

ON OUR JOURNEY FROM MANUFACTURING TO SMARTFACTURING!

Miss the shift – Miss the future

ZETA SYMPOSIUM 2024

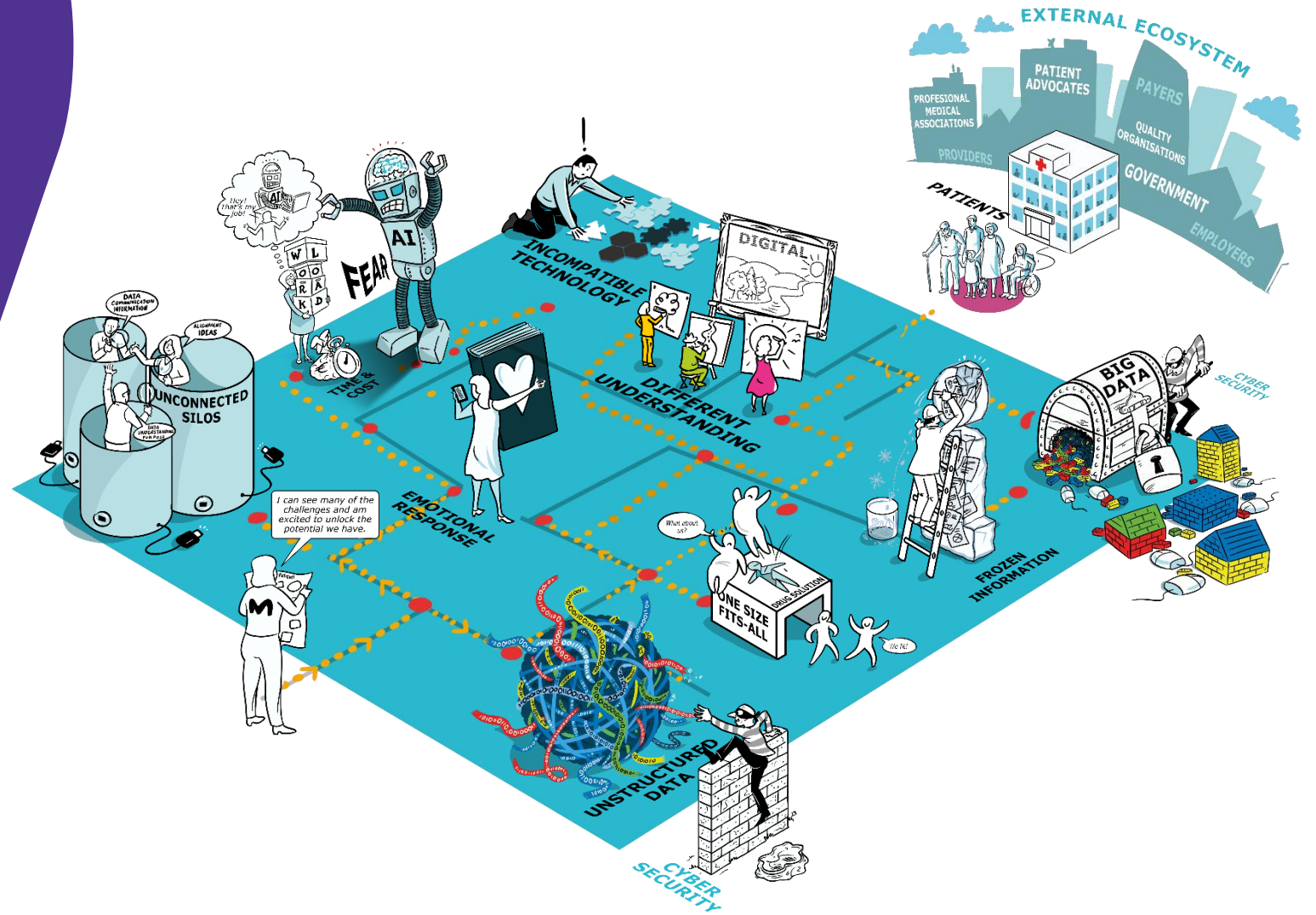
MARCH 12th, 2024

prof. dr. Michelangelo canzoneri
Global Head of Group Smart Manufacturing
Merck KGaA Darmstadt, Germany

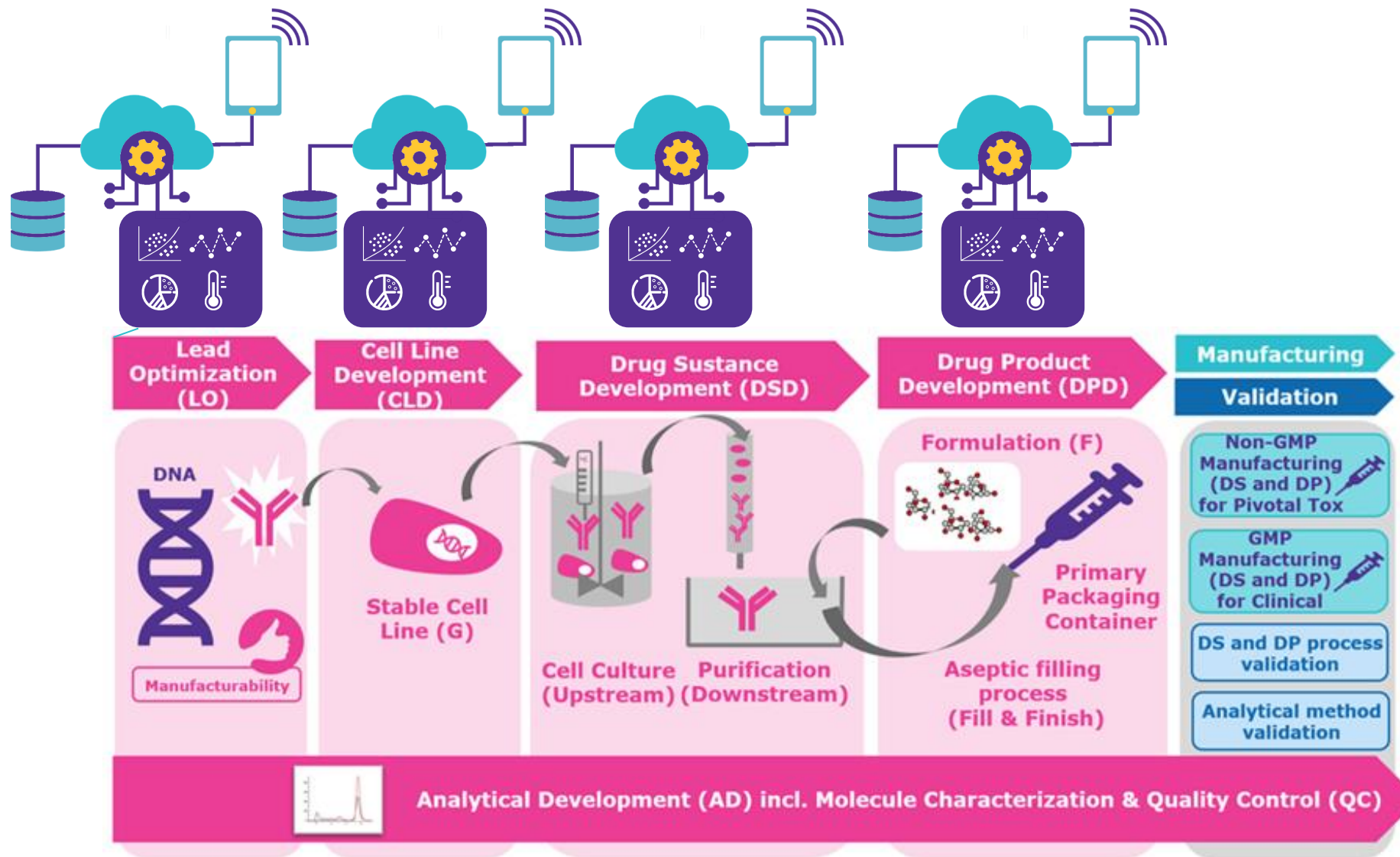
MERCK

current state of industry

Siloed work on digital solutions to answer individual business questions **without scaling** & unlocking the full potential of our data assets

