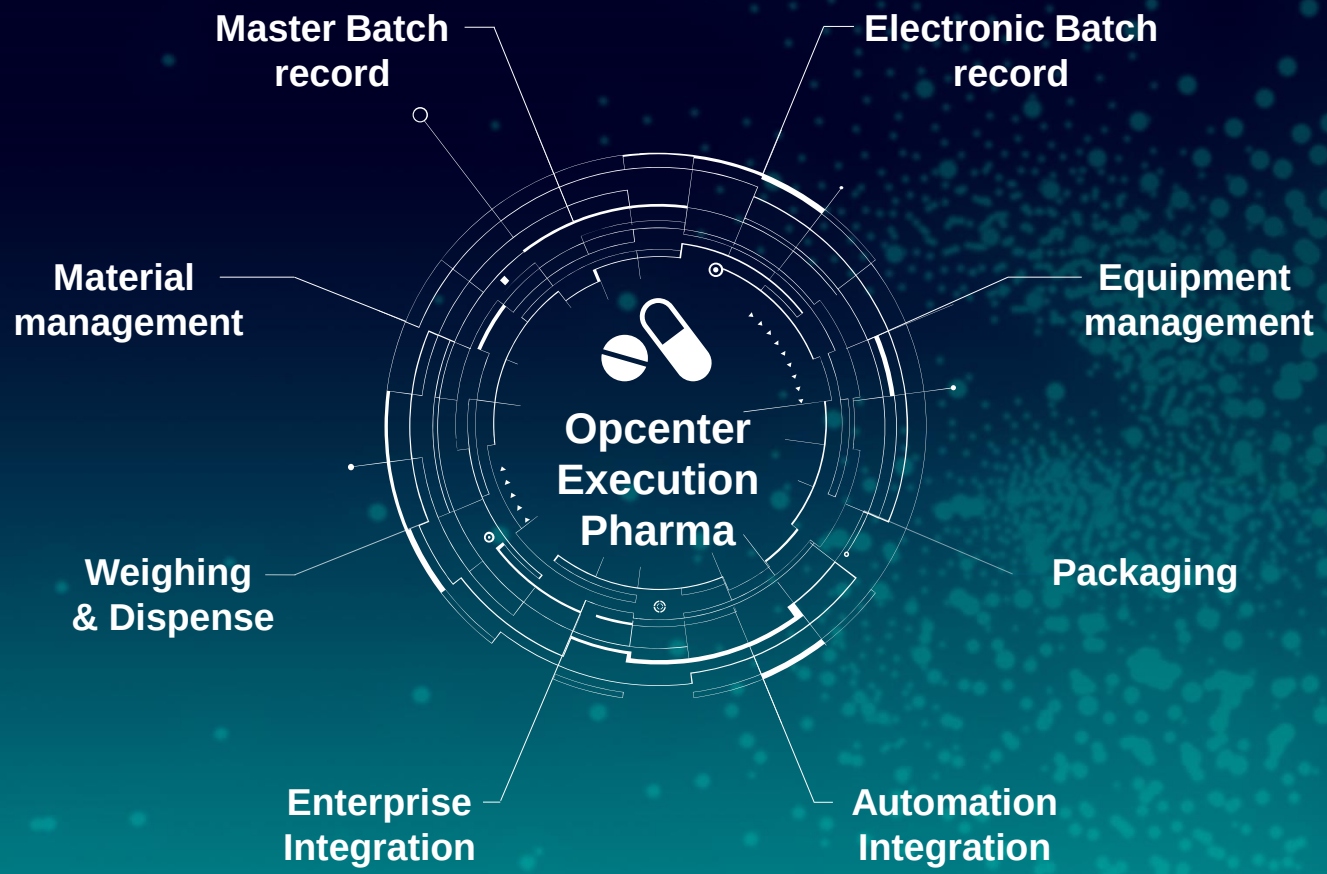
Paperless Manufacturing
Driven by Opcenter Execution Pharma



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BioNTech

Fast-Track COVID-19 production

Marburg, Germany

Opcenter Execution Pharma MES for orchestrating subsystems and processes

Precise measurement of weight for high product quality

SIMATIC PCS 7 and TIA portal for control system and engineering framework

In-depth service and on-call readiness 24/7

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Fast-Track COVID-19 production

Marburg, Germany

One of six possible mobile stainless steel **reactors** is moved to **one of four** possible drug-product **cleanrooms**, and the contents was transferred to **one of 30** possible single-use **mixers**

