

| Siemens in Pharma

Mid-Level Presentation



Win the race against time

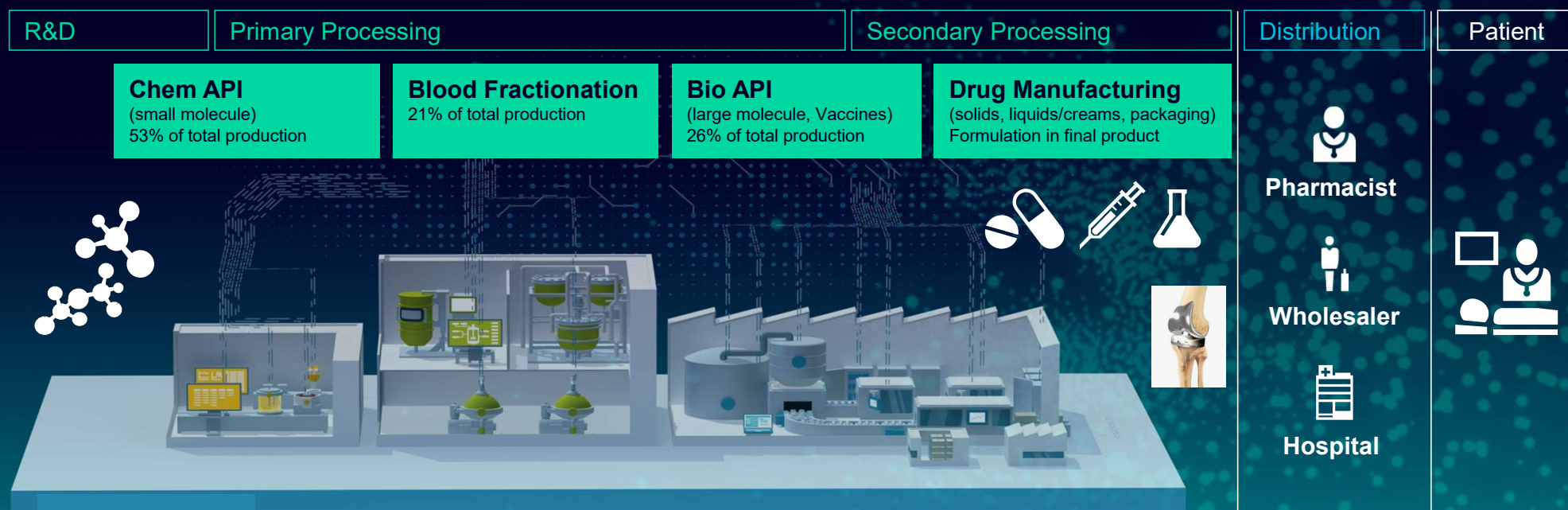
<https://youtu.be/tTAAgOatgml>

<https://youtu.be/tTAAgOatgml>

It's a race against time

Siemens provides End-to-End Solutions to the Pharma Industry

Closing the Gap between R&D and Primary & Secondary Manufacturing



Corporate/
Global
Accounts



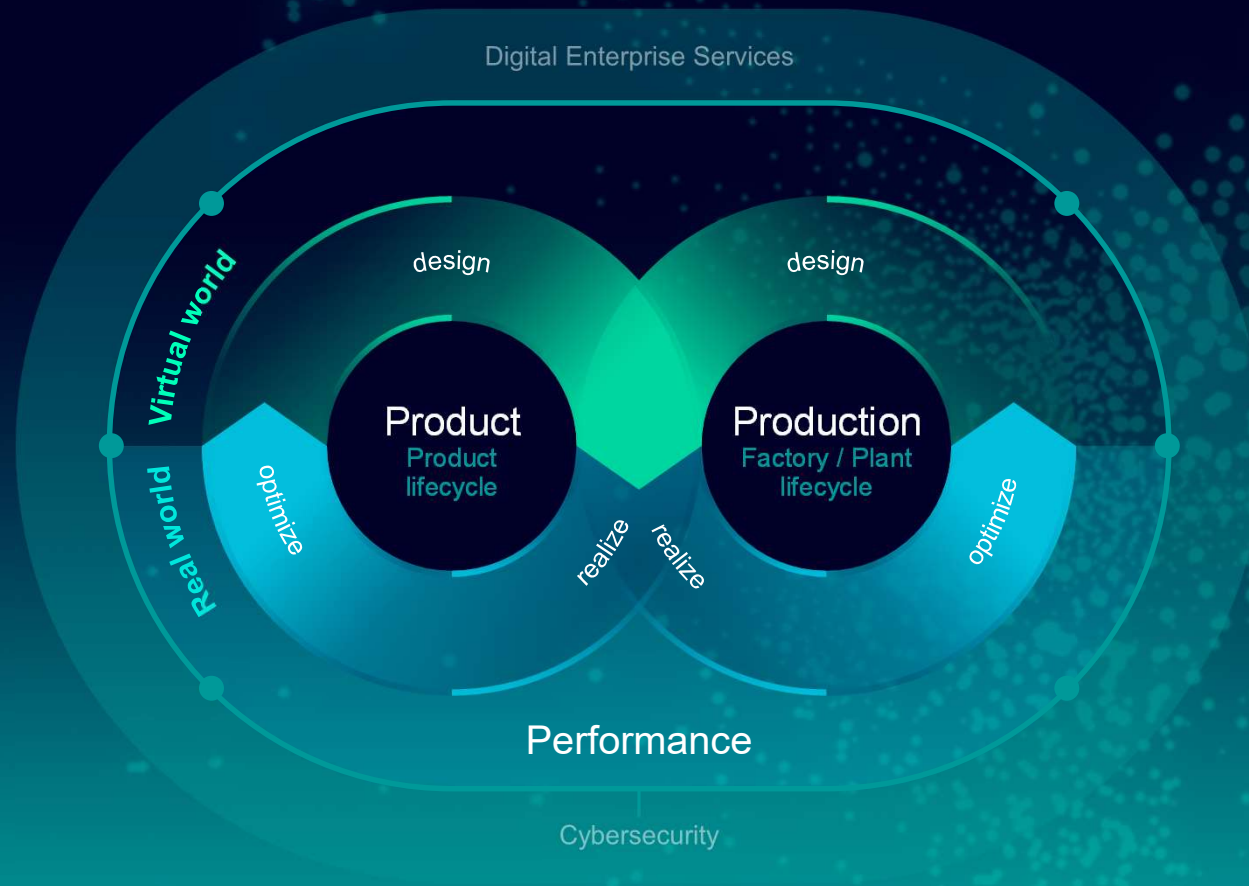
Strategic
Initiatives



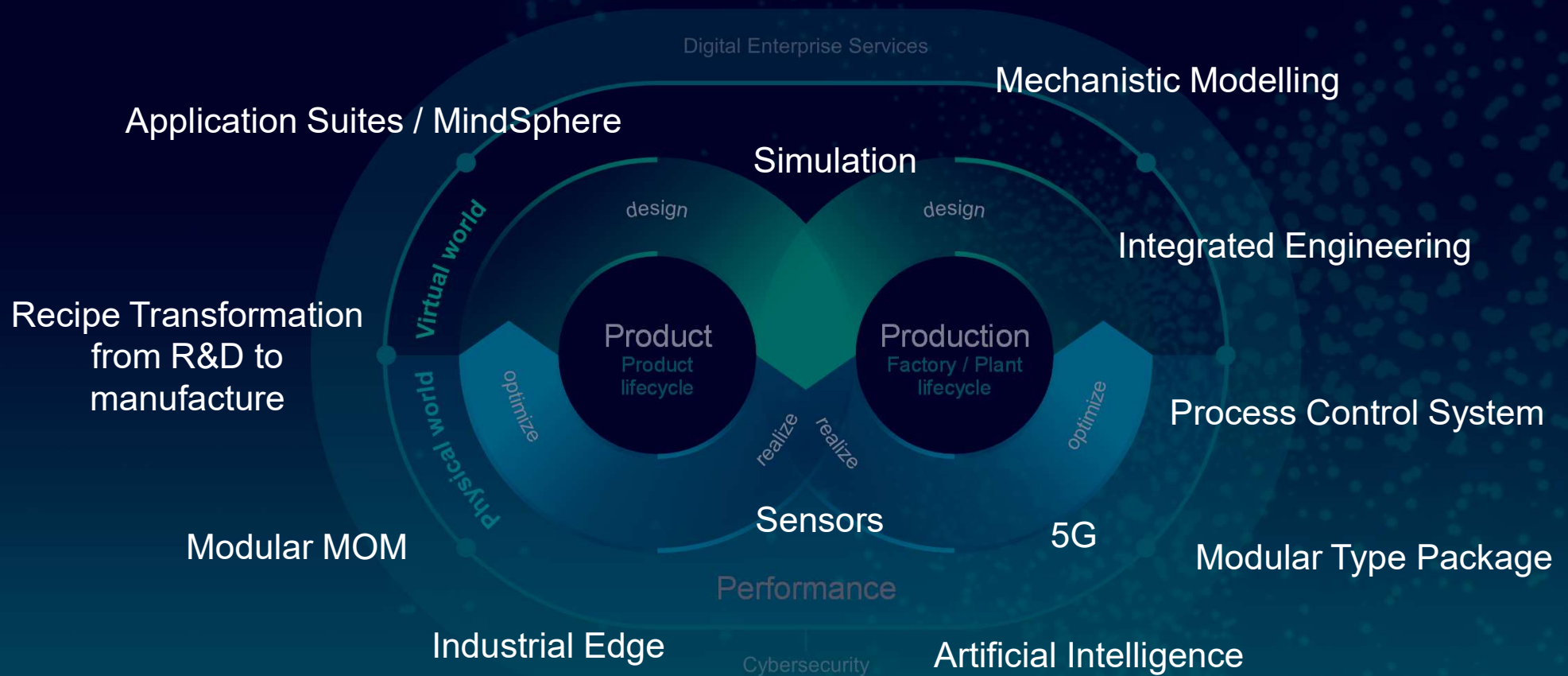
Global
Networks



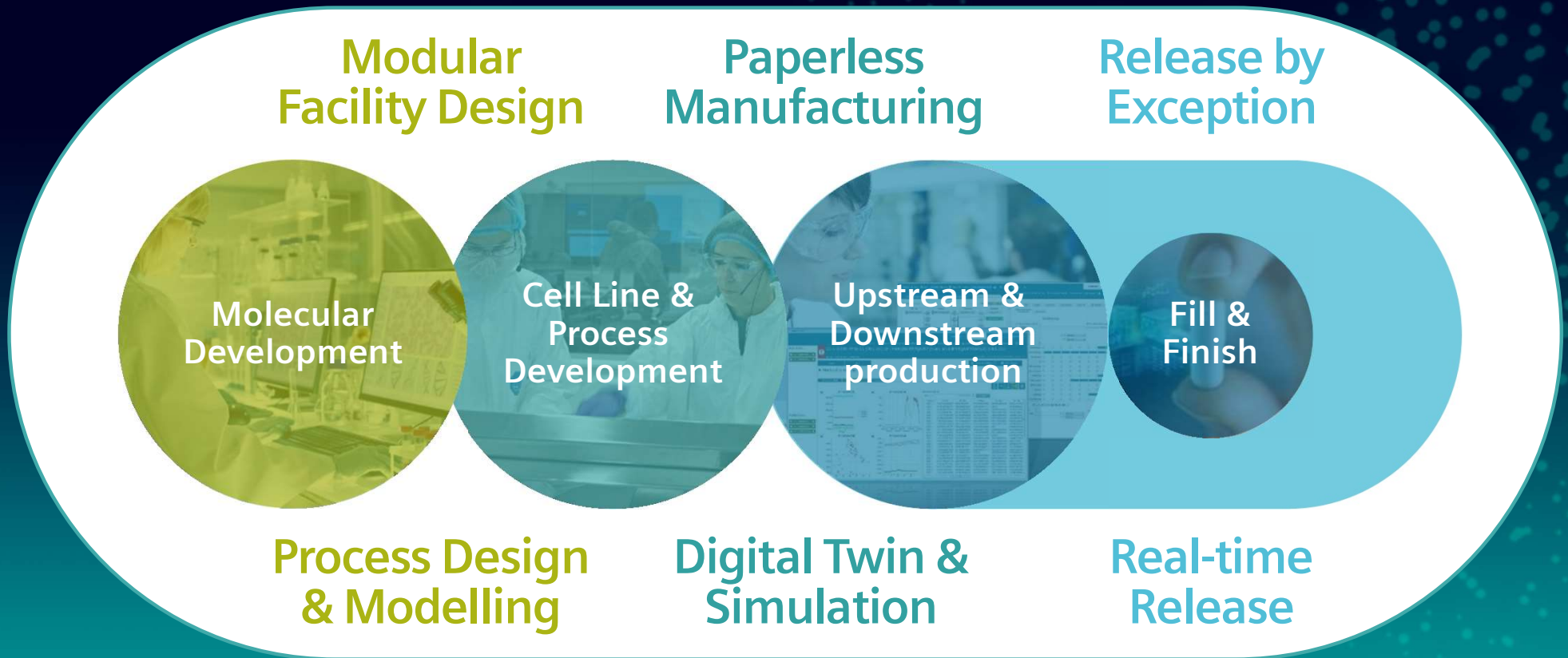
Combining the real and the digital worlds with the comprehensive Digital Twin



Combining the real and the digital worlds with the comprehensive Digital Twin



Concepts that accelerate development and manufacturing of pharmaceutical products through the value chain



Digital Transformation in Pharmaceutical & Life Science