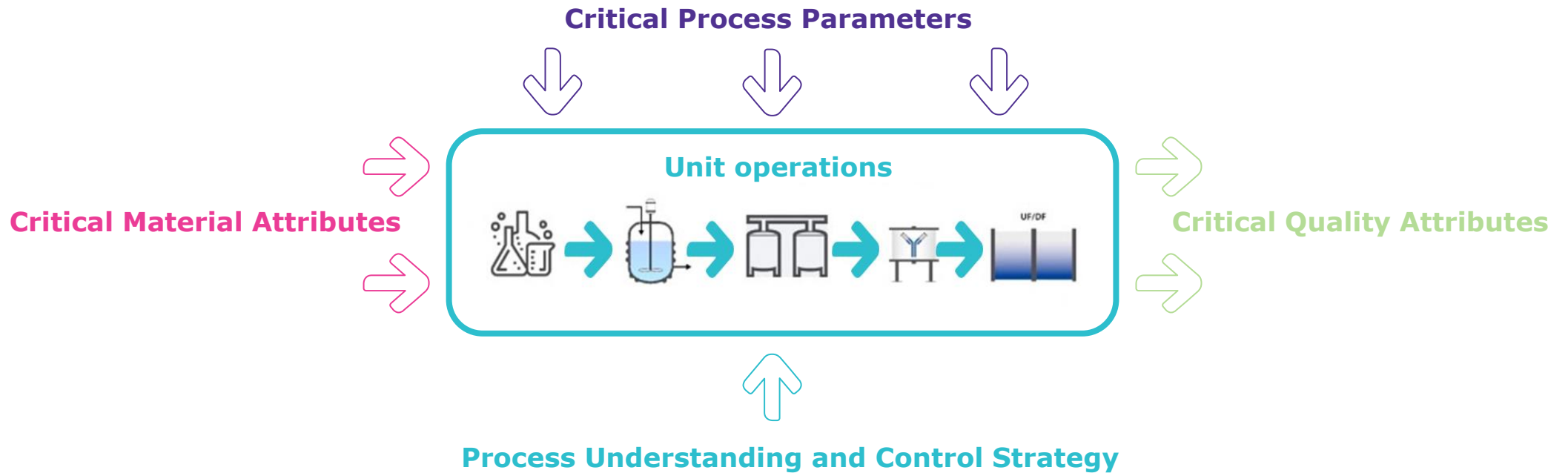


Ever-Increasing Data Along the Drug Development Life Cycle



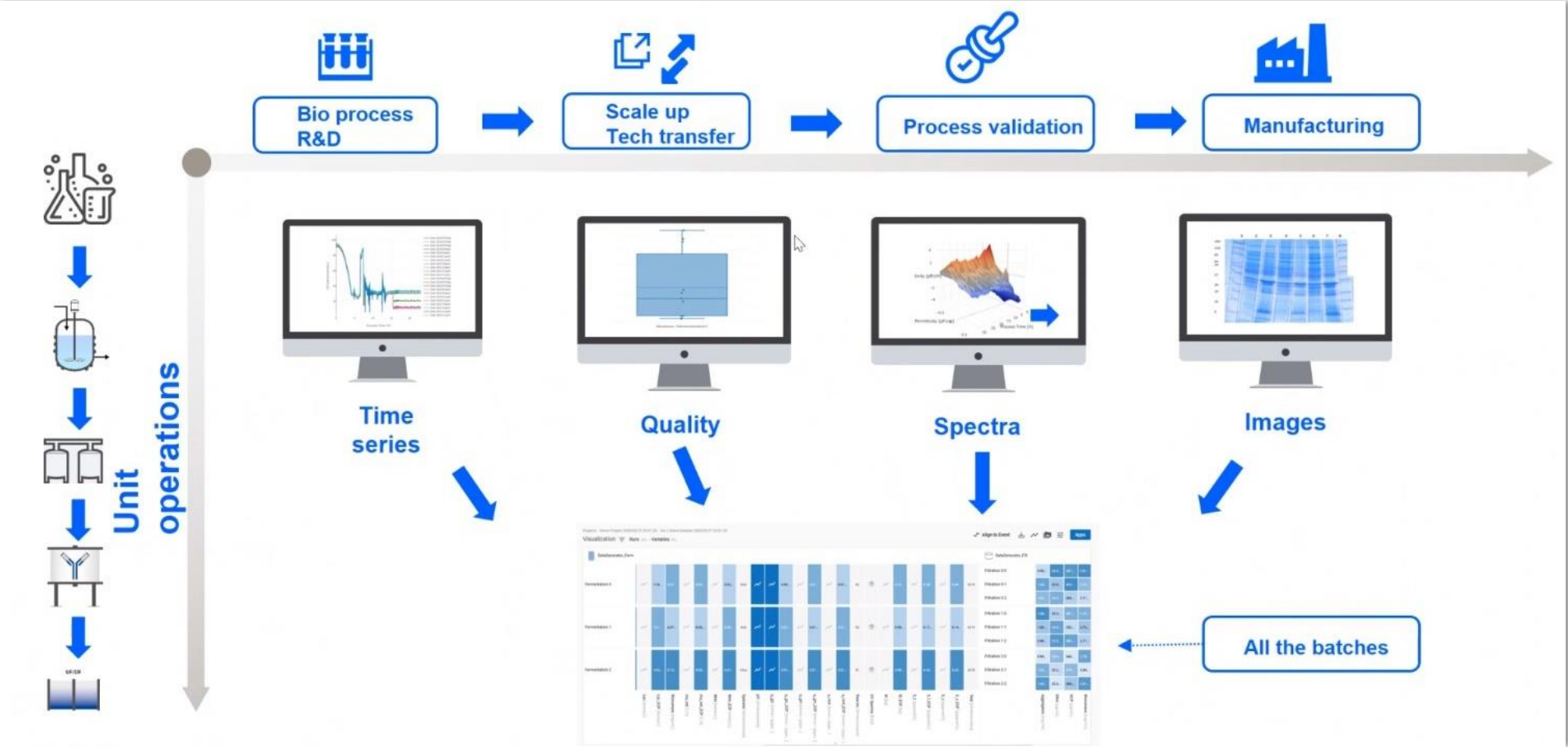
Defining the right process control strategy

The **impact and multidimensional interdependency** of manufacturing parameters



The **holistic understanding** of manufacturing processes

Data should be available from multiple dimensions



Pain Points Impacting Supply Chain

Increase in raw material cost

- Costs are expected **to worsen**, price increases not holding to prior expectations
- Continuous and quick **actions** based on **solid and harmonized data** remains crucial

Inventory capacity management

- Increased **waiting time** for clearance of shipments
- Balancing **stock levels** due to **high uncertainty** on the markets is very difficult

Unpredictable demand

- Need to **predict and respond** to changes in demand in **real-time**

Logistics challenges

- **Cost of shipping** a container increased seven-fold
- Supply chain **turbulence** due to geopolitical conflicts

Economic downturn

- **Macro** economic conditions continue to change with potential for **more downside**
- **Recession** is now seen in several regions across the globe

From MANUfacturing to SMARTfacturing

The Next Generation Manufacturing Excellence



From MANUfacturing to SMARTfacturing

The Next Generation Manufacturing Excellence



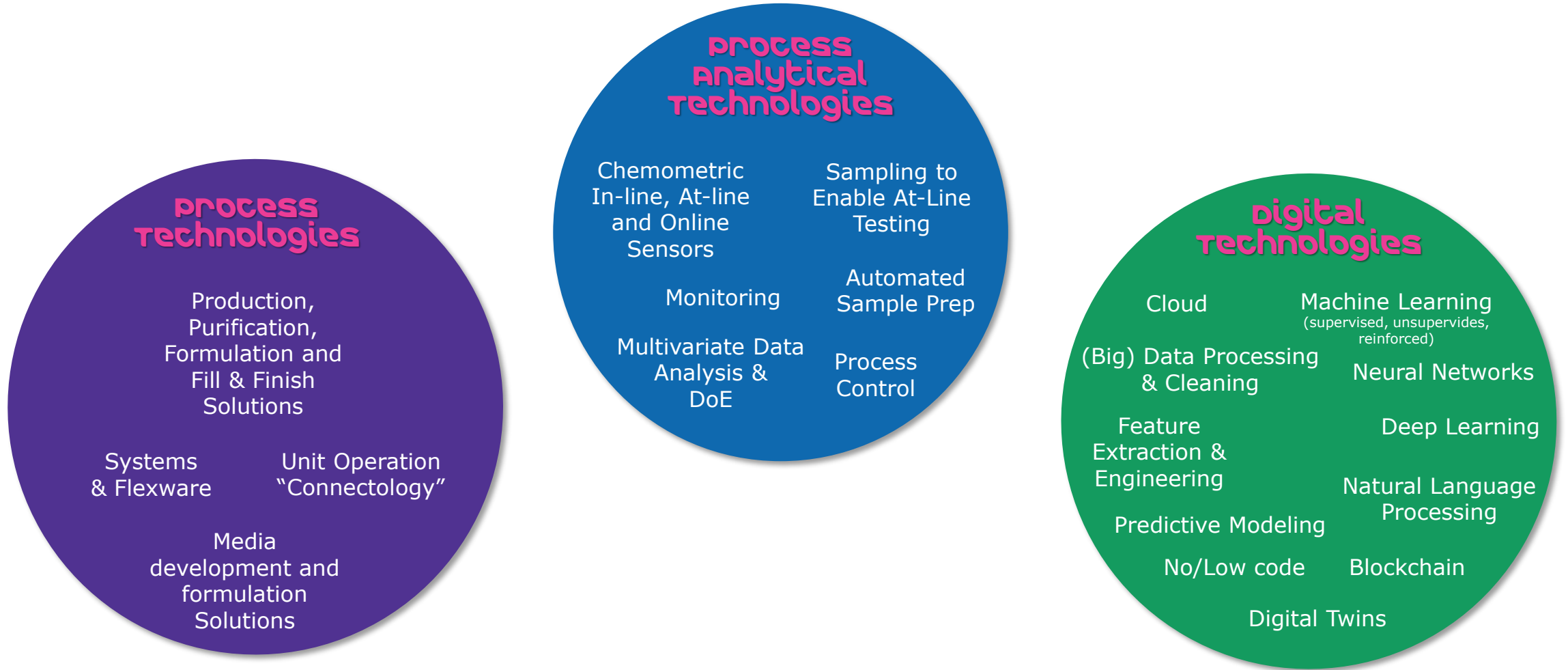
From MANUfacturing to SMARTfacturing

The Next Generation Manufacturing Excellence



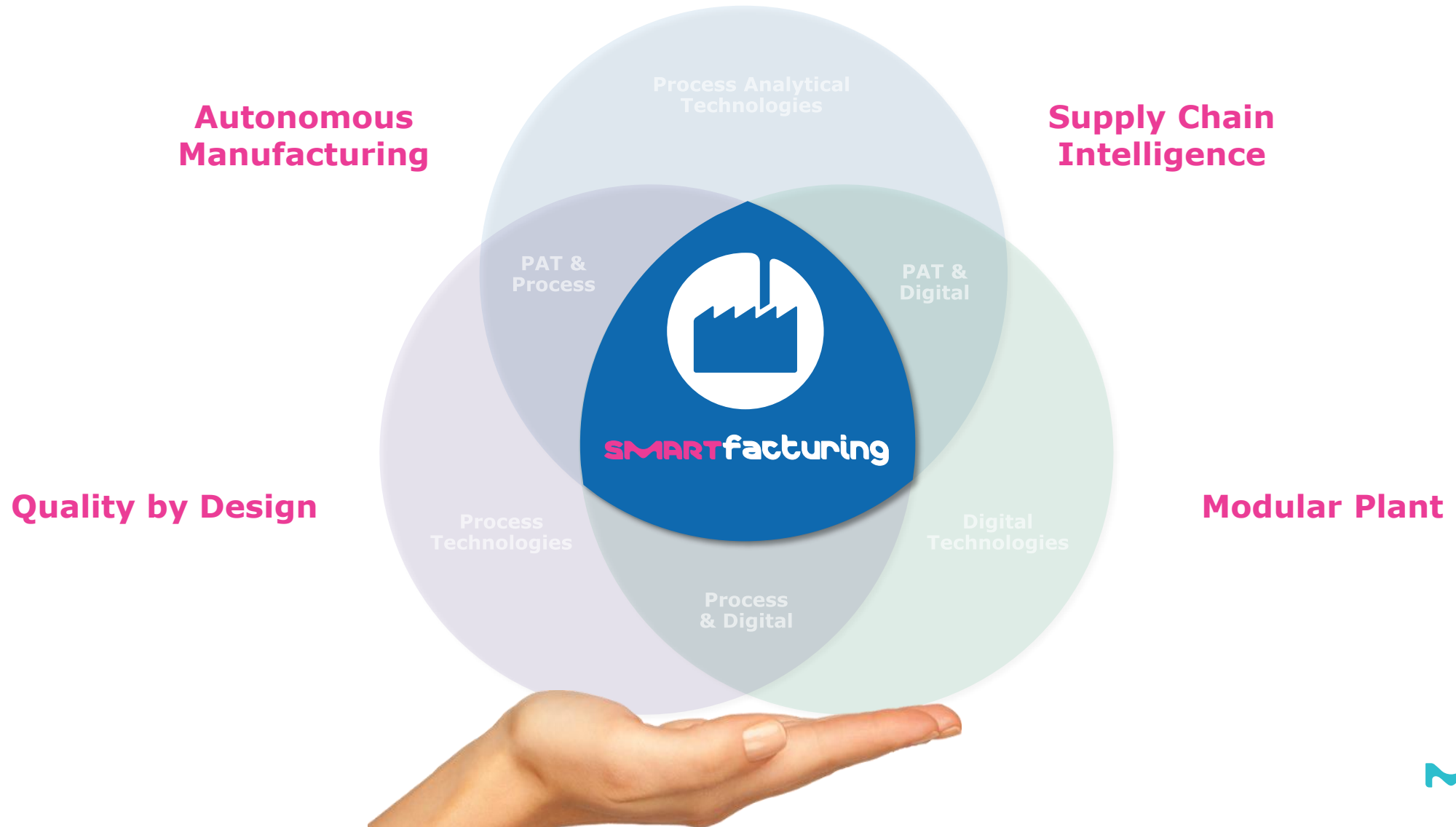
Evolution from MANUfacturing to SMARTfacturing

