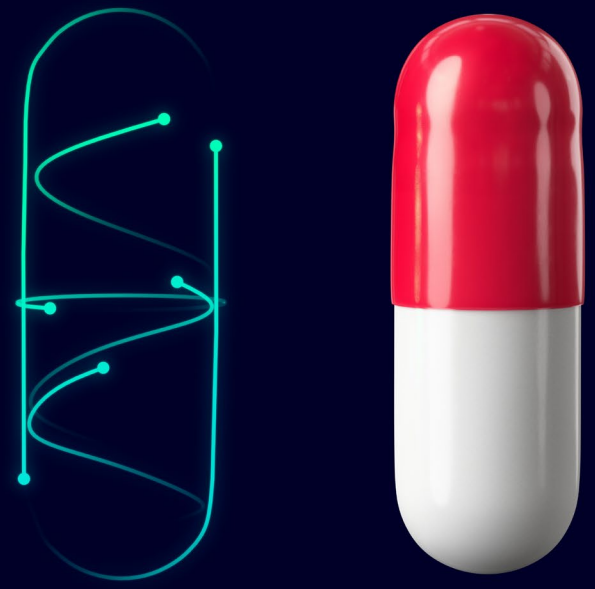


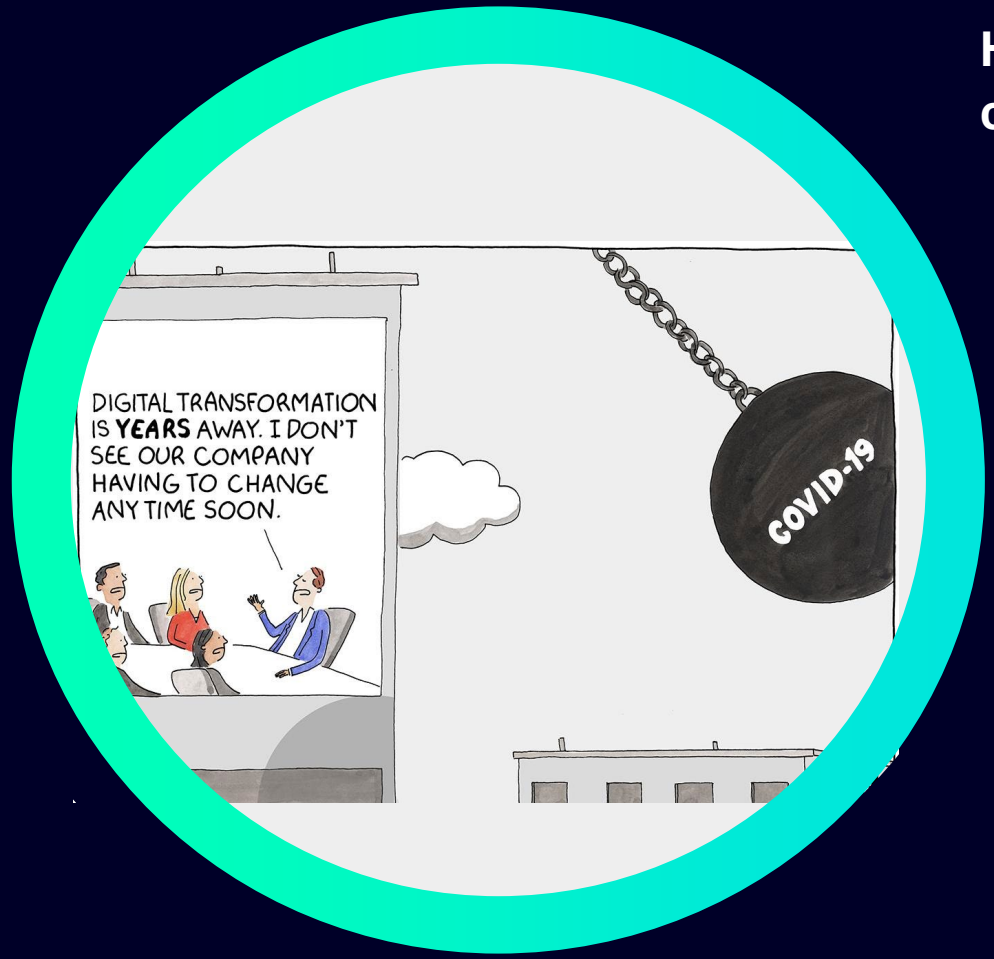
Technology to empower Indian Pharma Industry to meet “Vision 2030“