The operator **plugs in the vessels**, and using profinet detection, the units were **identified** and passed on the batch system and **recorded in the MES**

BIONTECH

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SMART BIO

Flexibility to **win the race against time**

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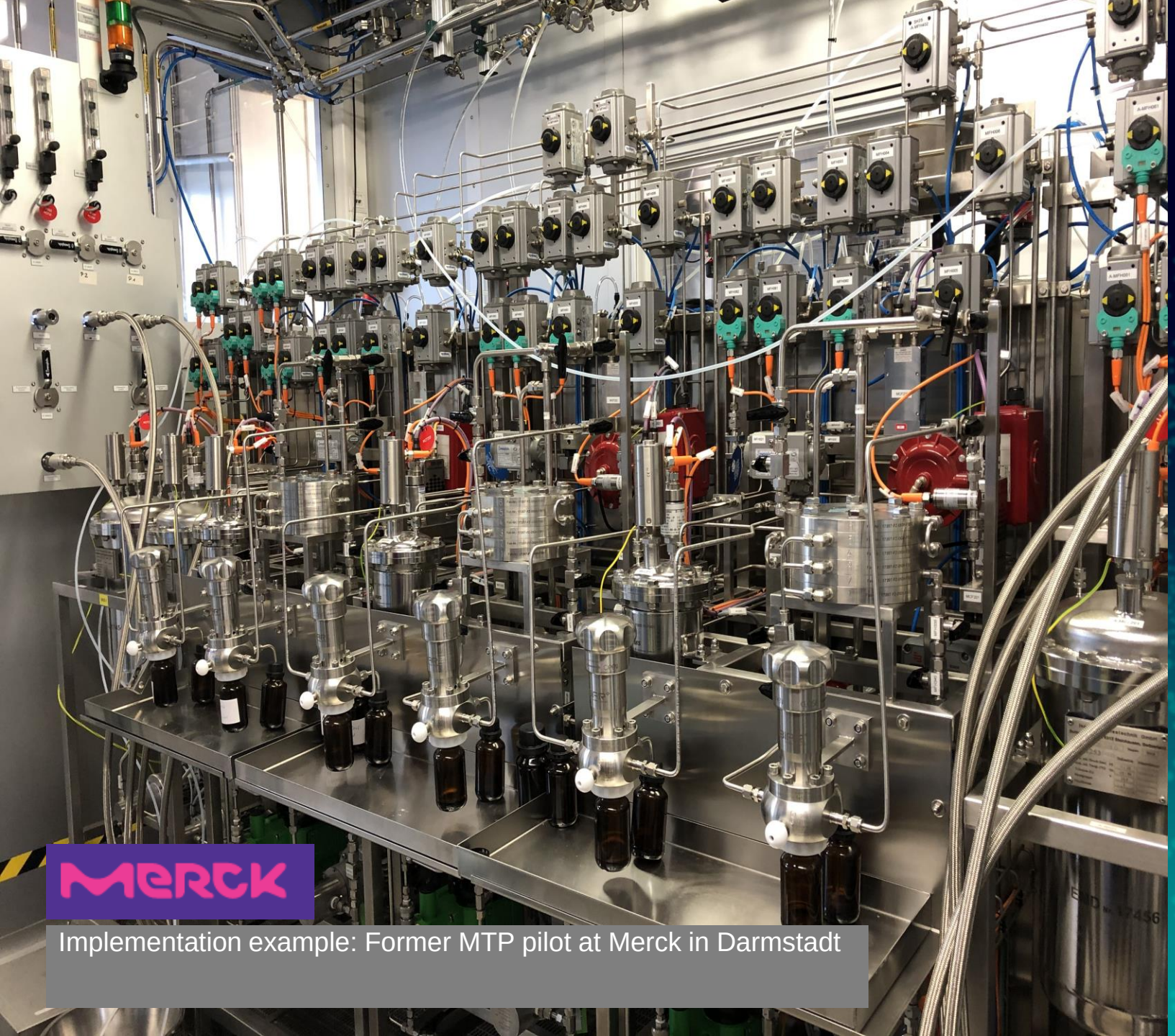