1. Foundation 2. Convergence



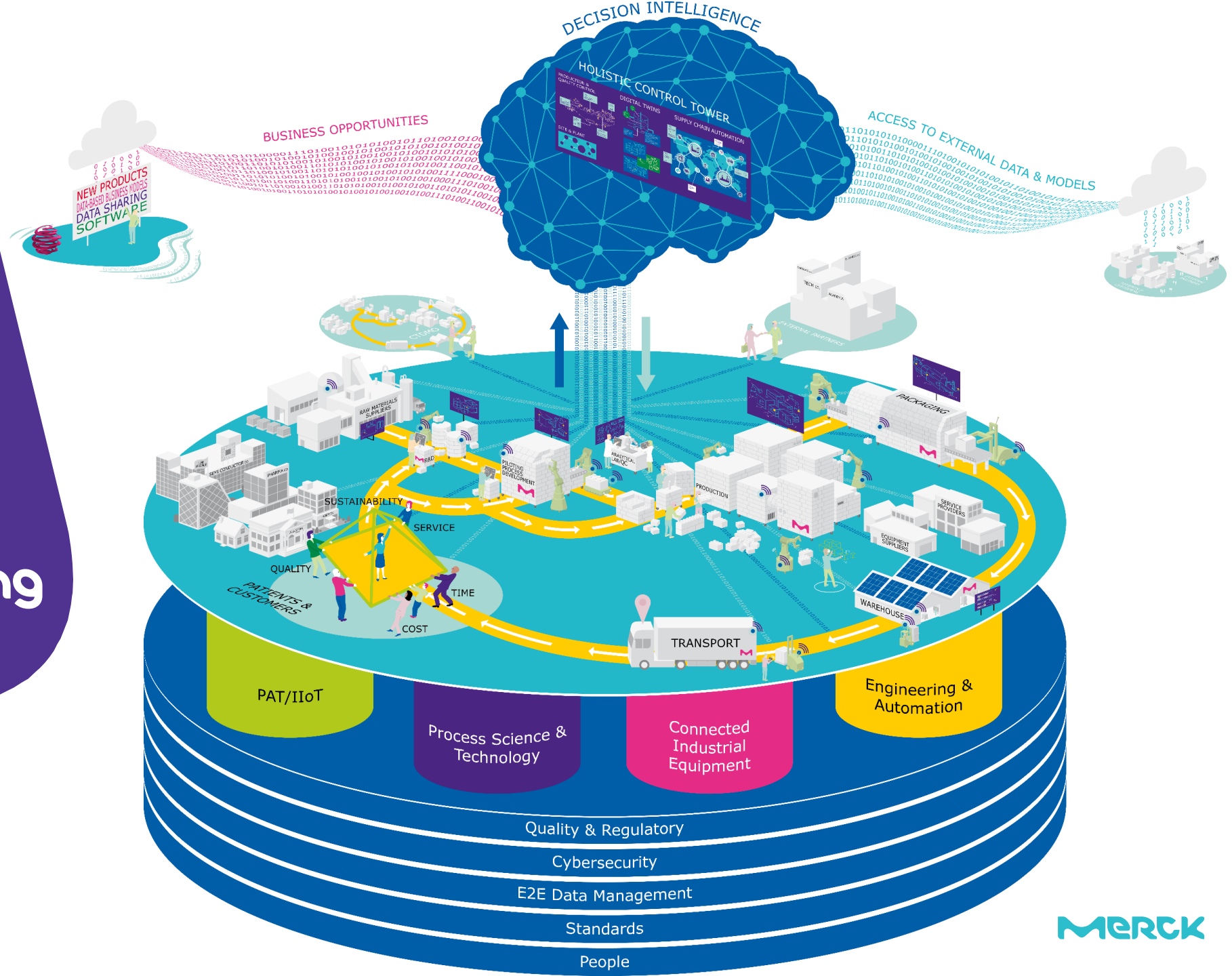
Evolution from MANUfacturing to SMARTfacturing

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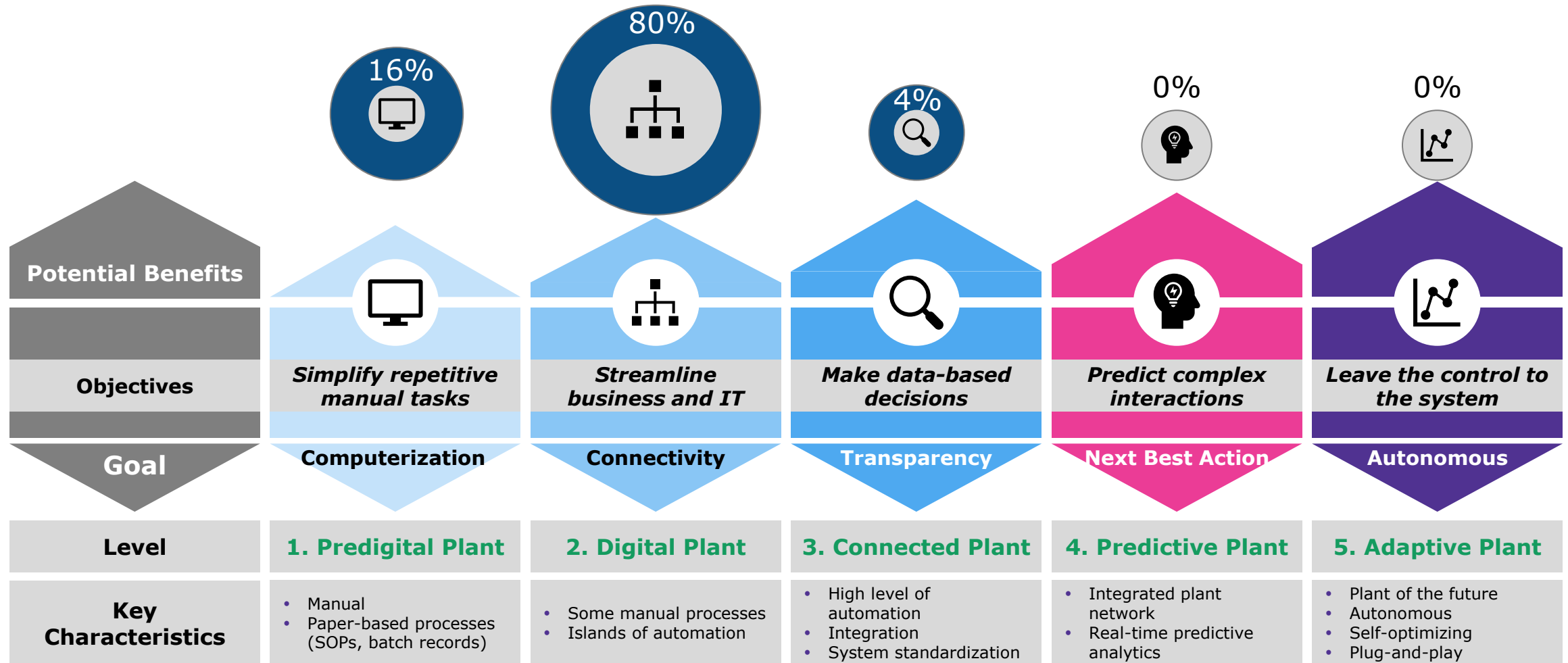




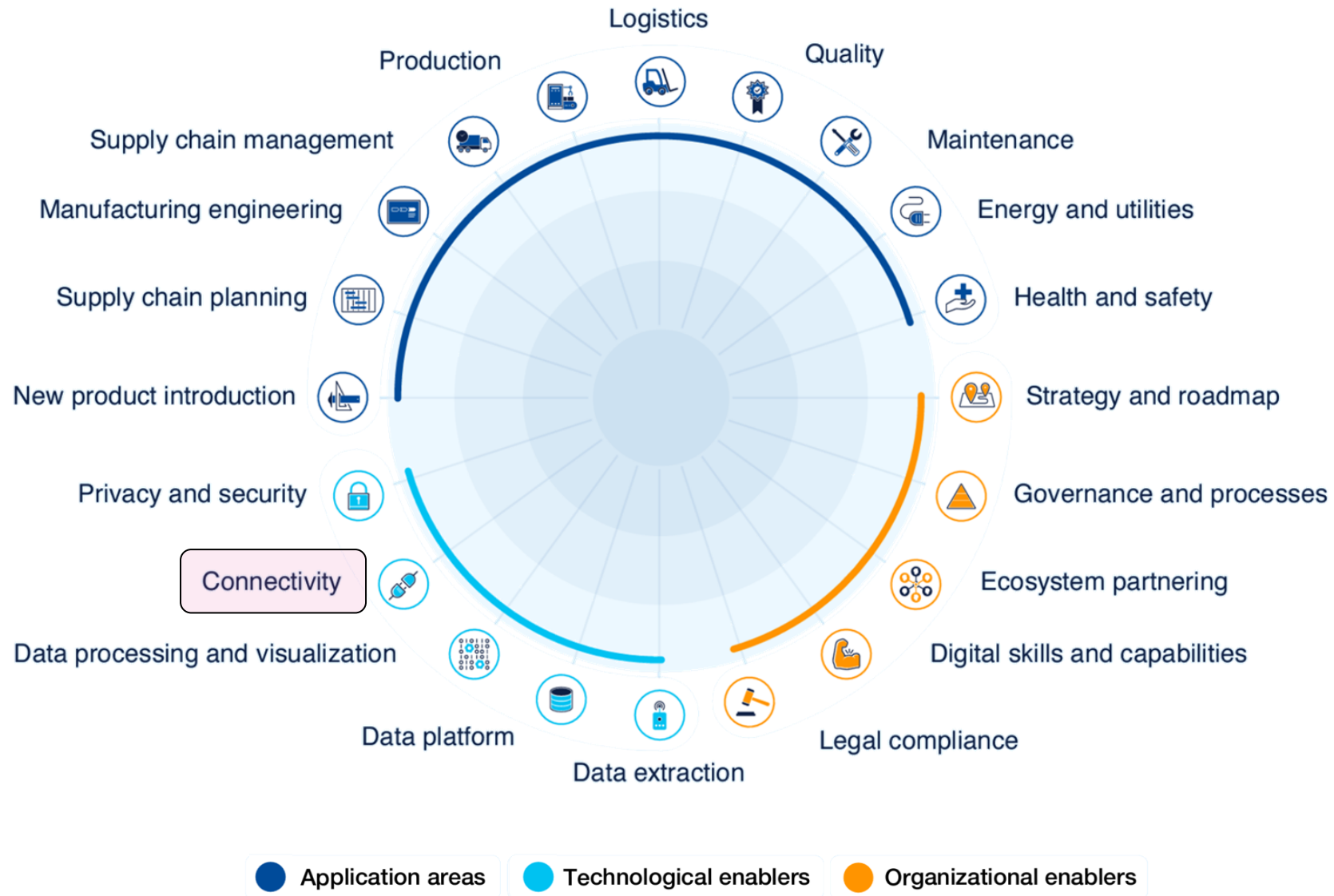
Envisioning our future with smart manufacturing



80% of manufacturing companies have taken initial steps to connect machines, systems and employees