Umesh Sathe

SIEMENS

Has the pandemic uncovered “needs” that the industry had but didn’t focus on?

The pandemic has had an undoubted impact on the pharmaceutical industry



How has the industry changed?

What opportunities has the pandemic brought to our customers?

How has the whole pharma and life science ecosystem, including regulators, evolved?

Has the attitude to innovation, digitalization & technology changed?

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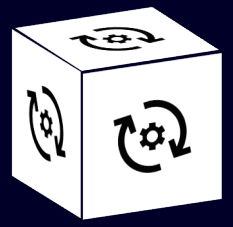
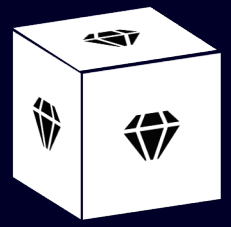
The multitude of challenges pharma companies are facing



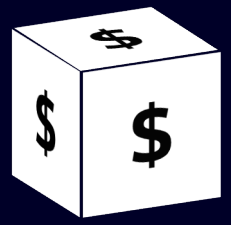
Uncertainties in R&D

- Long Development Cycle
- Complex and costly process
- Intellectual Property Protection



Quality Control & Regulator Compliance

- Document Management
- Validation
- Different Regulatory Authorities

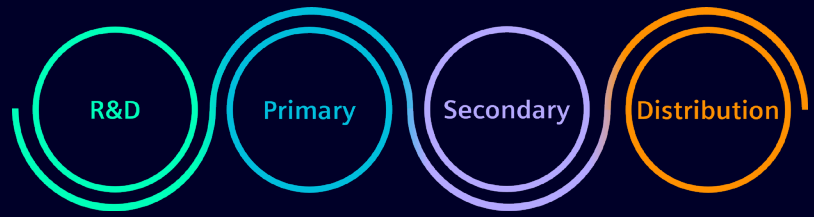


Cost Pressure

- Price erosion in Generic drugs
- Production Inefficiencies
- Scale-up

Time To Market

- First-to-File
- First-to-Market
- Market Disruptions
- Product Efficacy



It is necessary to **accelerate** and **scale the digital** and sustainable transformation. The need is to use “Technology with a Purpose” to fight these challenges.