Implementation example: Former MTP pilot at Merck in Darmstadt

Merck KGaA

Co-creation for Modular Production with MTP

Darmstadt, Germany

Close collaboration & co-creation to advance modular production

First project with SIMATIC MTP Library

SIMATIC PCS neo as Process Orchestration Layer

Eliminate programming & reduce engineering efforts

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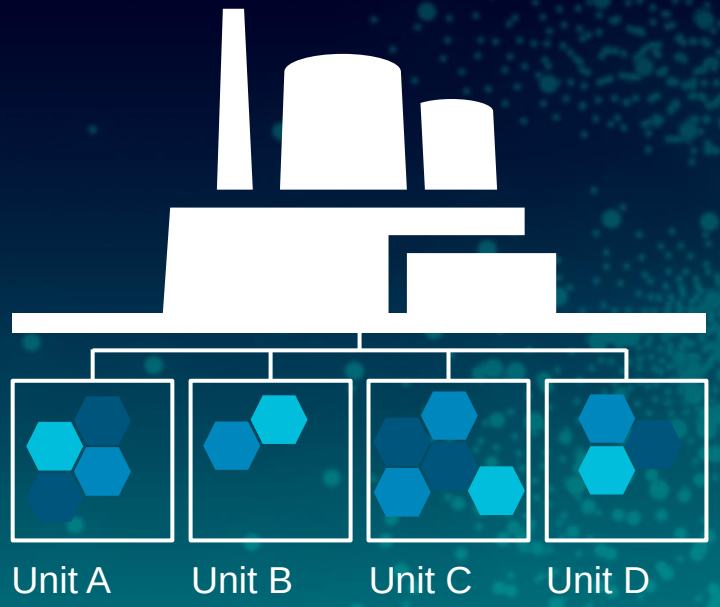
Modular Production with Module Type Package (MTP)

Challenges

- Fast changing products
- Smaller batch sizes
- Fluctuations in demand
- …

“Modular Production”



Benefits

- Reduced costs
- Increased flexibility
- Higher quality
- Shorter time-to-market

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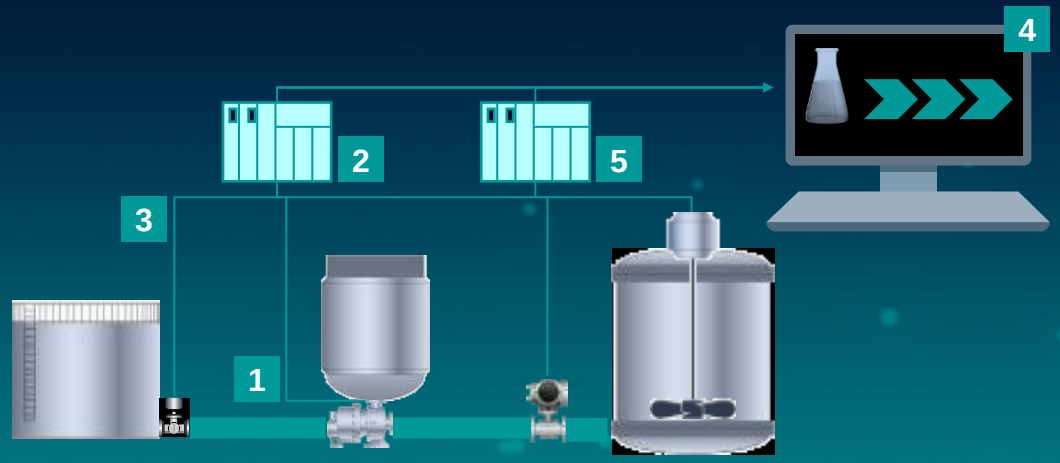
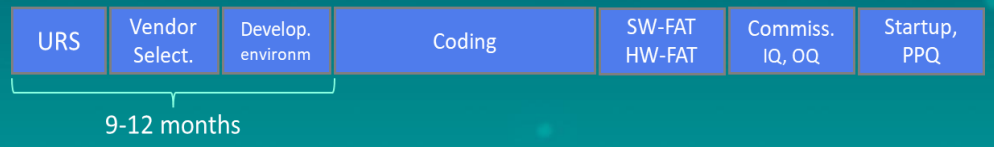
Modular production leads to modularization of assets
perfectly embracing discrete and process modules

Automation today

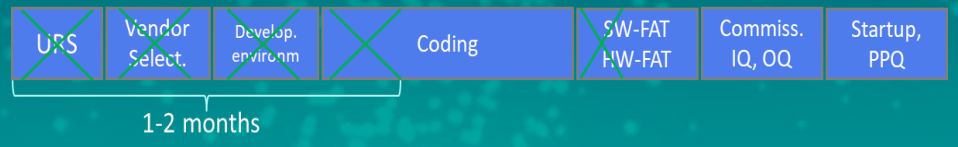
1. **Manual interconnection** and integration of process equipment
2. **Proprietary** SW interfaces
3. Different **pre-engineered** communication channels
4. **Manual engineering** of process sequence
5. **Centralized** large-scale controllers