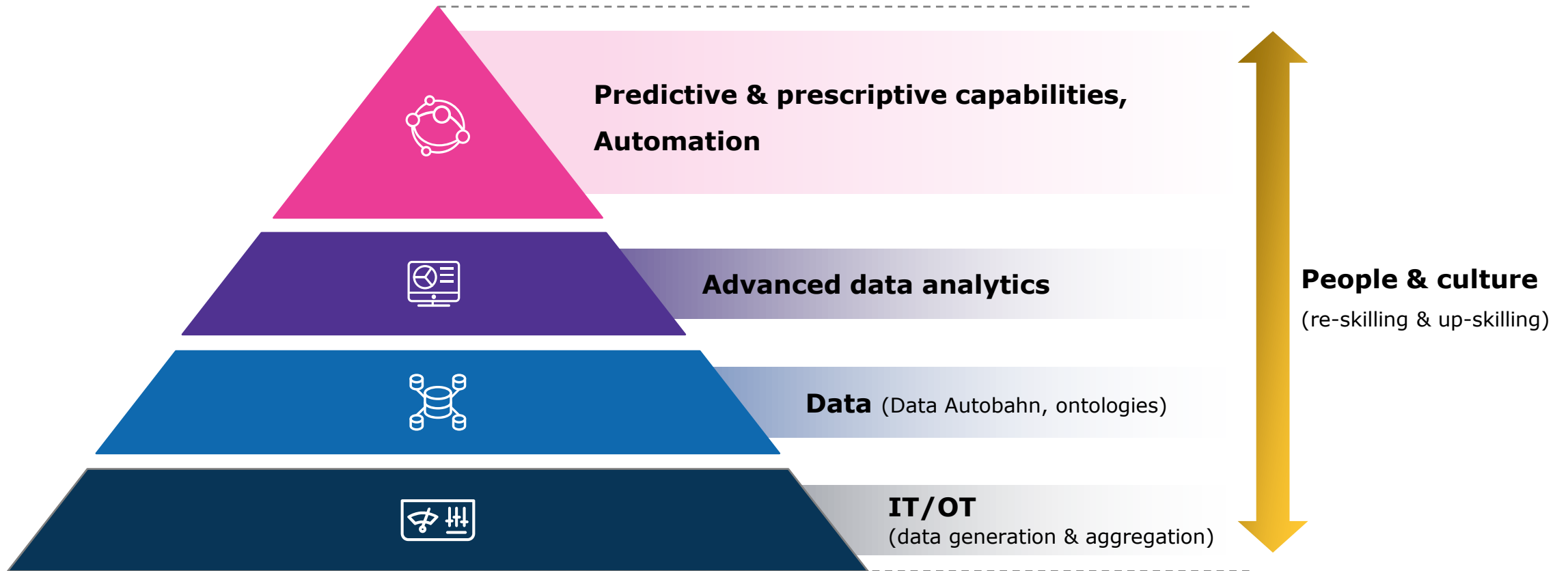


The **SMART** Manufacturing Enabling Framework



Enablers of Smart Manufacturing

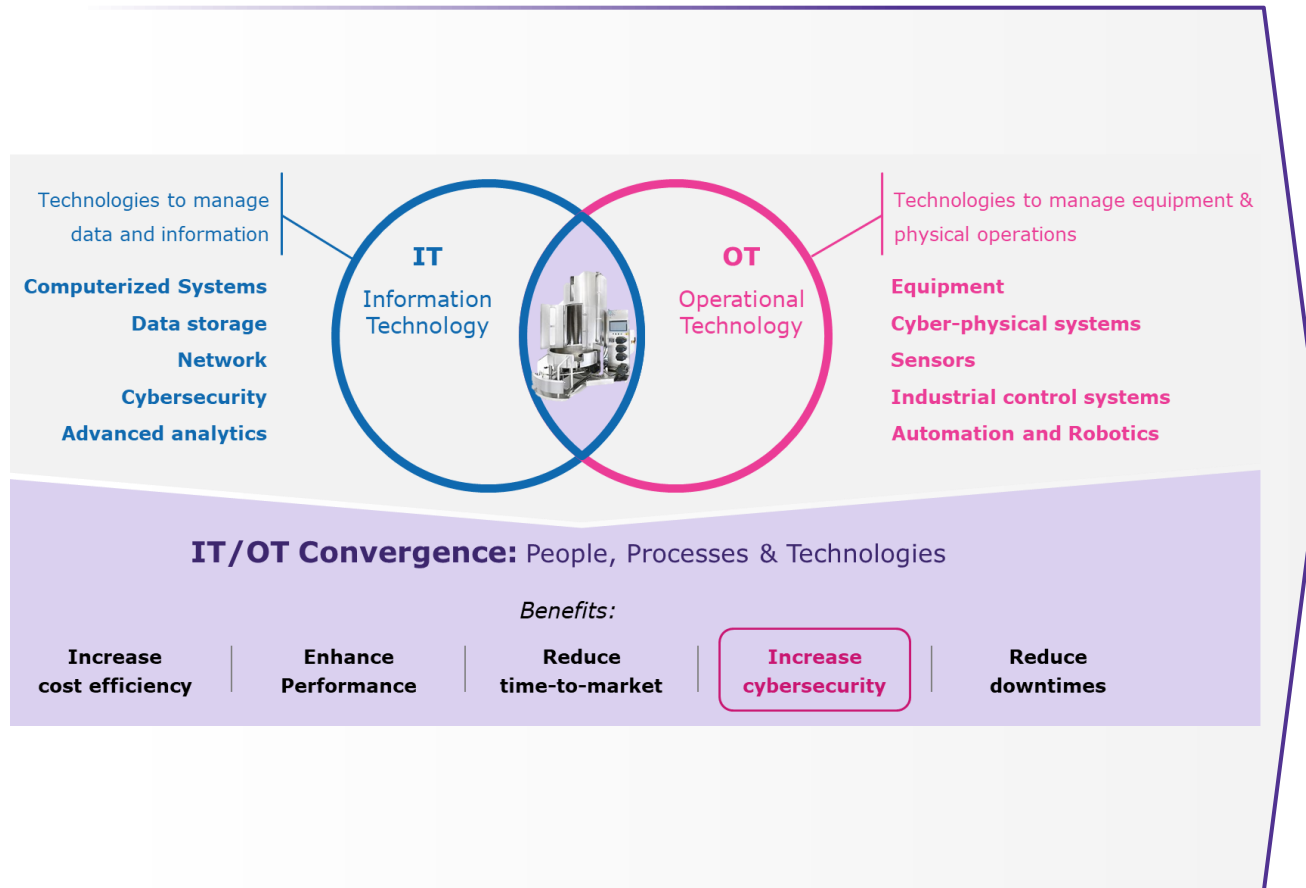
To unlock the true value of Smart Manufacturing the technological and organizational foundations need to be set



Value drivers of IT/OT convergence

A holistic approach to IT/OT convergence for scalability, efficiency and effectiveness

Benefits and value drivers of IT/OT convergence



Seamless and smart integration of physical equipment, sensors, and systems into IT infrastructure



Continuous data ingestion enabling visualization, analytics and automation to drive data-supported decisions



Foundation for **implementation and scaling of SMFG capabilities** across plants (e.g.: predictive maintenance)



Establishment of **strong OT cybersecurity measures**, increasing protection and resilience of critical assets

Benefit realization requires infrastructural investments

SMARTfacturing is a journey that requires long term strategic planning

NPV	Examples	Key Benefits
++++	<ul style="list-style-type: none"> Predictive Analysis 	<ul style="list-style-type: none"> + % QC lab productivity + % production productivity
+++	<ul style="list-style-type: none"> Advanced Data Analytics 	<ul style="list-style-type: none"> - % reduction on deviations - % changeover time
++	<ul style="list-style-type: none"> LIMS MES ELN 	<ul style="list-style-type: none"> Paperless environment (EBR) Lead-time reduction Data availability from machine and across systems
+/-	<ul style="list-style-type: none"> Server hardware Data Historian Workforce enhancements 	<ul style="list-style-type: none"> Compliance, data Integrity & cybersecurity Setting the basis for Fully Connected Plant, Higher investment Easy data transfer

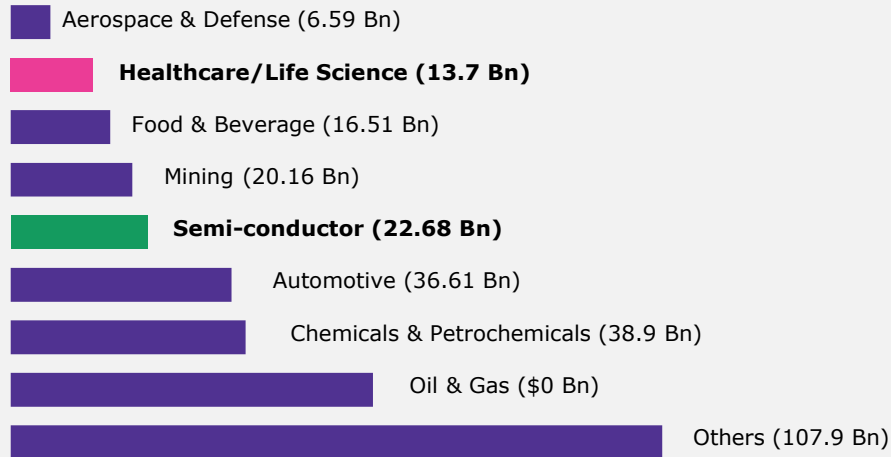
Digital Maturity Phases



Global Healthcare/Life Science Investment in Smart Manufacturing will double from until 2027

Investments in SMFG capabilities in 2022

(in USD, 2022) - Cross Sector Analysis:



41%

Global manufactures are adopting smart manufacturing technologies.



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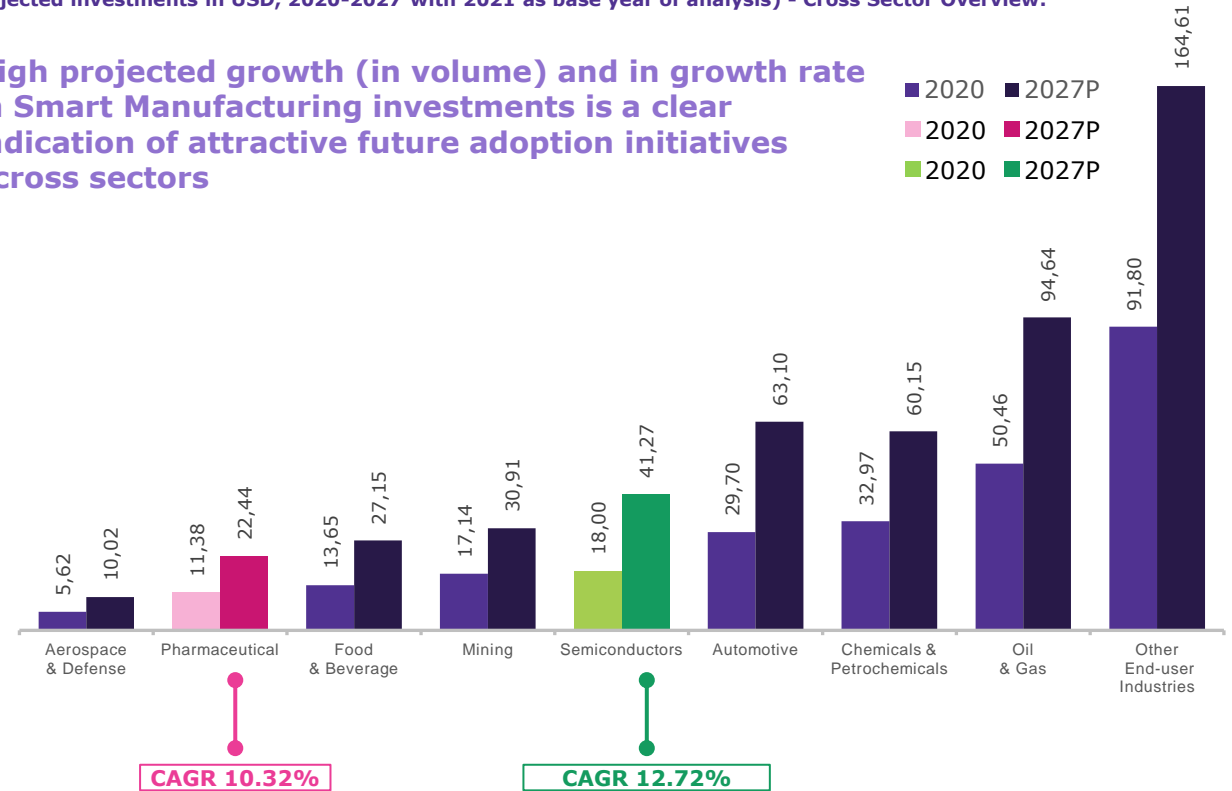
Manufacturing sites selected as global lighthouses* by World Economic forum Lighthouse network, since 2018.