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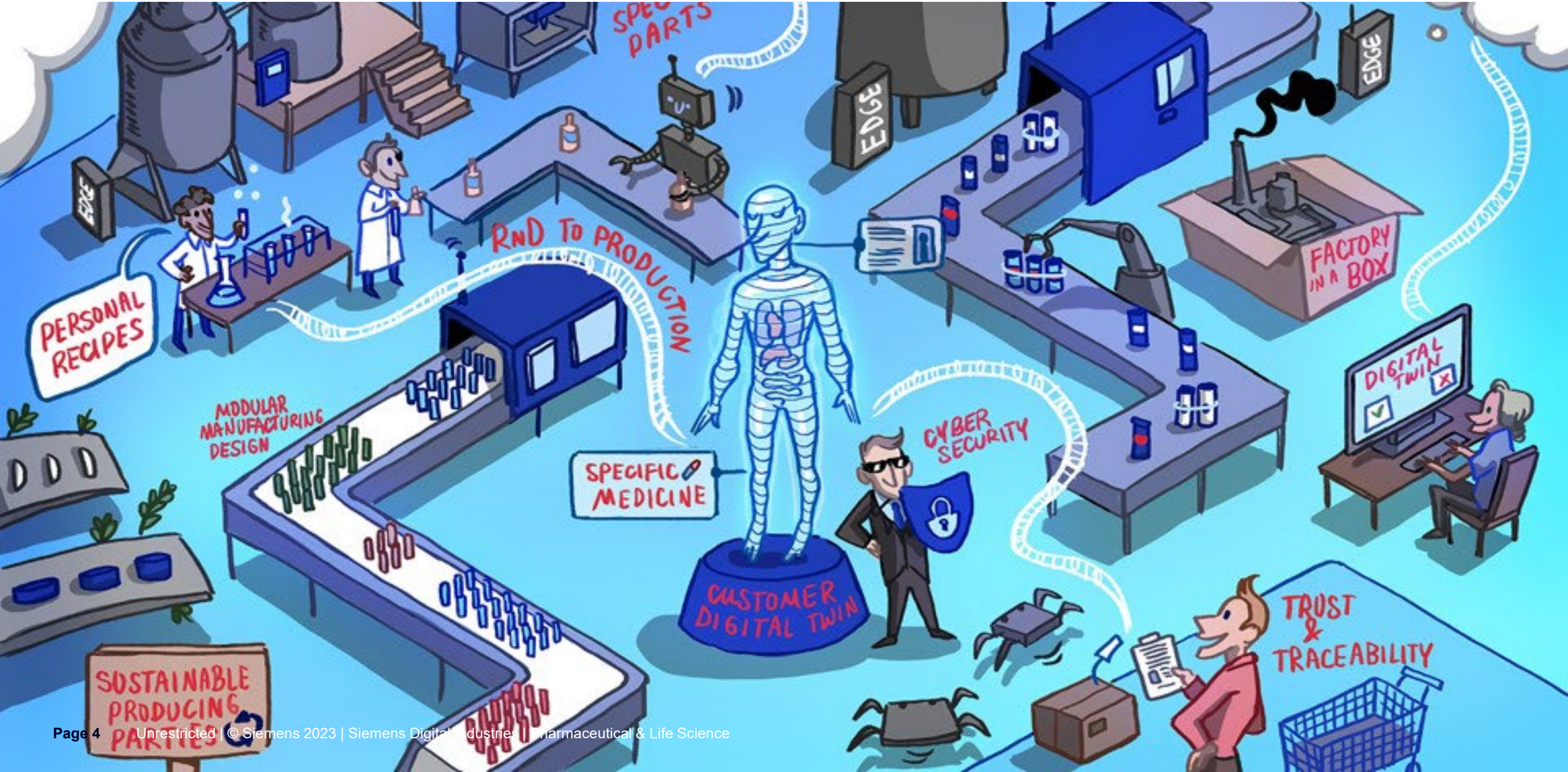
Accelerated R&D to Adaptive Manufacturing



DIGITAL TWIN AND SIMULATION in R&D

Speed to **win the race against time**

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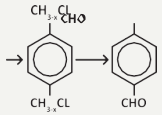
Accelerate R&D- Be the first to file

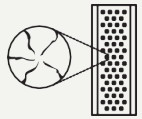
Our Science based modelling platform-gPROMS cuts down the need to do physical DOE's, improves accuracy

Accelerate process and product development and risk assessment

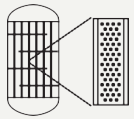
Data analysis, experiment design



Conceptual process design

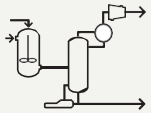


Understand phenomena

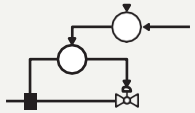


Detailed equipment design

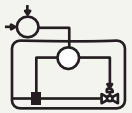
Process validation, tech transfer, and control strategy definition