Future of automation

1. **Modules** with defined physical interfaces
2. **SW interfaces** based on **standardized semantics** (data structures, services, etc.)
3. **Open** and flexible **connectivity frameworks**
4. **Orchestration** of modules via services
5. **Decentralized intelligence:** Modules/components with small controllers



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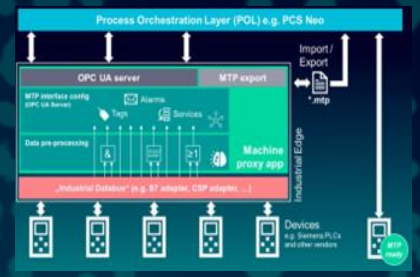
Future flexible and modular operations must embrace a holistic approach in order to accelerate new product introduction (NPI) and enable “Click and Produce”

	From		To	
Modular Control System	Monolithic Control System		Distributed Orchestration Layer	
Process Equipment	Super Skid		Modular Process Equipment	
Scalable and expandable operations	Large Production Sites		New Manufacturing Ecosystems	

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Container-based modular facilities that provide maximum flexibility thanks to a “Factory in a box” concept, co-created with partners like Exyte, G-CON & BioNTech

- **Highly flexible** plant design from **standard** building blocks
- **Adaptable** to any process layout
- **Ballroom layout** ready
- 50% **faster** time-to-market

- Process equipment layout is the starting point, not the “box”
- Flexible layout & flexible height to enable “ballrooms”
- Expandable in phases
- Equipment Vendor independent, designed with process-focus

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Driving our Focus Topics with our key customers through co-creation

- Flexibility
- Speed
- Quality
- Sustainability
- Efficiency

Digital Twin & Simulation

Paperless Manufacturing

Smart Biopharma

Continuous Manufacturing

Cell / Gene Therapy & Personalized

Integrated Engineering

Integrated OEM & Secondary Lines

IIOT, Cloud & Edge

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And what about Digital Transformation?

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Digital transformations is not easy, and industry is still waiting on an easy digitalization concept

63%

of digitalization projects fail!

Digitalization challenges

86% have avoided critical projects due to complexity of legacy systems

45% don't know where to begin to adopt IoT

40% struggle to find digital partners with experience in their industry

1 2018 Chaos report Standish Group | **2** Harvard Business review Study | **3** Logica Management Consulting and the Economist Intelligence Study

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Most digital transformations fail, but the world is still waiting on an easy digitalization concept

Digitalization challenges

86% have avoided critical projects due to complexity of legacy systems

45% don't know where to begin to adopt IoT

40% struggle to find digital partners with experience in their industry

Key to success

Easy — Simple access to the latest technologies that are easy to integrate, adopt, and build upon

Flexible — Modular and interoperable concept to pick products, solutions, and services throughout the entire lifecycle

Open Eco-system — Ecosystem bringing together best-in-class players across the market

Sources: The Forrester Wave: Global IoT Services for Connected Business Operations, Harvard Business Analytic Services Internet of Things Report for Siemens

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A new way is needed …

Siemens Xcelerator open digital business platform

Digital transformation made easy, flexible and open

Easy

simple to access the latest technologies that are easy to integrate and adopt and that can be built upon and combined

Flexible

a modular and interoperable offering, where you can pick what products, solutions and services you need

Open

an open ecosystem bringing together the best-in-class players in the market and open technology providing digital and IoT-enabled offerings from Siemens, partners and third parties