Source: Global Smart Factory Report - Mordor Intelligence 2021

7-year growth horizon in investments in SMFG Capabilities

(Projected investments in USD, 2020-2027 with 2021 as base year of analysis) - Cross Sector Overview:

High projected growth (in volume) and in growth rate in Smart Manufacturing investments is a clear indication of attractive future adoption initiatives across sectors



Pharma industry has the fourth highest CAGR following Semiconductors, Automotives and Food & Beverages 2027P - Projected revenue for 2027

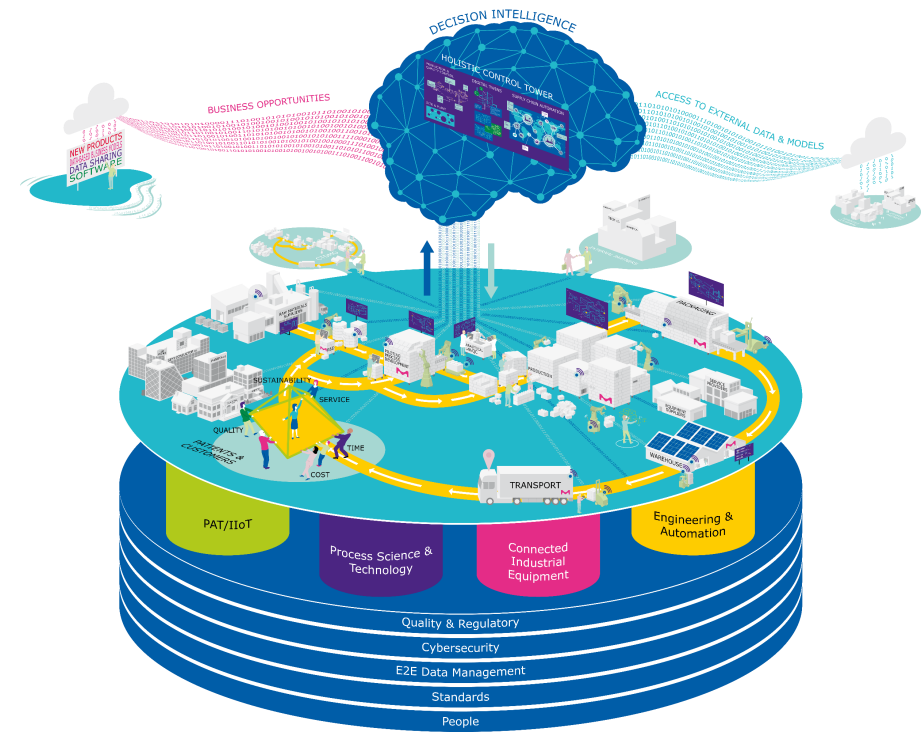
SMARTfacturing Value Drivers realize Business Outcomes & Benefits

Key Value Drivers	Smart Manufacturing Use Case Examples	Potential Benefits
1 Time-to-market	Digital twin technology	▼ 83% Speed in market
2 Service & After Sales	Leveraged predictive maintenance systems to reduce machines' maintenance and defect costs	▼ 25% Decrease in maintenance costs
3 Resource/Process Optimization	Utilized an analytics platform for managing yield and root-cause analysis	▲ 22% Increase in product yield optimization
4 Asset Utilization	Machine visualization and maintenance with digital dashboards	▲ 20% Increase in asset utilization
5 Labor Productivity	Advanced analytics for quality failure aggregation and prioritization	▲ 90% Increase in labour productivity
6 Inventories	End-to-end supply chain management with visibility platform	▼ 25% Reduction in inventory
7 Quality	Output quality optimization platform with IoT	▼ 52% Reduction in quality deviations
8 Matching Supply and Demand	Incubated an AI-enabled demand predicting and inventory replenishment solution	▲ 4.5pp ¹ Improved OTIF ²

Note : Global lighthouses are the factories that have taken Fourth Industrial Revolution technology from pilots to integration at scale
 Source: Assessment of Smart Manufacturing report([URL](#)); Microsoft Smart manufacturing report([URL](#))

¹Percentage Points ²On-time-in-full

To realize the benefits, potential data and digital solutions can be implemented across all **SMART** manufacturing building blocks



Production Planning and Scheduling
Automated S&OP process, real-time synchronization of supply chain and production, advanced planning/scheduling

Materials & Inventory Management
Track and trace, data-driven inventory management and optimization, additive manufacturing, digital utilities

Production
Continuous manufacturing, 3D printing, industrial robots, automated guided vehicles, additive manufacturing

Manufacturing Engineering
Virtual simulation and experimentation, AI/ML-based routing & job scheduling, additive manufacturing

Manufacturing Reliability & Maintenance
Predictive / remote maintenance, virtually guided maintenance, analytics, additive manufacturing, robotics and automation, workforce enablement

Environment, Health & Safety (EHS)
Waste management optimization and smart energy consumption, workforce enablement, digital utilities, digital EHS

Manufacturing Network Operation
Analytics, dynamic routing, real-time supply chain optimization/risk mgmt., next best action/ predictions, advanced process control, connected lab

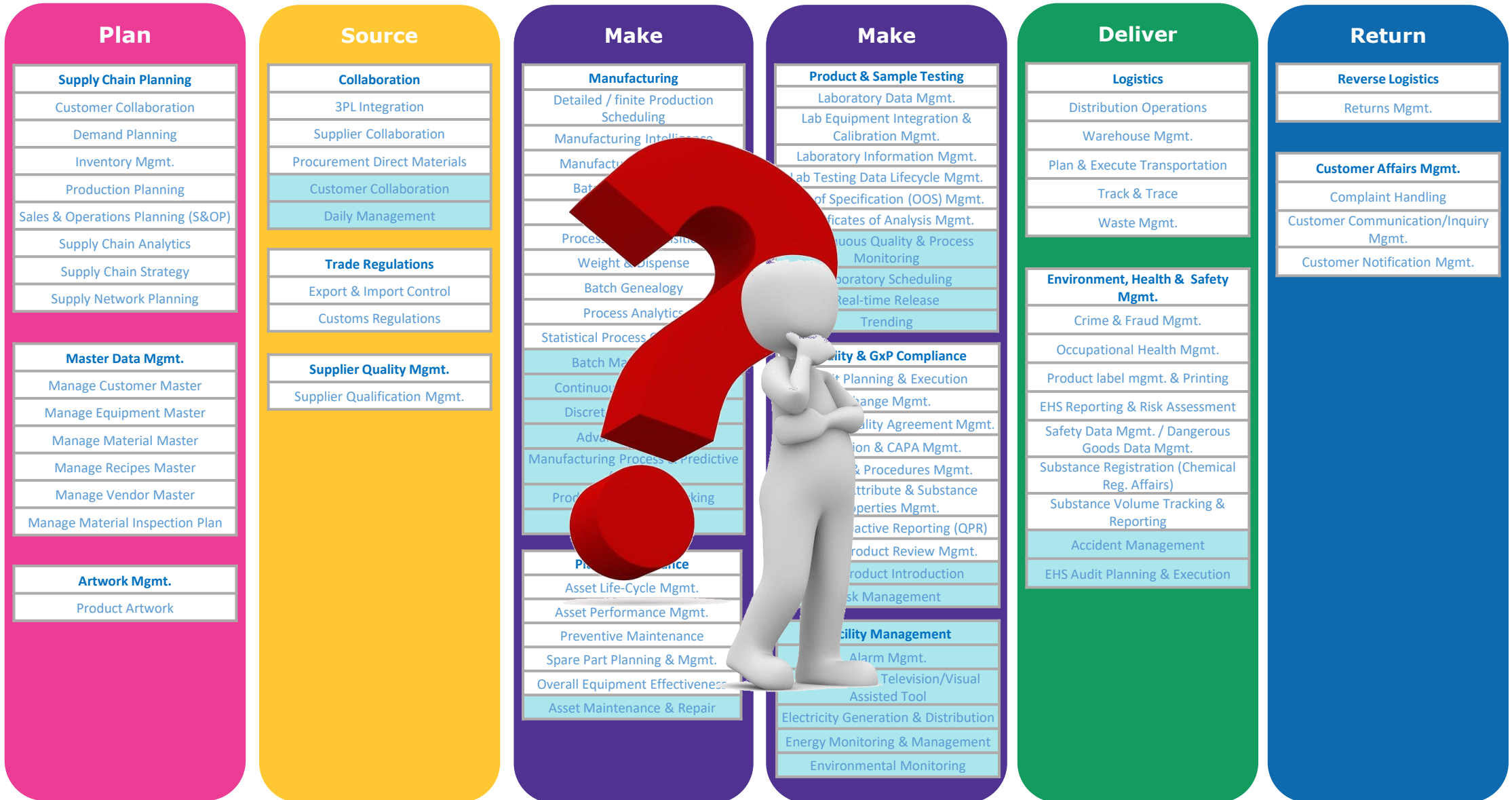
3rd Party Manufacturing & Service
Automated sourcing agents, supplier rooms, shared cloud platforms, control tower

Performance Mgmt. & Business Intelligence
Real-time KPIs, advanced production and asset utilization based on digital twins, advanced process control, EBR, digital utilities

Quality
Automated quality in-line testing, digital quality management, robotics and automation, workforce enablement, EBR

Skills, culture & behaviors

Capability Map Smart Manufacturing, Supply & Quality



Smartfacturing Priorities

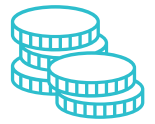
Setting our objectives

DIMENSIONS



CUSTOMERS

- Time-to-market
- Individualization
- Delivery reliability
- Transparency



FINANCES

- Operating Costs



EMPLOYEES

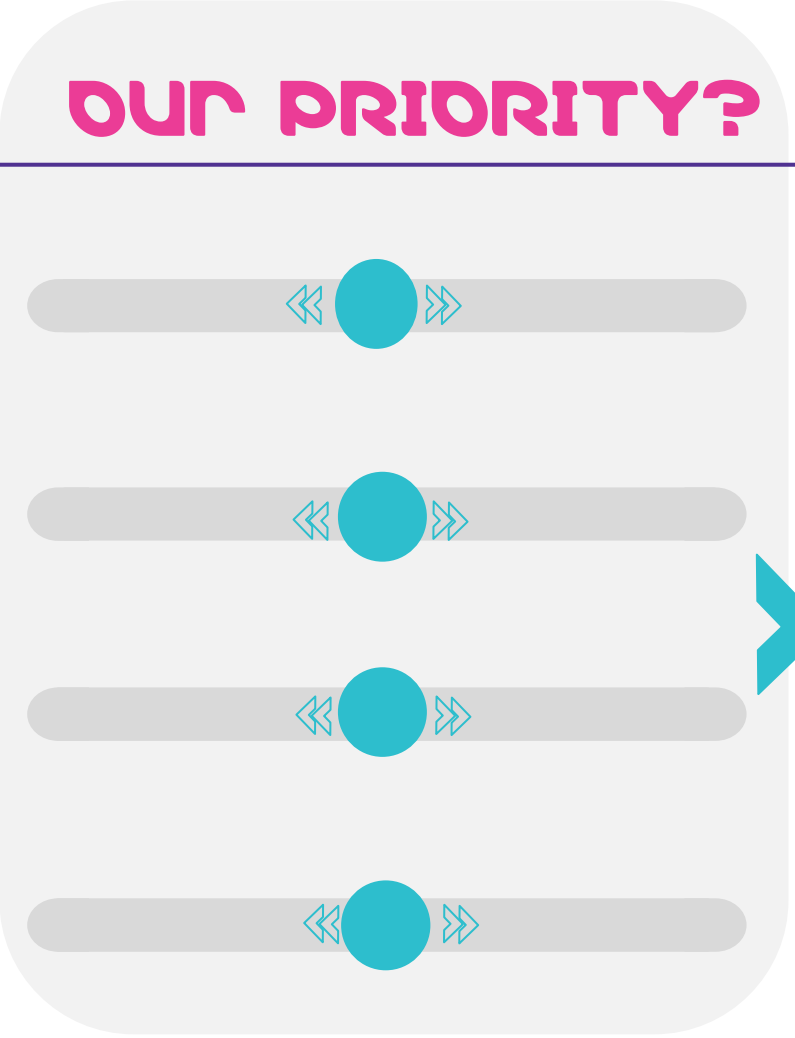
- Attractive Employers
- Attractive Tasks
- Ergonomic workstations



SOCIETY

- Zero impact
- Responsible sourcing

OUR PRIORITY?