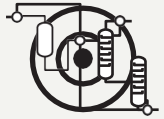
Scale up & tech transfer



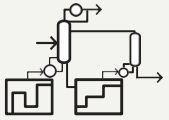
Control design & verification



Virtual commissioning



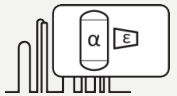
Process optimization



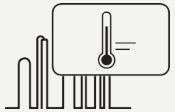
Operating policy

Operator training

Monitor, soft-sense, optimize real-time operation

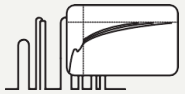


Long-term health monitoring



Soft sensing

Real-time optimization



Batch recipe optimization

Lot genealogy

Operations decision support

DIGITAL R&D **DIGITAL ENGINEERING (DESIGN)** **DIGITAL OPERATIONS**

Benefits using gPROMS in real Industrial case studies

Crystallization process modelling	**~50% decreased engineering time** **~30% increased plant availability**
Dry granulation and tableting process	**>3000 virtual experiments in a multi-dimensional design space**
Spray Drying	**~80% projected reduction thru experimentation**

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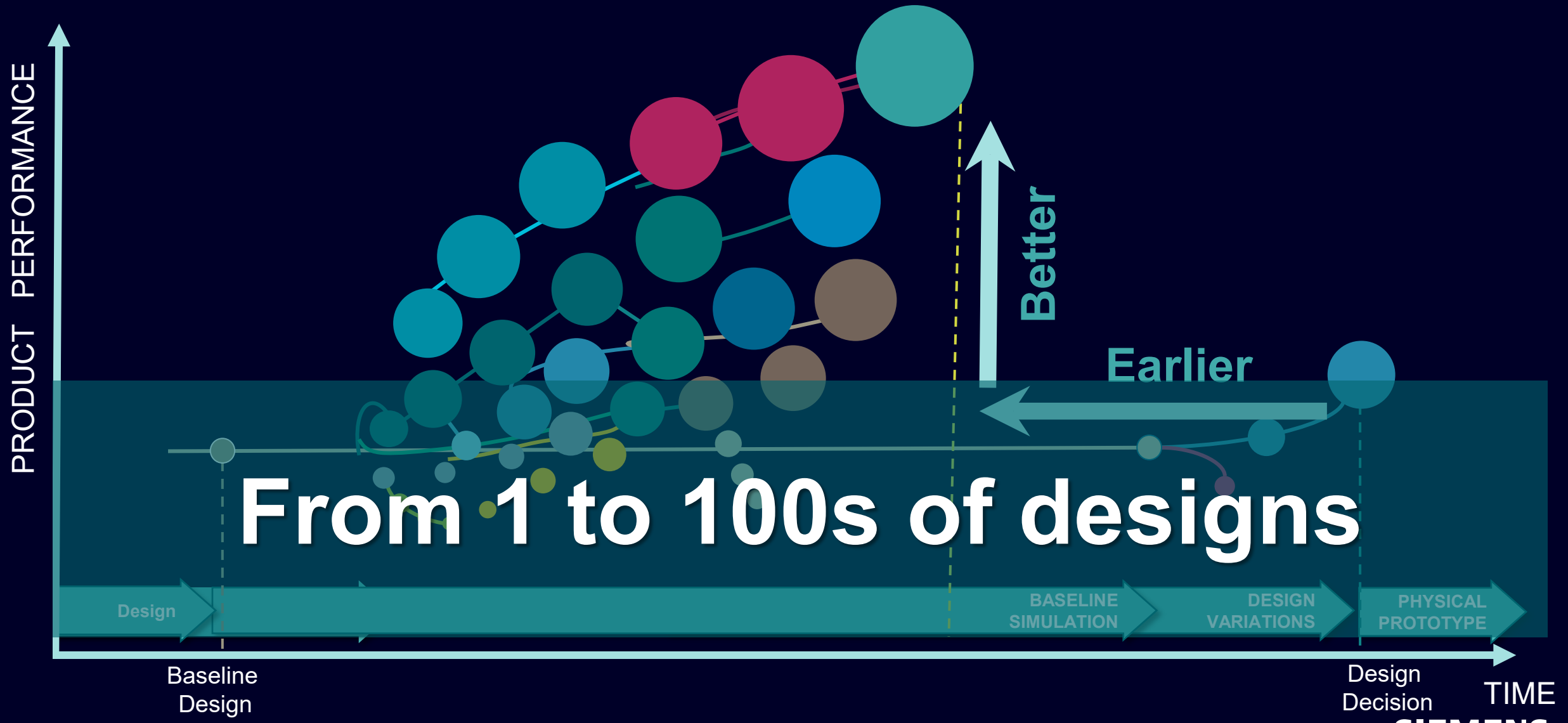
Source: OPPI 2020 annual report , CDCP, SBTi progress report 2021, biospectrumindia.com