.... a comprehensive digital portfolio from Siemens

Design & simulate products & processes

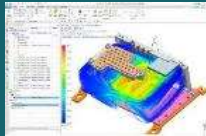
Mechanistic
Modelling

gPROMS



3d Material
Simulation

SimCenter



Product
Lifecycle
Management

TeamCenter



Quality by
Design

SIPAT



Plan, simulate, predict and optimize production

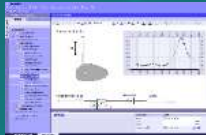
Integrated
Plant
Engineering

Comos



Operator
Training
(OTS)

SIMIT



Plant Design
& Layout

Tecnomatix



Machine
Design

Nx



Run production efficiently and securely

Electronic
Batch
Recording

OpCenter



Dashboarding

Mendix / XHQ



Automation
& Control

PCS 7 / TIA Portal



Transparent
Operation &
Analytics

Indust. Edge / BioMAC



Operate and monitor building infrastructure

Integrated Building
Management
Platform

Desigo CC



Integrated Security
for Critical
Infrastructure

Siveillance



Plant & Room
Automation,
Field Devices

PX, DX, Symaro



Fire Protection
Systems

Sinteso





Harleysville

We develop our vision
with a strong global
organization of pharma
experts, together with
our strategic partners

Global Pharma Hub

Pharma HQ

São Paulo

Mumbai

Singapore

Shanghai

Market Trends & Business Drivers



Patients

Market Growth

- Global demand for biologics
- Patient centric healthcare
- Patient data transparency
- Affordability



Products

New Therapies

- New drug delivery methods
- Manufacturing challenges
- Tech transfer



Pace of Change

Uncertainty

- Pace of tech development
- Supply chain complexity
- Lack of guaranteed success for new products



Performance

Pressure to Deliver

- Operational excellence
- Cost pressure, outsourcing
- International collaboration