TARGETED KPIs

Evolving to meet our cross-sectoral ambitions From **MANU**facturing to **SMART**facturing – our priorities



Rethinking supply chains



Greater focus on seamless engineering, plug & produce, automation and IT/OT convergence



Digital Twins and AI driven use cases to support new levels of resilience and flexibility



Increase workforce agility and amplify capabilities to enable resilience



Reflect regulatory requirements in AI enabled capabilities incl. qualification/validation of technologies and algorithms used for supporting decisions

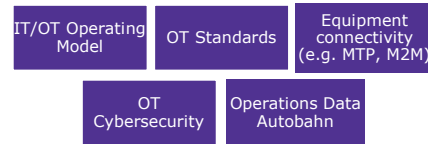
Merck has the ambition to enable the following **SMART**facturing Goals & Levers



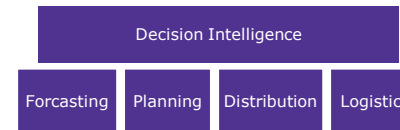
Manufacturing Excellence by Design



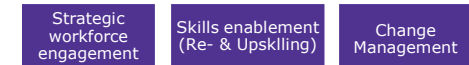
IT/OT convergence



Supply Chain Intelligence

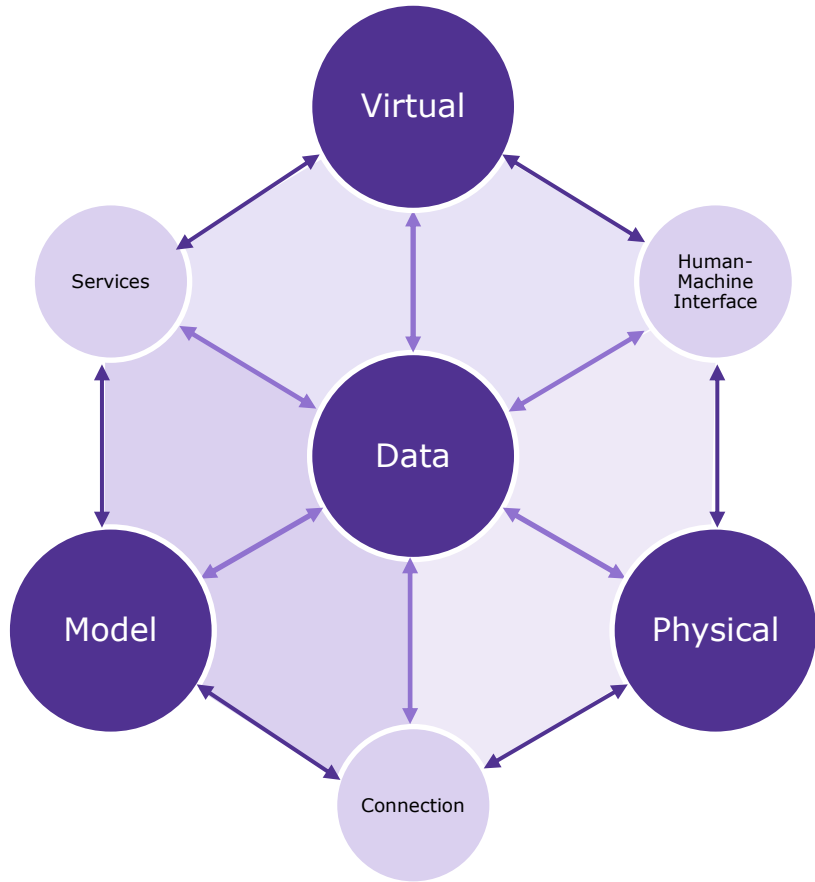


Workforce Readiness & Change Management

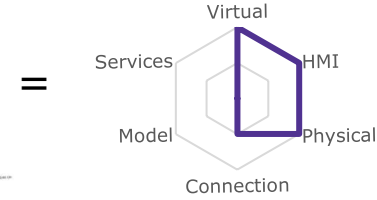


Digital Twins maturity levels

Digital Shadows, Digital Thread, or Digitalization

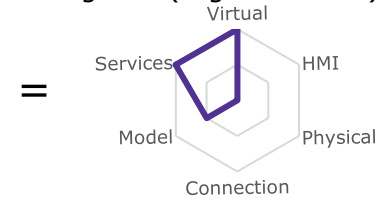


Virtualization: HMI-weighted (Digital Shadow)



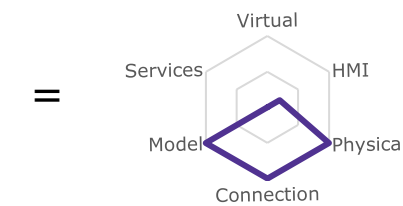
Score = 3.5 out of 6

Data Mining: Digital services-weighted (Digital Thread)



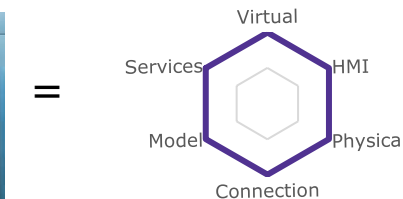
Score = 2.5 out of 6

Conventional Automation: Connectivity-weighted (Digitalization)



Score = 3 out of 6

A Digital Twin: Lights-off Cognitive Manufacturing

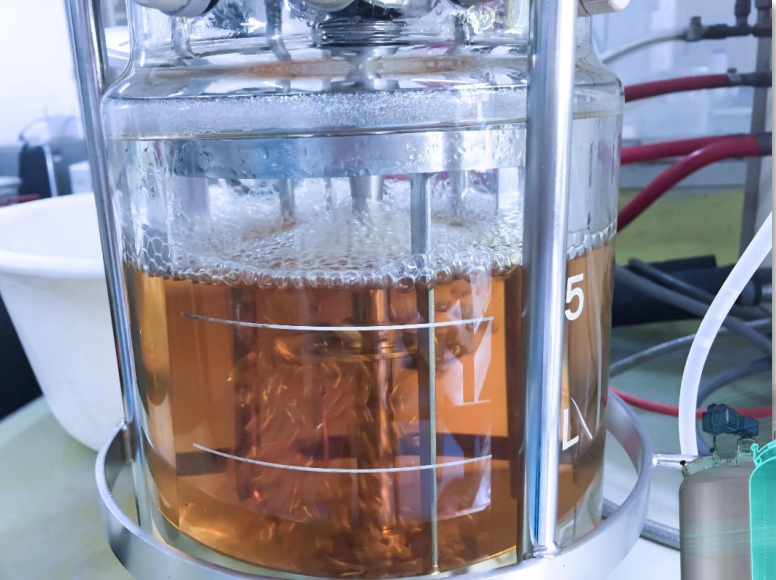


Score = 6 out of 6

Digital Twins of Drug Production Processes aim to reduce Process Development timelines by 50%

Digital twin of an mAb bioproduction process

- Based on Ai modeling (Data driven, Mechanistic, Hybrid,...)
- Used for process simulation, prediction, optimization and control

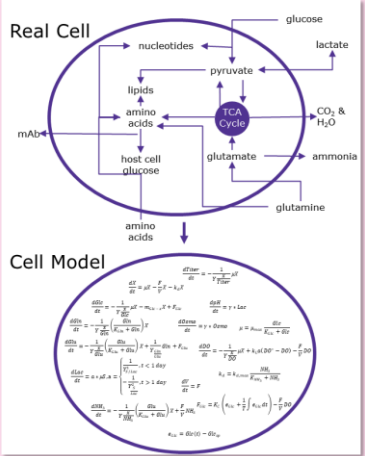


3D digital twin

- Based on 3D computer graphics and AR/VR
- Used for equipment design, SME training, navigation in the plant...



$$\frac{\partial u}{\partial t} = k \frac{\partial^2 u}{\partial x^2}$$



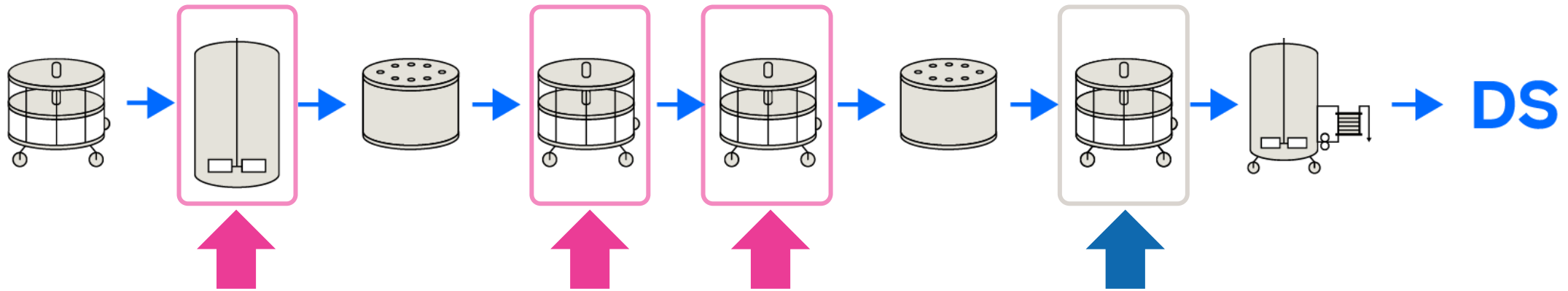
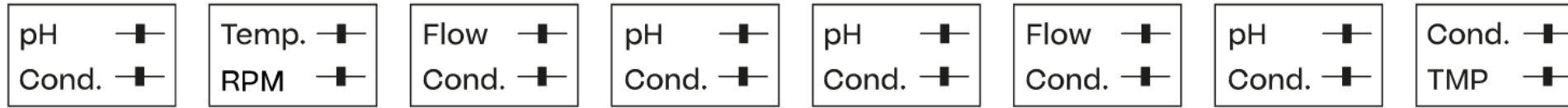
Computational Fluid Dynamics (CFD)

CFD snapshots → Reduced Order Model

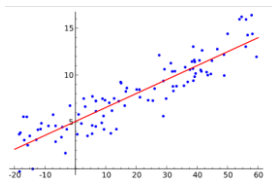
$$\begin{cases} \nabla \cdot \vec{v} = 0 \\ \rho \frac{D\vec{v}}{Dt} = -\nabla p + \rho \vec{g} + \mu \nabla^2 \vec{v} \end{cases}$$

$$Y(x, y, t) = U(x, y)A(t)$$

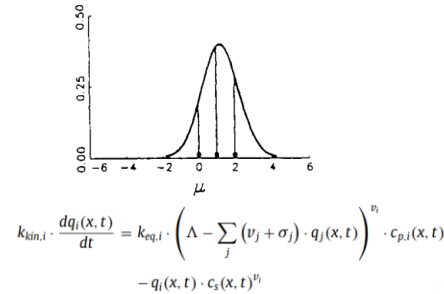
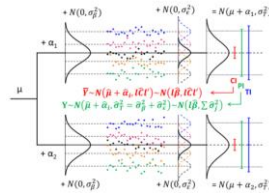
End-to-End Process Models as a Framework