Faster & better design with multiple automated simulations



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SMART Manufacturing

Adaptive manufacturing to **win the race against time**

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„Through the use of Digital Twins, faster, less wasteful, more cost-effective vaccine development and manufacturing is possible. Which ultimately helps improve the health of millions of people around the world"

Mott Harrison
Head of Sciences, Digital Innovations & Business Strategy in Vaccines, GSK

GSK

Improve yields & produce "Right first Time"

Digital Twins for development and production of adjuvant technologies

Powered by IoT, AI and Advanced Analytics

Real time capable model that has ability to predict adjuvant particle size

SIEMENS
Modelling and control expertise

+

Atos
Data science & UX knowledge

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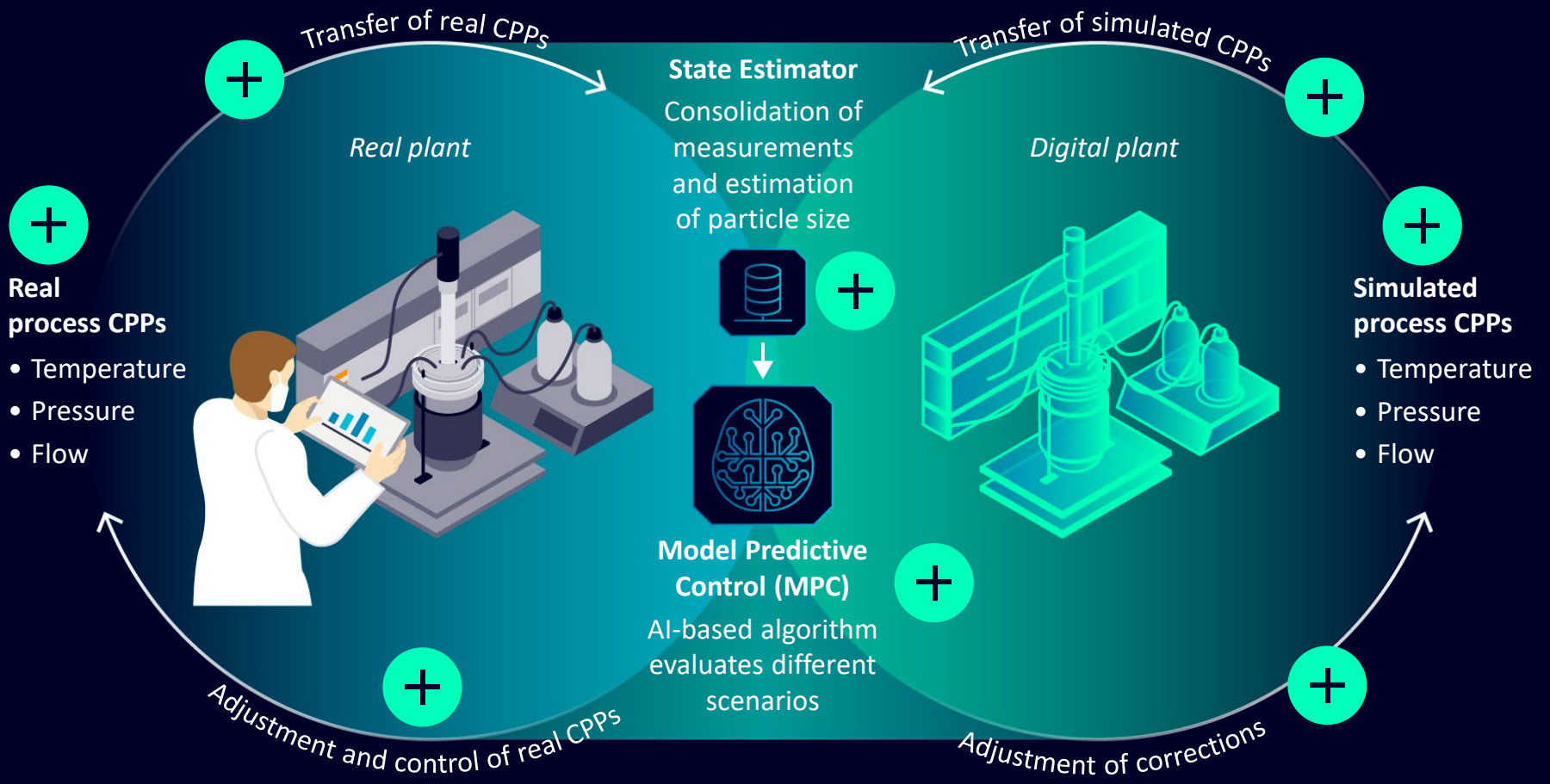
GSK Case Study - Digital twin in Liposomal Adjuvants
Reduced development time in R&D – Increased yield & quality in manufacturing