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

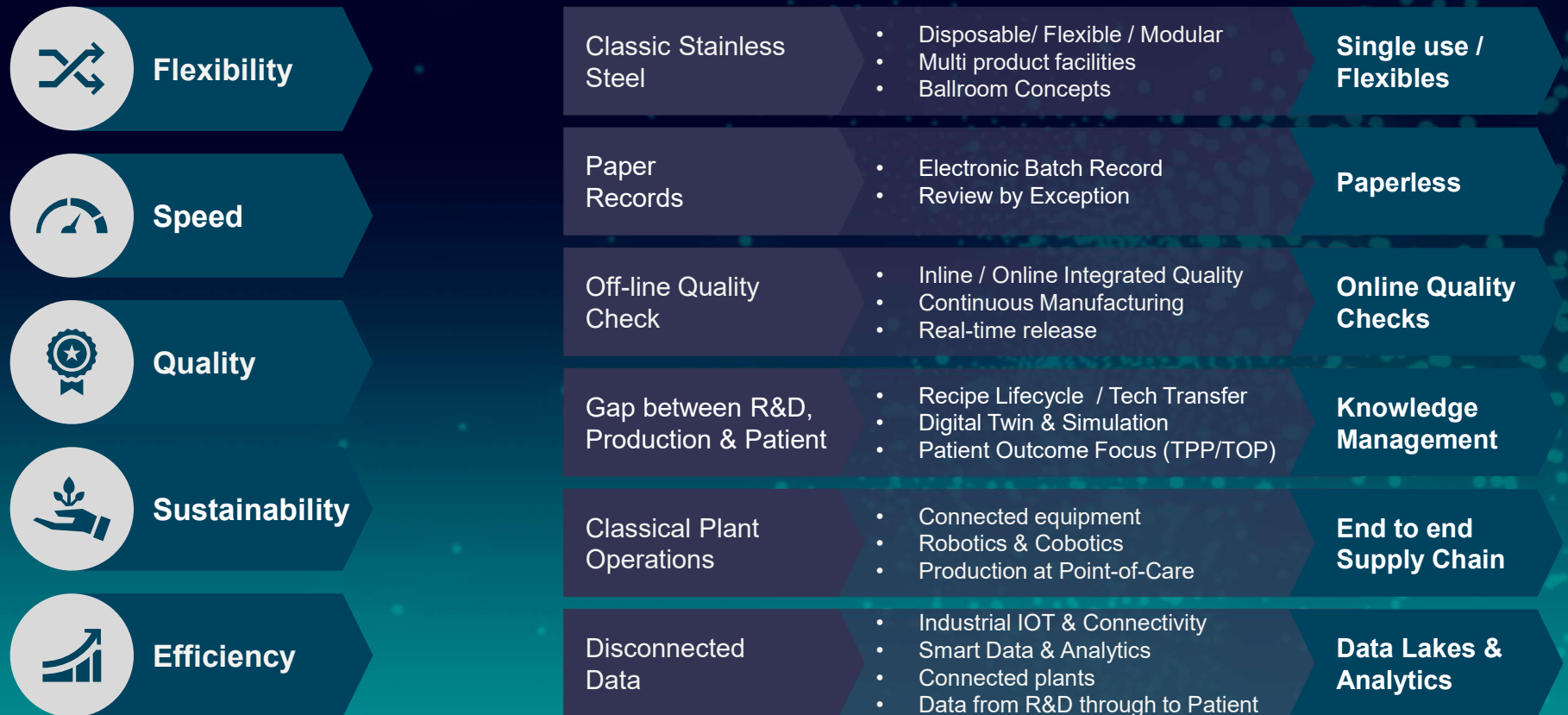


Efficiency

- Lower waste
- Improved productivity
- Improve equipment utilization

Source : www.biophorum.com

Manufacturing Transformation driving Focus Topics



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



Flexibility



Speed



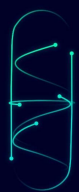
Quality



Sustainability



Efficiency



**Digital Twin &
Simulation**



**Paperless
Manufacturing**



**Smart
Biopharma**



**Continuous
Manufacturing**



**Cell / Gene Therapy
& Personalized**



**Integrated
Engineering**



**Integrated OEM &
Secondary Lines**



**IIOT, Cloud
& Edge**

DIGITAL TWIN AND SIMULATION

Digital twins to win the race against time

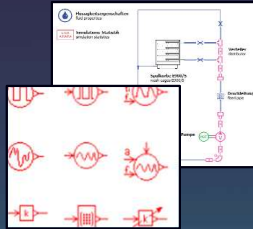


The Digital Twin

Different Tools for Creating Different Digital Twins

...to discover better designs,
optimized process, faster.

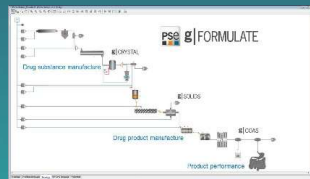
1D Controls
...ready-to-use multi-
physics libraries combined
with application



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

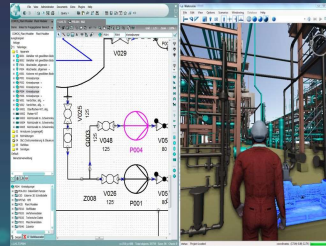


1st principle
mechanistic models,
flow sheet modeling &
process design

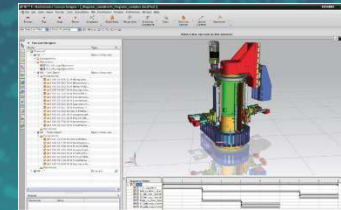


...to engineer faster,
for virtual commissioning and
Operator Training.

Digital twin
process plant and OTS



Mechatronic Concept
Designer
for machine building
and
virtual commissioning



Process Simulation
& virtual controller

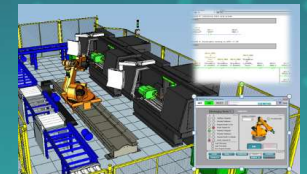


...to optimize
operations.