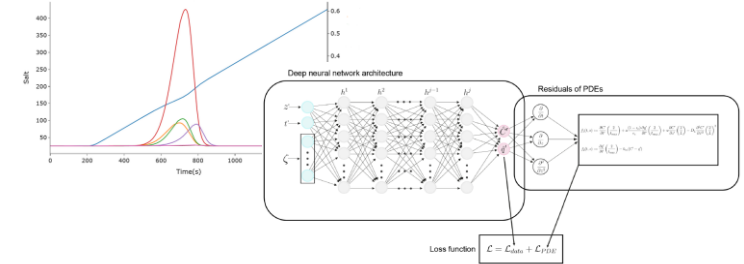
Ordinary Least-Squares Linear Mixed Model (e.g. via DoE)



Mechanistic Models

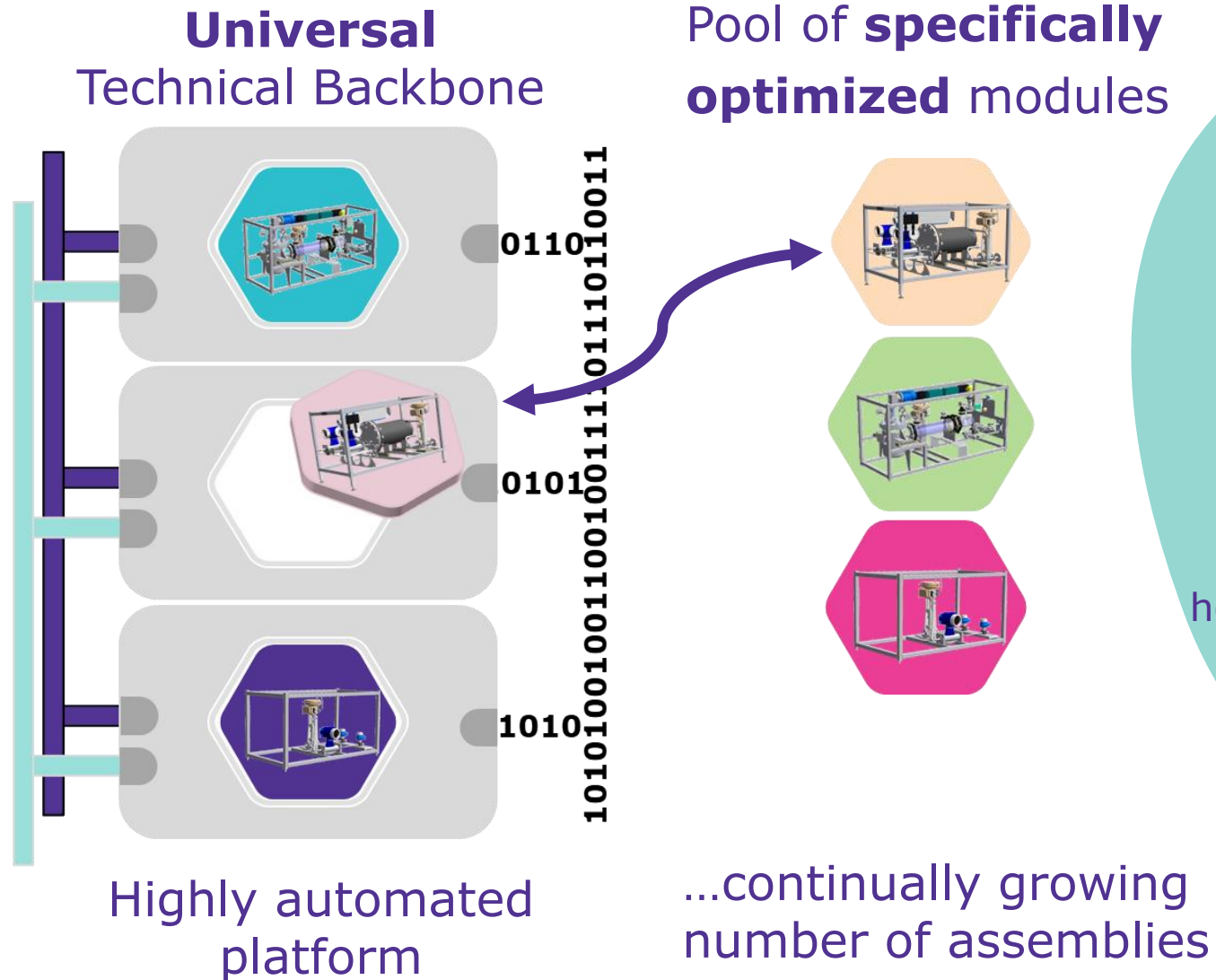


Hybrid and AI Models



MTP enabled Plug and Produce & DT enabled Guided Process Design

Configure the best matching system for any application

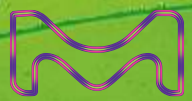
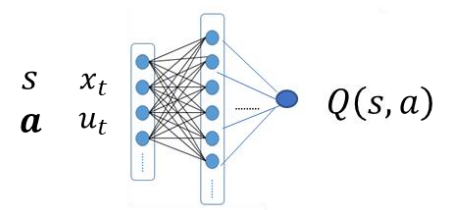
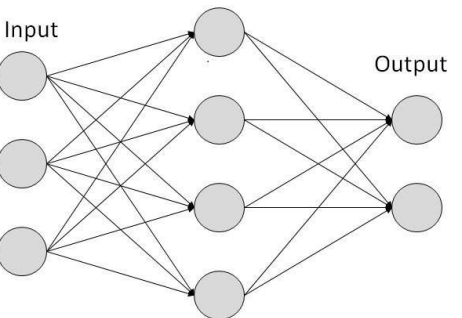
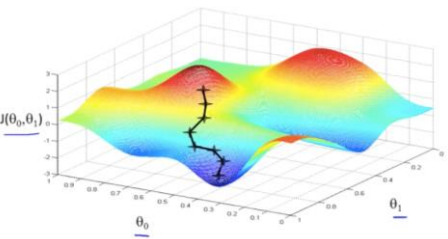
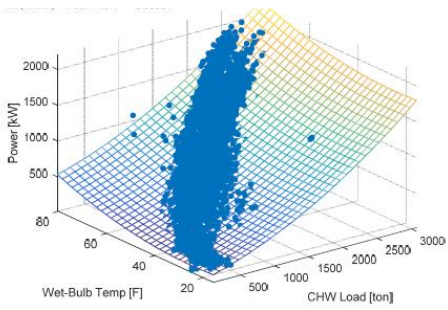
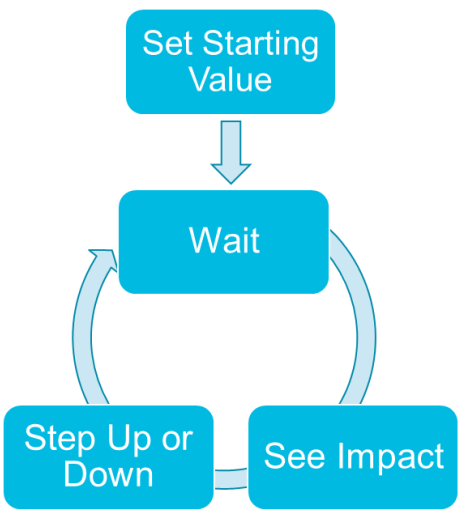
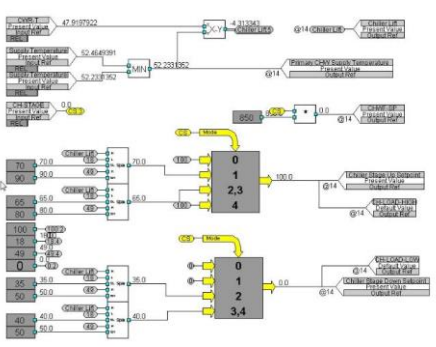


Break the paradox

between **flexibility** and **efficiency**.
Dedicated or specialized modules are hooked into the manufacturing eco system whenever beneficial

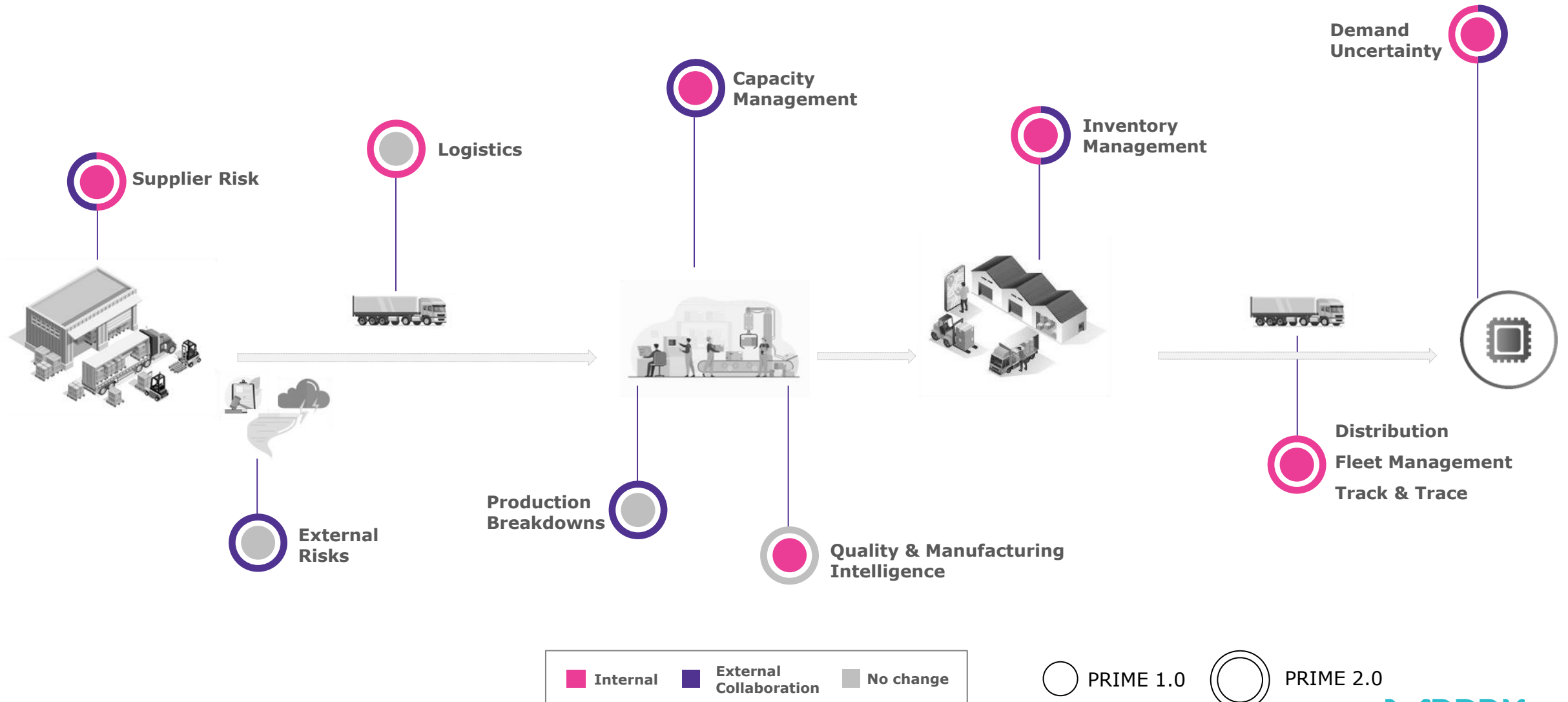
Control and optimization methods for energy consumption