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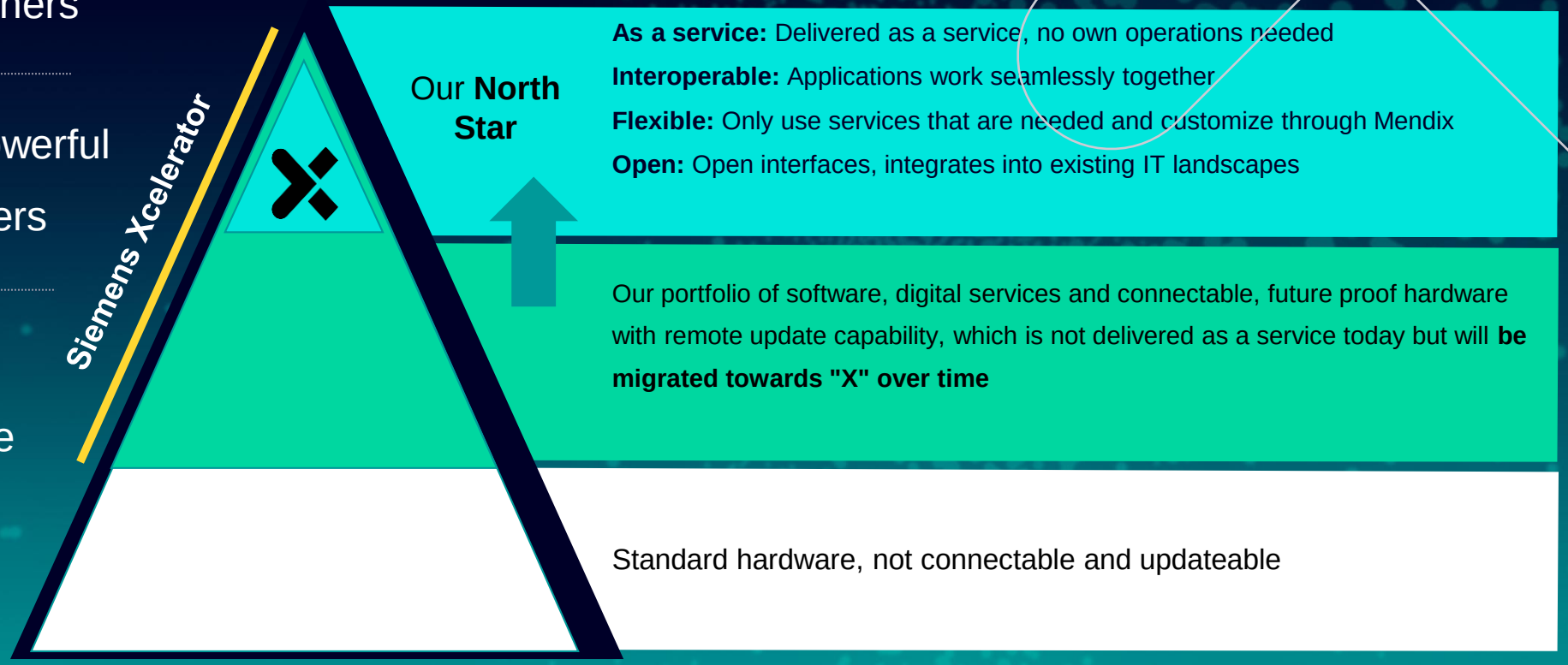
XCELERATOR

Introducing Siemens Xcelerator

A comprehensive, curated **portfolio** that includes digital and IoT-enabled offerings from Siemens, and certified partners

A continuously growing, powerful **ecosystem** of partners

A **marketplace** to explore, educate, exchange and transact alongside a community of customers, partners and experts



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Unique requirements of pharma and life science industry require new approach and unique solutions from the lab to manufacturing

EASY FLEXIBLE OPEN

Safety & Security
Prevent cross-contamination in cleanrooms with integrated security.

Fume Exhaust Controls
Optimize energy usage when fume hood is not in use and monitor contaminants within the critical environment space.

Asset tracking
Locate research and manufacturing equipment quickly and easily.

Improve batch review & release times
Control, monitor and record processes in real-time to enable paperless and continuous manufacturing

End to End Traceability
Ensure products are safe and genuine throughout the manufacturing and supply chain lifecycle

Smart Air Quality
Maintain healthy environment conditions to protect occupants & valuable research.

End-to-end data management
Connect from sensor to edge and to cloud to bring together OT & IT and provide intelligence for data-driven decision making

Lab and Pressurized Room Control
Optimize lab room conditions and airflow to ensure safe, compliant and efficient operations.

Improved Process Understanding
Use simulation software and digital twins to enhance process understanding and improve efficiency

Smart workspace solutions
Check availability and book labs or workspaces on the go or improve orientation and find co-workers with the navigation app.