*CQA – critical quality attribute

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SMART Manufacturing

Intense manufacturing to **win the race against time**

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Process Intensification

Improve Operational Efficiency by applying innovative technologies in chemical reaction engineering and process design

Cost

- Reduce batch cycle time helping to insert
- Increasing the % yield.
- Reduce losses

Quality

- No more human intervention resulting in errors!
- Repeatable and consistent
- High accuracy

Safety

- Reduced human presence
- Safety interlocks inbuilt

Regulatory

- Repeatable consistency on attributes like %yield, batch cycle time
- Transparency of information
- Better understanding of process steps

With improved accuracy with the solution, it is able to bring more transparency in the system and increasing the productivity

The purpose of our Innovation cell is to solve your chronic manufacturing challenges.

Our use of process engineering, chemistry, control systems and digitalization knowledge is unique and allows us to develop indigenous innovations.

Our existing innovations on challenges in LLE, Crystallization and centrifuge are already benefiting Quality, yields and wastage.

We are keen to take on more of your long-standing chronic pains and eliminate them.

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SMART Manufacturing

Tying it all up- Ecosystem of COTS and co-created solutions

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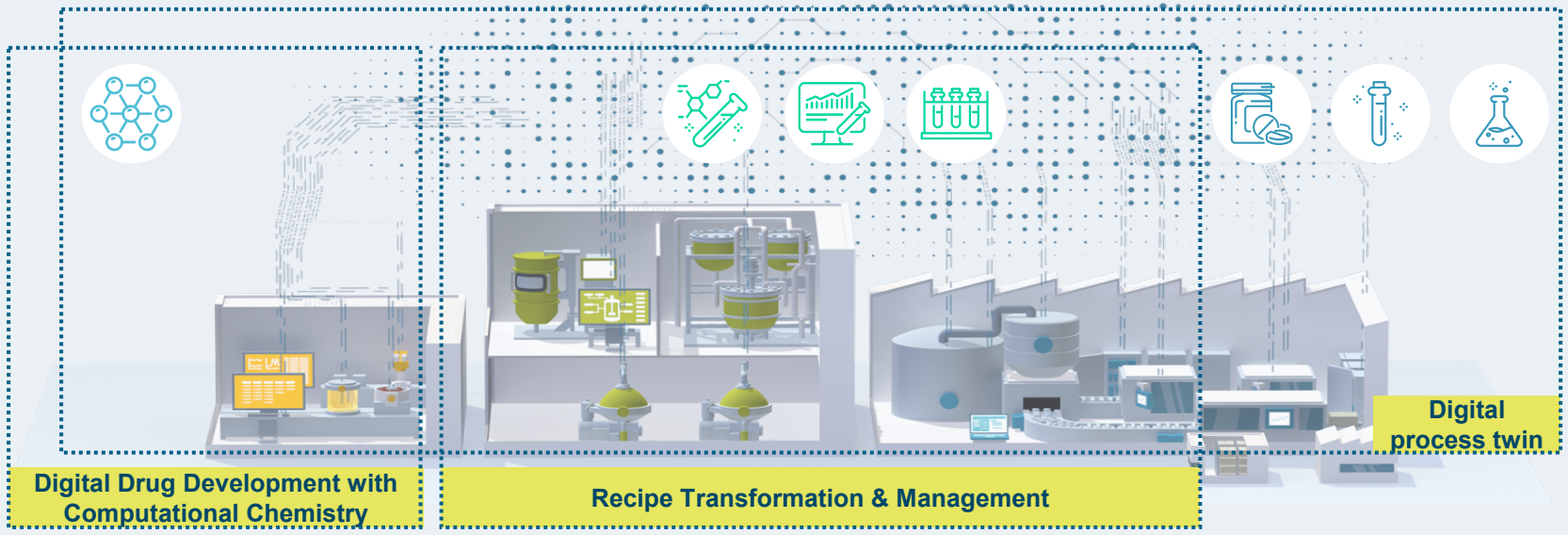
Siemens provides **End-to-End** Solutions for the entire Pharma lifecycle
Closing the Gap between R&D and Primary & Secondary Manufacturing