Simulate material and
logistics flow in
operational factory



Production Cells
Cobots simulation





Transforming pharma industry

**Digital twins accelerate
vaccine development**

Shorter vaccine
development process

Less waste
of raw materials



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Digital Process Twin

Benefits of the Digital Twin

Integration of

PAT

Continuous monitoring



Data analytics

Integrate all available data



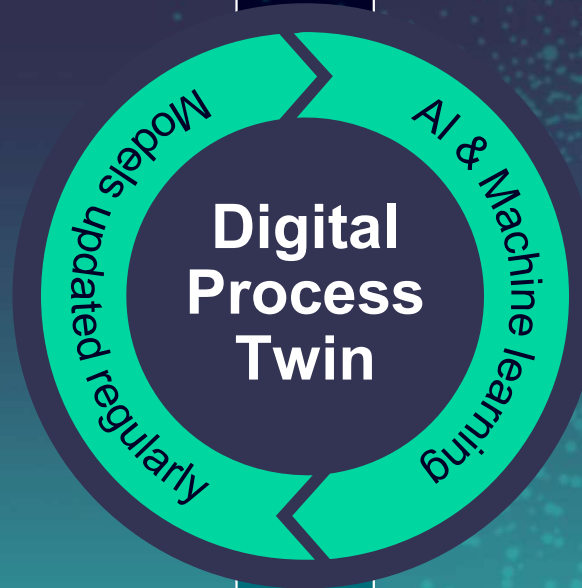
Process understanding

Models



Process control

Regulation and automation



To enable

Adaptive control
Golden Batch/Production

Simulator
Faster dev. and Training

Close monitoring
Online release

Digitalization
Towards a full digital plant

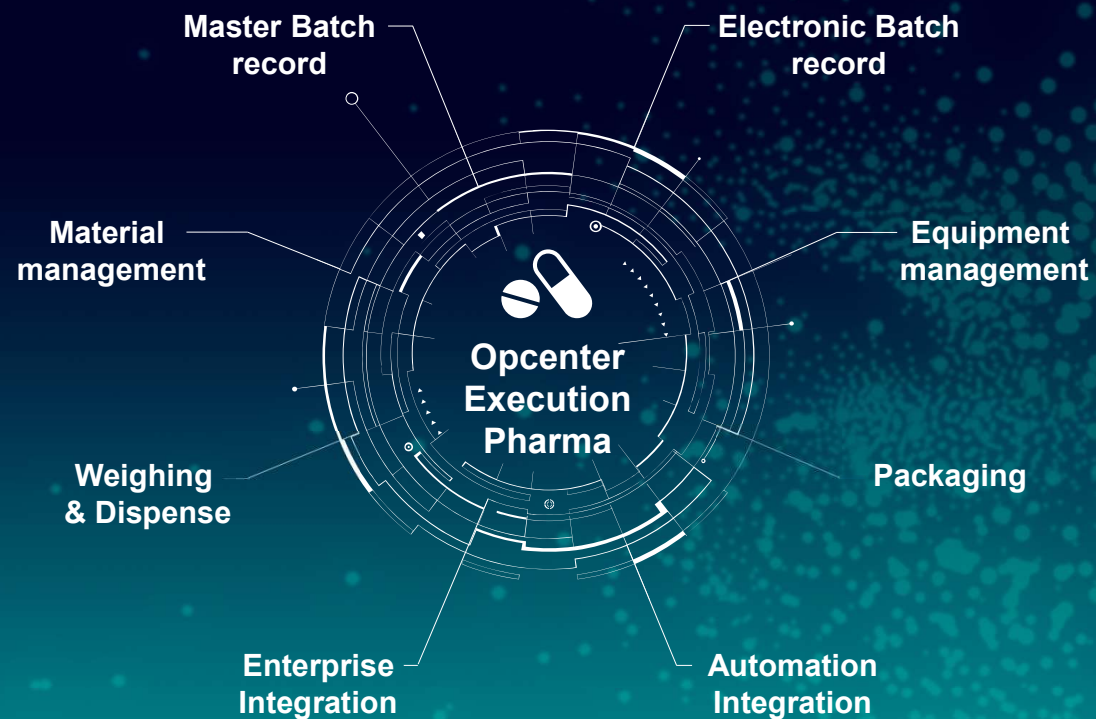


PAPERLESS MANUFACTURING

The platform to win the race against time

Paperless Manufacturing

Driven by Opcenter Execution Pharma





Portfolio Elements:

- Opcenter EX PH
- SIMATIC BATCH
- SIMATIC PCS 7
- SIMIT
- Weigh & Dispense
- Virtualization/SIVaas

Bayer

Modernization of large scale tablet production Bitterfeld, Germany

Guarantee plant uptime for years to come

One face to the customer for MES, DCS, Cybersecurity, Network, Virtualization

Uniform, comprehensive & integrated standard solution

Quicker batch release thanks to review by exception concept

Long term support & Lifecycle Service Contract

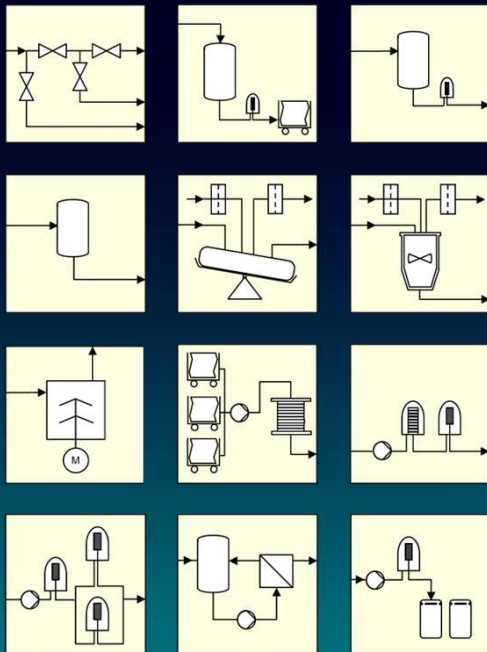
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SMART BIO

Flexibility to win the race against time

Modularization of BioProcess Equipment Single use and Mobile Equipment



Source: Sartorius

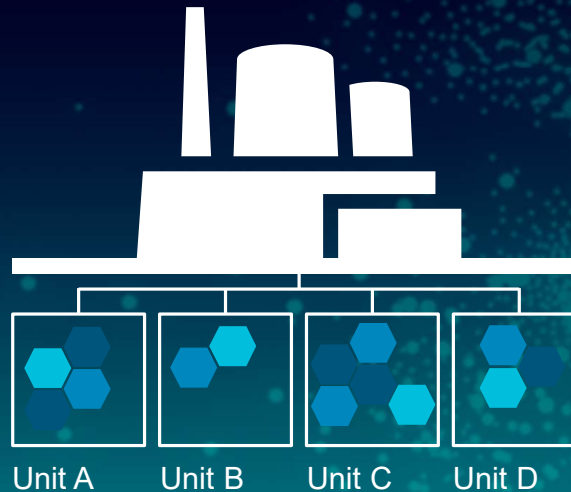
Modular Production with Module Type Package (MTP)