Enterprise Recipe Management
Share knowledge and data across the entire organization, from R&D to manufacturing, to enable recipe transfer and tech transfer and break down silos

Manufacturing flexibility & optimization
Use modular solutions to improve efficiency and plug and play different equipment in multi-product facilities

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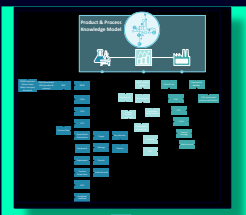
ENTERPRISE RECIPE MANAGEMENT

Share knowledge and data across the entire organization, from R&D to manufacturing, to enable recipe transfer and tech transfer and break down silos

Drug Discovery | Formulation Design | Process/Product Development | Tech Transfer | Drug Substance Manufacturing (API) | Drug Product Manufacturing (Secondary)



Backbone for a Knowledge Model, for the orchestration and workflow management along the whole lifecycle of a product supporting the drug development and optimization process

Recipe

Experiments

Simulation

Formula & LIMS

Modeling

Further tasks

Engineering

3rd-party authoring system

Siemens product as authoring system

Connectors

Connection between authoring system and backbone

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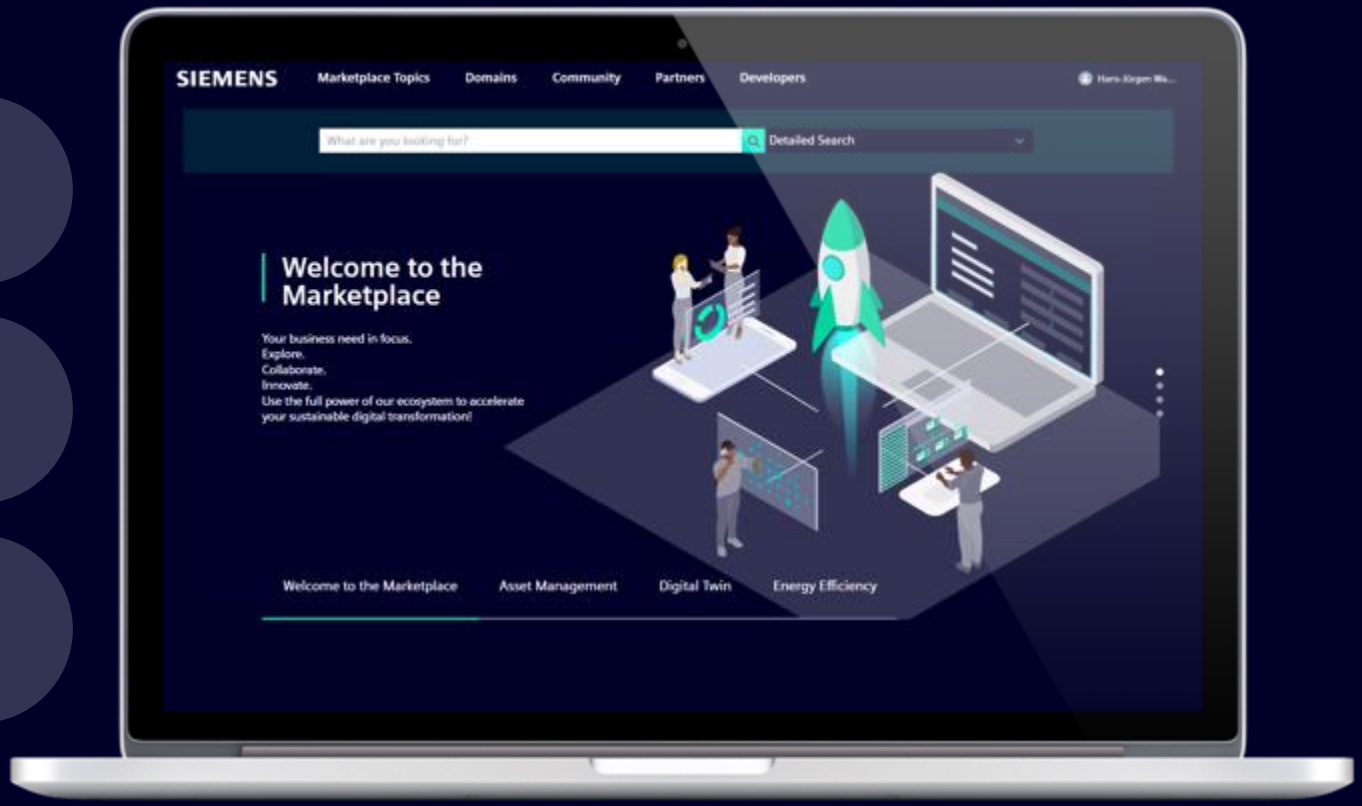
Join us and Xcelerate your digital transformation

Join the marketplace

Explore the communities and engage with experts

Let's Xcelerate your digital transformation



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