Pharma Lifecycle

R&D | Primary Processing | Secondary Processing | Distribution | Patient

Use cases

Cloud-based, open IoT operating system



Pharmacist

Wholesaler

Hospital

Available solutions

- Simcenter CULGI
- HEEDS
- Star-CCM
- Riffyn X
- gPROMS
- SIPAT
- Opcenter Ex Ph
- PCS 7 / PCS Neo
- COMOS
- SIMIT

Charter of Trust

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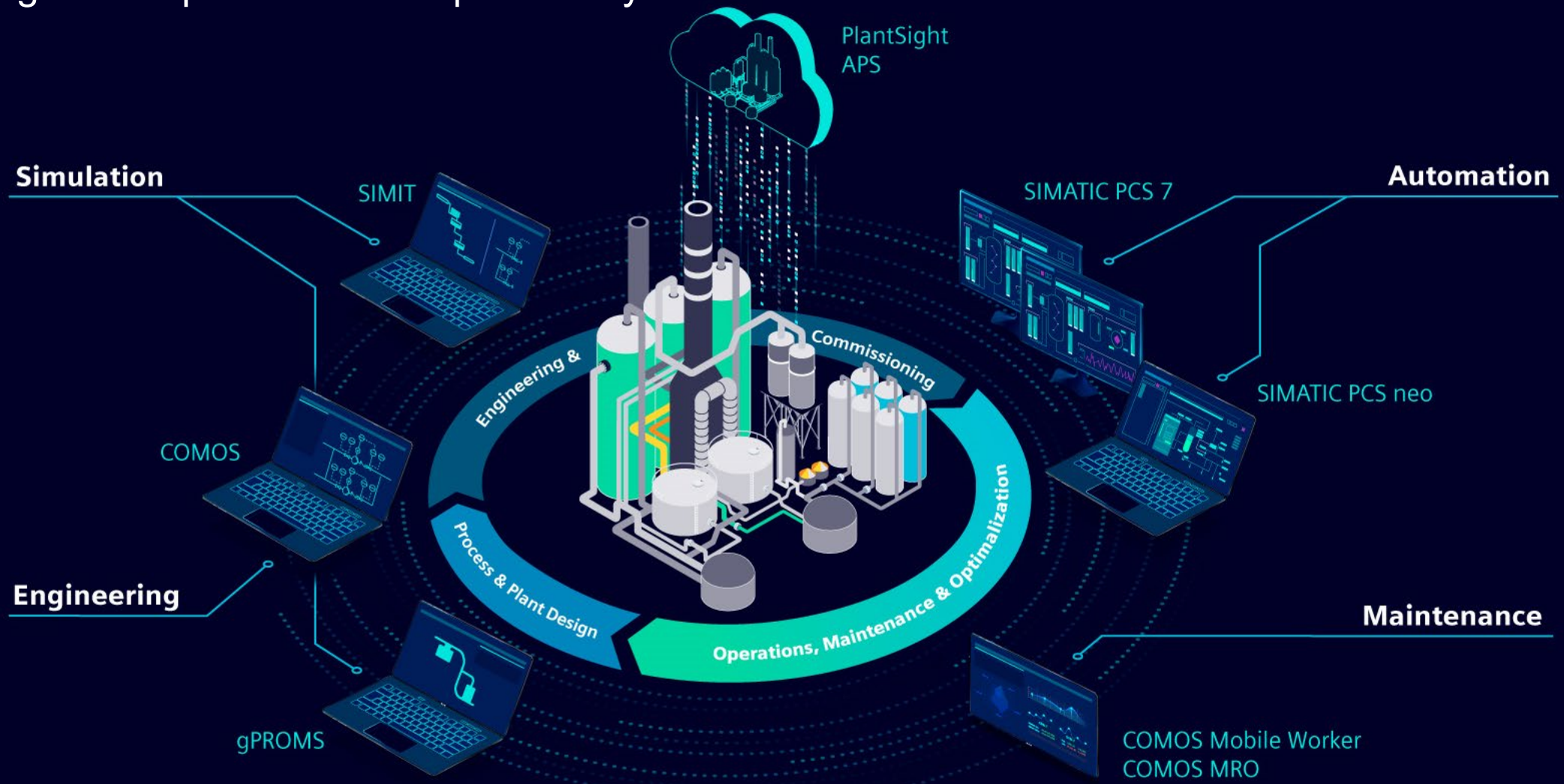
Create and maintain a Digital Twin
Covering all disciplines over the plant lifecycle