Challenges

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



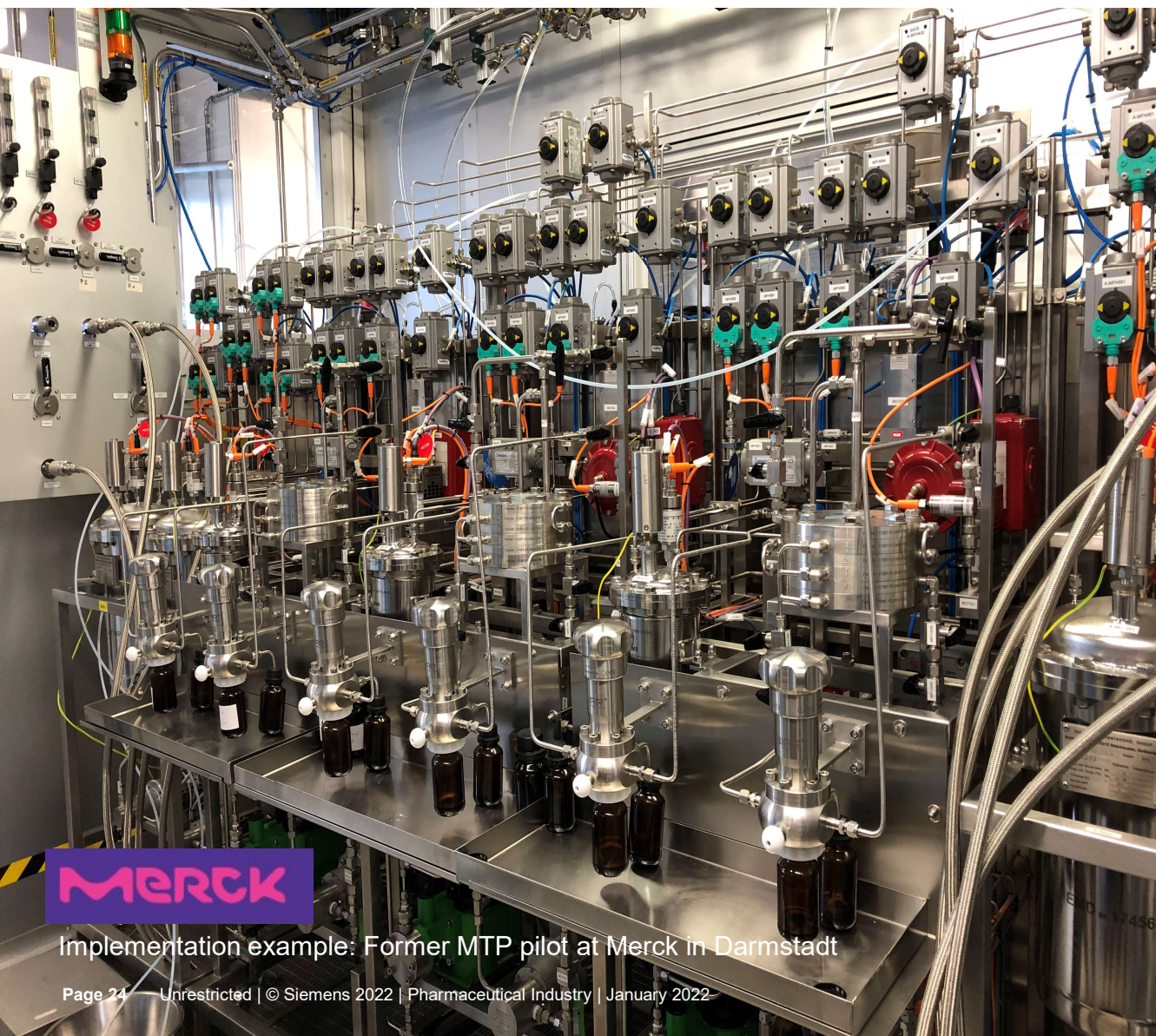
“Modular Production”



Benefits

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





Implementation example: Former MTP pilot at Merck in Darmstadt

Page 24 | Unrestricted | © Siemens 2022 | Pharmaceutical Industry | January 2022

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

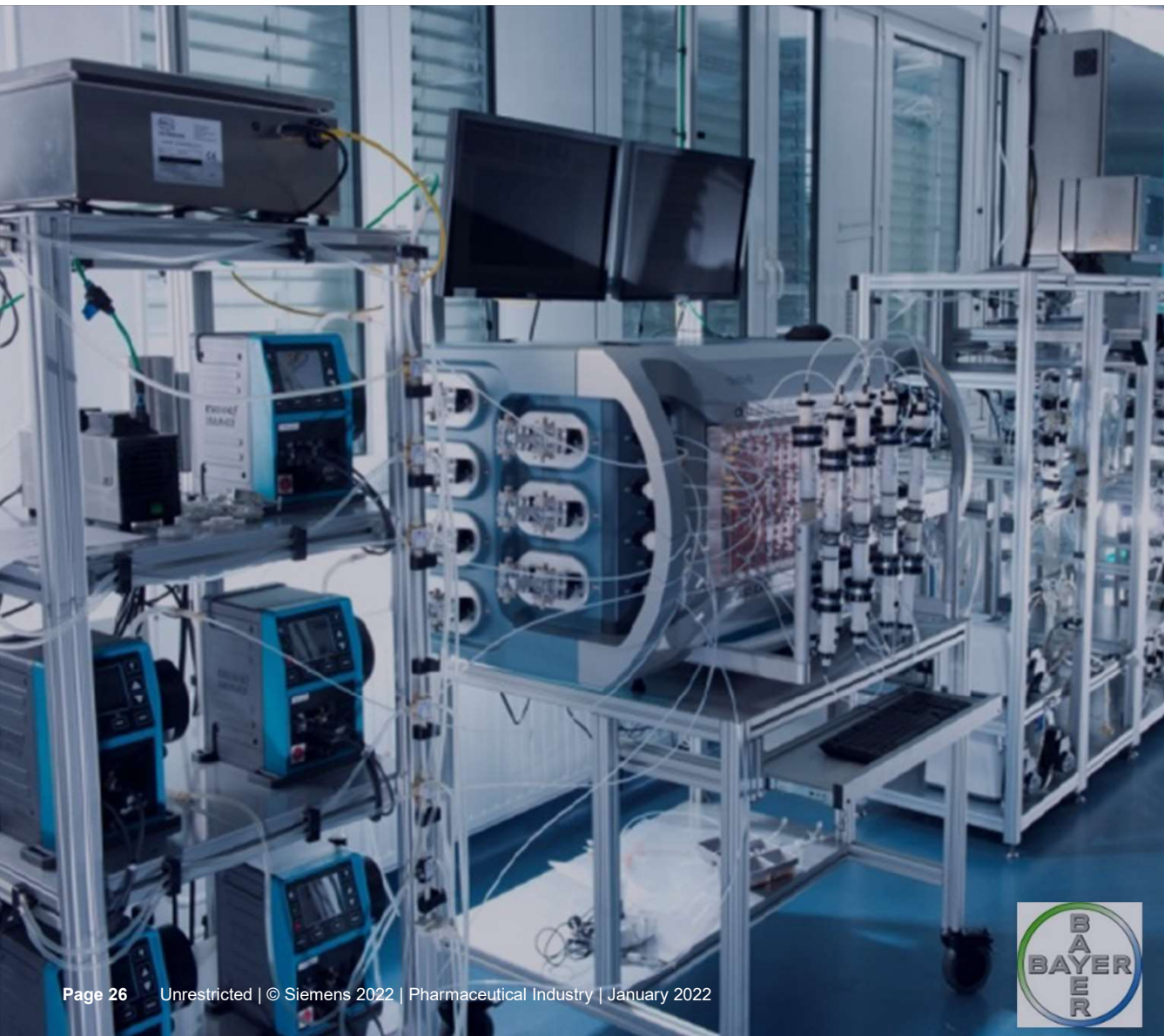
Eliminate programming & reduce
engineering efforts