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A new way is needed...
Siemens Xcelerator - Open Digital Business Platform for Pharmaceutical Industry

An ever-growing, powerful **Ecosystem** of Partners

A comprehensive curated **Portfolio** with Digital and IOT-enabled offerings from Siemens and its certified Partners

A **Marketplace** to get informed, educate and buy products, soluion and services

Easy

simple to access the latest technologies that are easy to integrate and adopt

Flexible

a modular and interoperable offering for products, solutions and services you need

Open

an open ecosystem bringing together the best-in-class players in the market and open technology

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SMART Manufacturing

Matters of Survival Data Security & Sustainability

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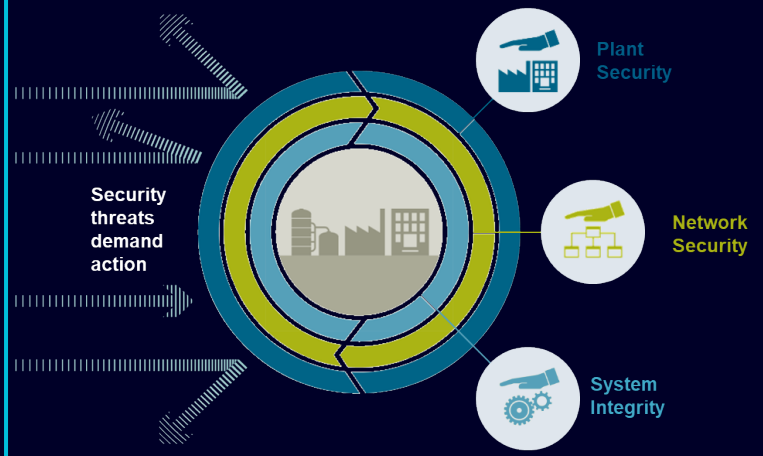
Enabling a secured and sustainable digital transformation

Apply *'defense in depth'* for the OT



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charteroftrust.com

Product Carbon Footprint Management for Scope 1, Scope 2 and Scope 3

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Siemens is your partner of choice!!

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