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CONTINUOUS MANUFACTURING

Real-time release to win the race against time



Bayer Mobidik Project
Continuous Bioprocessing

Germany

Real-time monitoring of protein
concentration

Upstream & Downstream

Feasibility study within the Wi-Pro
consortium



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AstraZeneca

Real-time integrated Quality Management on a conti tableting line in R&D

Gothenburg (Sweden)

Accelerating process development
by inline quality management on a
conti process

PAT Data Management Platform as
cornerstone for integrated control
strategies on batch & continuous
processes in R&D and
Manufacturing

SIMATIC SIPAT as corporate
standard within AstraZeneca

SIEMENS



PERSONALIZED MEDICINE

Individualized production to win the race against time



Towards Individualized Production

Advanced paperless manufacturing

Provide Individualized Vaccines against Cancer at an affordable cost

Eliminate paper documentation & manage significant amounts of data

Build a robust, reliable and repeatable process that includes software, automation and robotics



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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IIOT, CLOUD AND EDGE

Big data to
**win the race
against time**





INTEGRATED ENGINEERING

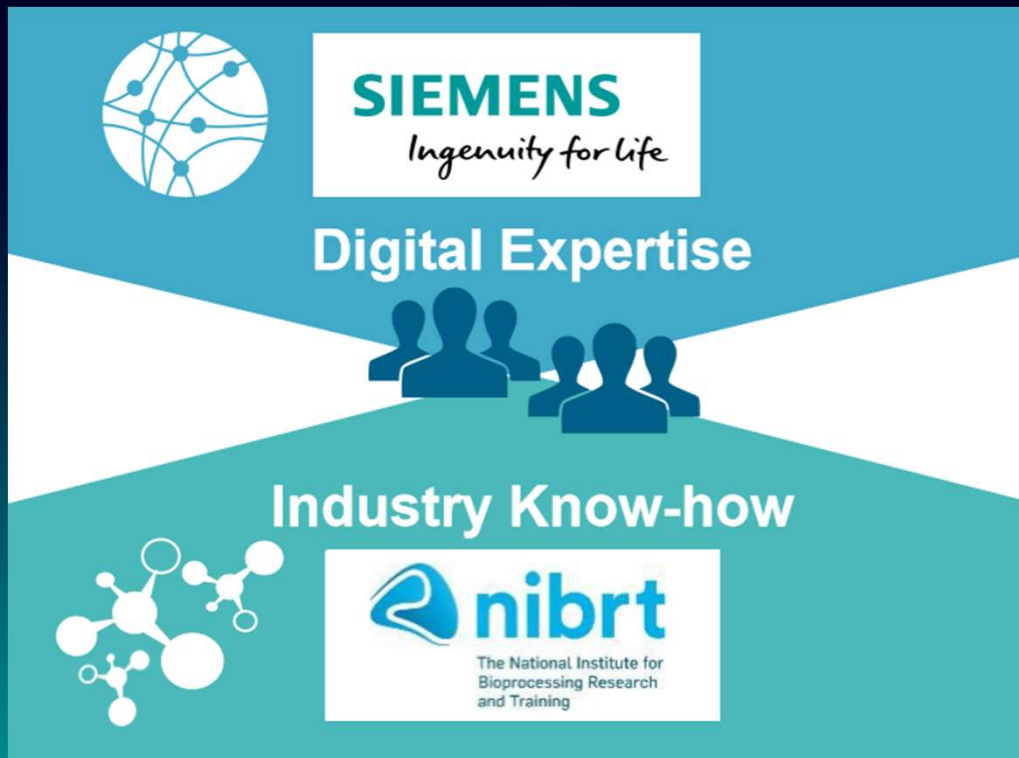
Collaboration to win the race against time



INTEGRATED SECONDARY LINES

Connected equipment to win the race against time

BioMAC: Collaboration focused on data analytics to support biopharmaceutical manufacturing

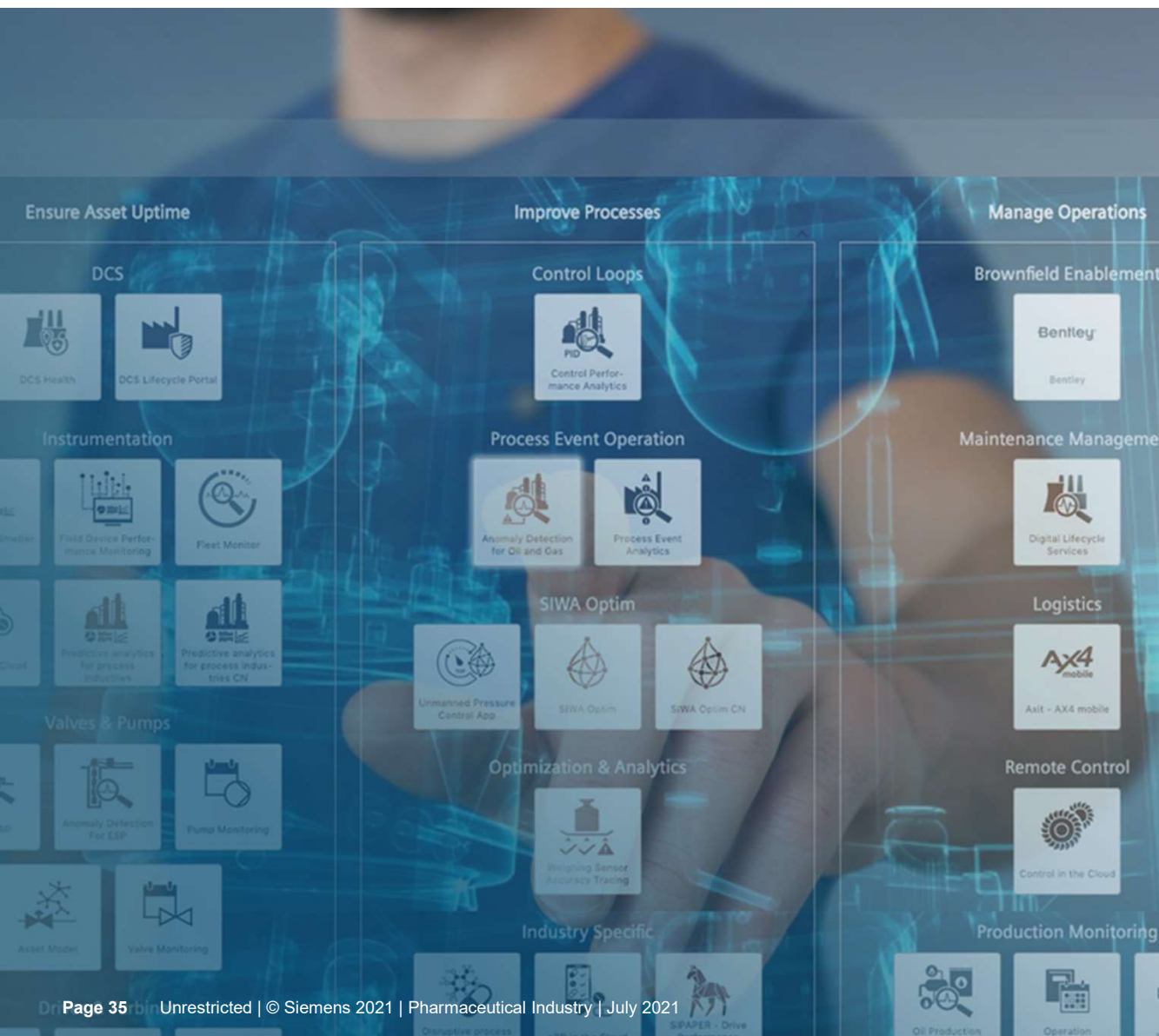


Siemens

focuses on data collection, infrastructure development, engineering and deployment of a framework for advanced analytics

nibrt

focuses on applying advanced data analytics, modelling, machine learning and artificial intelligence to large and complex bioprocess data sets



Leading Biopharma Company Data Analytics for Increased Yield BioMac, Ireland

Consolidate Historical Data

On-demand analytics,
visualization, reporting

Enhanced Process
Understanding

SIEMENS

Driving our focus topics with our key customers through co-creation



Digital Twin

Digital twins accelerate vaccine development

- Shorter vaccine development process
- Less waste of raw materials

Speed up Production

Fast-Track COVID-19 production

- Accelerate production for Covid-19 vaccine with Siemens automation and digitalization solutions
- Purpose a vaccines plant in less than half of the planned time
- Project engineering, implementation and 24/7 ongoing support

Modular Production

Enhance flexibility and time to market

- Fast product changes to successfully respond to market conditions
- Modularization to flexibly and efficiently adapt plants to new market demands
- Modular automation based on Module Type Packages (MTP)
- Implementation of Process Orchestration Layer (POL)

Living Lab Vienna

Integrated Siemens portfolio based on a real fermentation process



Siemens – partner for industry in the digital transformation

Portfolio

Providing all the tools to overcome data silos in the virtual and real world

Consulting

Making sure our customers' way toward digital transformation is the right one

Implementation

Helping customers implement and optimize the digital enterprise

Optimization

Continuous improvement by analyzing ongoing operations

Winning the Race against Time

How Siemens supports its Pharma Customers

Mission

The Pharma vertical provides the answers to the industry's toughest questions and puts customer and patient benefits at the center of Siemens Technology

Vision

Be the #1 trusted partner in Pharma, capable to digitalize all operations from R&D to manufacturing by fostering innovation, by delivering what we promise and by being an attractive employer for the best global talents, so that our customers can do what matters:

Develop and produce new medicines faster and cheaper



WIN THE RACE AGAINST TIME

Bringing the Vision to Life
Key Components of Digitalization

Use **Simulation** to
achieve foresight
in the Virtual
World

Use **Big Data
Analytics** to
gain insight
and drive
continuous
improvement

Drive intra-company and
supplier **collaboration** via data
integration

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