AI operation provides a global optimal solution for energy efficiency



Projects and activities to boost our digital capabilities

Our current activities

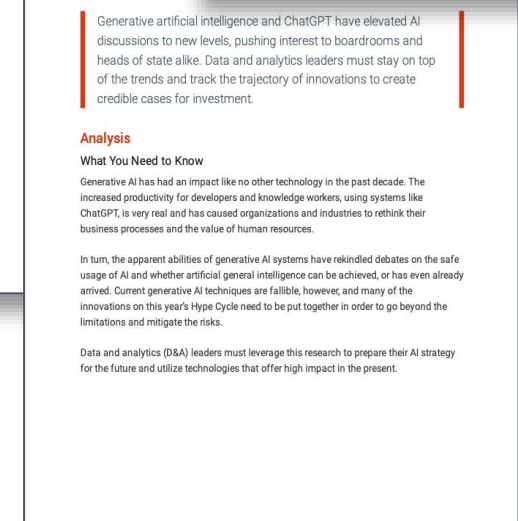
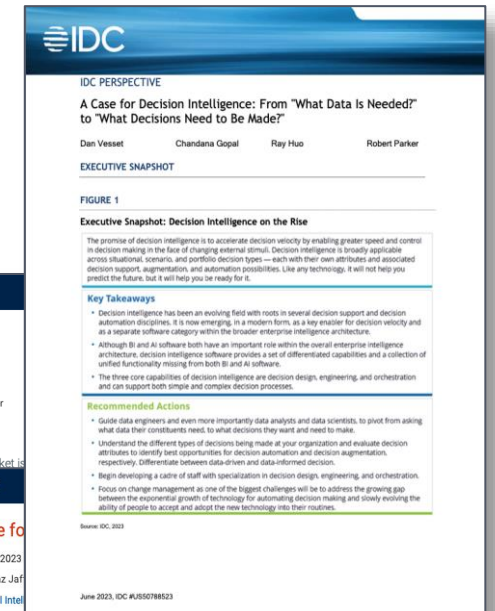
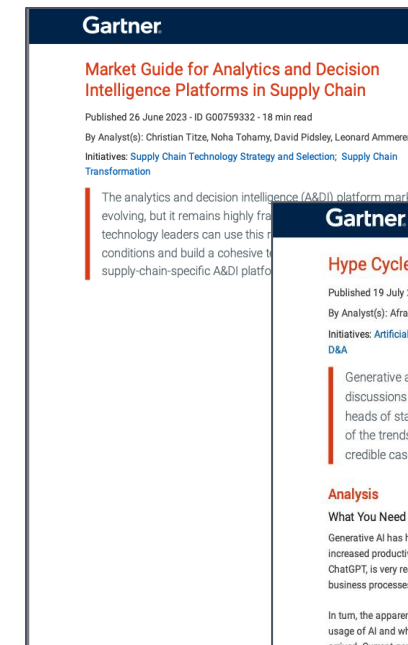


Leading to poor and unmade decisions at scale..

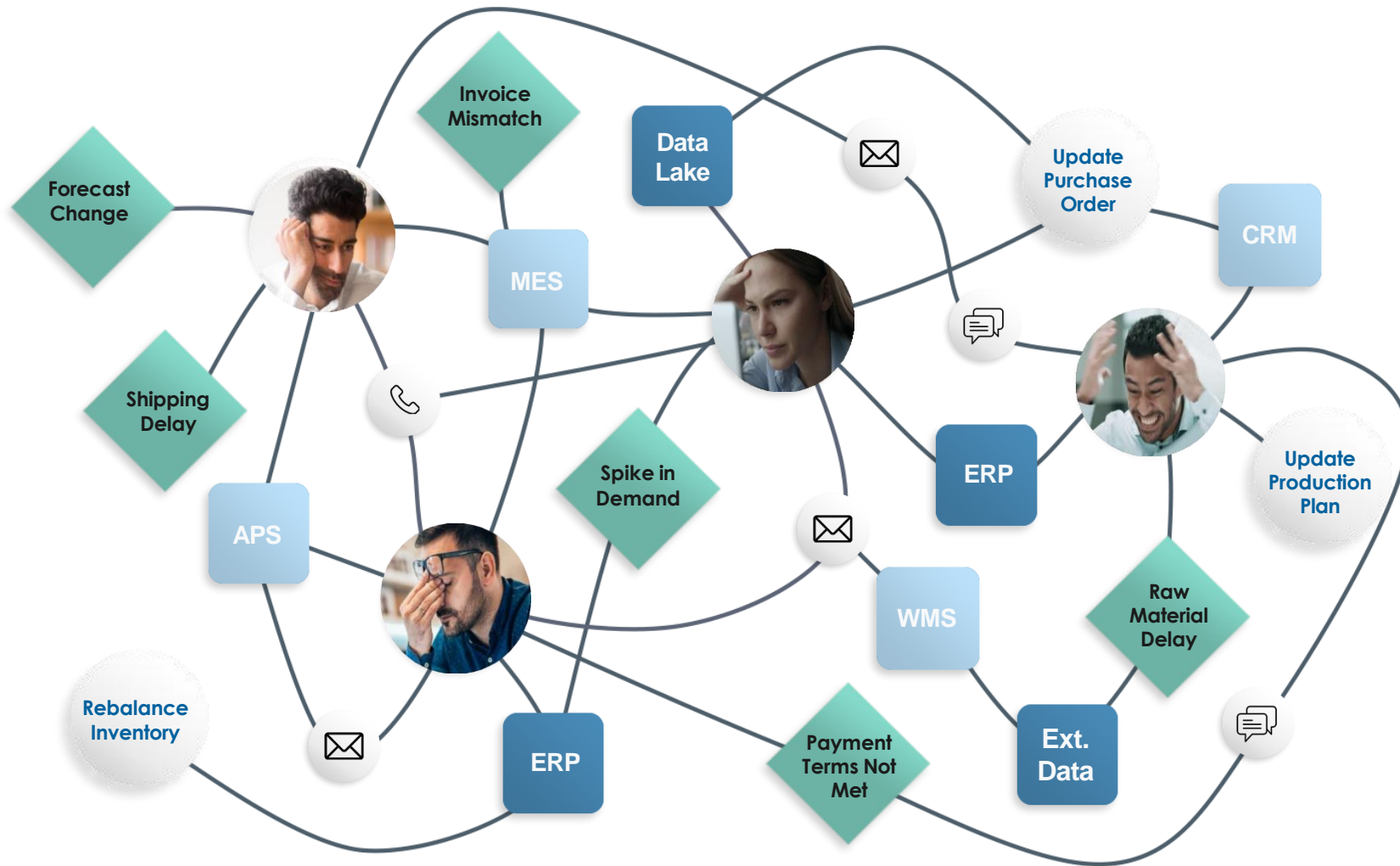
The economical impact of **decisions that are not made** or not properly made is estimated at **\$4.26 trillion**

An S&P 500 Index Company currently loses an average of **\$250M per year** on **ineffective decision-making processes** (McKinsey)

72% of executives believe that **bad decisions are as frequent as good ones.** (McKinsey)



Our vision is to : Move from people making decisions supported by machines

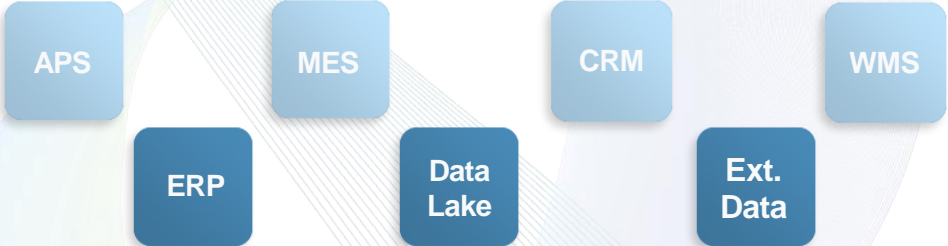


❌ Decision making is slow

❌ Fewer decisions get made

❌ Complex decisions take longer

To machines proposing decisions guided by people



- ✓ **Faster Decisions**
- ✓ **More Decisions**
- ✓ **Higher Complexity**

AI for decision automation is becoming a standard practice for large enterprises

Gartner Hype Cycle for AI, 2023:

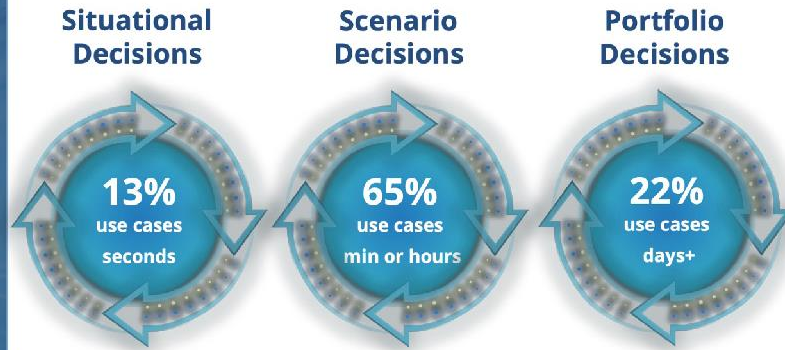
Benefit	Years to Mainstream Adoption			
	Less Than 2 Years	2 - 5 Years	5 - 10 Years	More Than 10 Years
Transformational	Computer Vision	Composite AI Decision Intelligence First-Principles AI Generative AI Intelligent Applications	Autonomic Systems Autonomous Vehicles Foundation Models Neuromorphic Computing Responsible AI	Artificial General Intelligence
High	Data Labeling and Annotation Edge AI	AI Maker and Teaching Kits AI TRISM Causal AI Cloud AI Services Data-Centric AI Knowledge Graphs Prompt Engineering Synthetic Data	AI Engineering AI Simulation ModelOps Multiagent Systems Operational AI Systems Smart Robots	Neuro-Symbolic AI
Moderate				
Low				

Source: Gartner (July 2023)

“By 2026, 75% of Global 500 companies will apply **Decision Intelligence...** making decision making the next **competitive differentiator.**”

Gartner, “Innovation Insight for Decision Intelligence Platforms,” 2023

Decision Types



Source: Data Management Survey, IDC, December 2022, N = 1,021

© IDC | 21



- **62%** of organizations say that **Automation** across the **Decision-Making** workflow has increased
- **64%** say that **metadata is growing** faster than raw data
- **39%** are prioritizing budgets for **streaming data analysis**

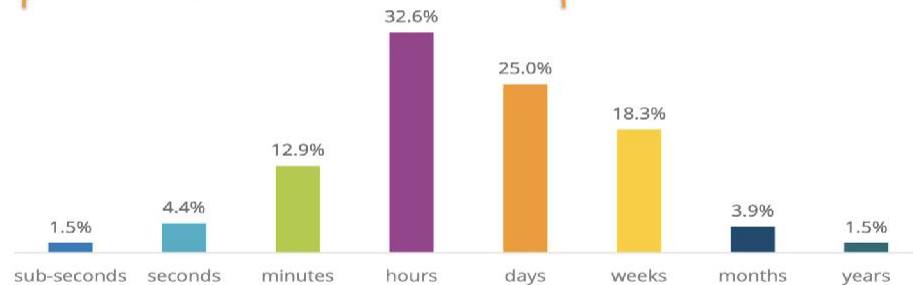


Source: Data Management Survey, IDC, December 2022, N = 1,021

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50% of Respondents Say Data Loses Value Within Hours

75% of Respondents Say Data Loses Value Within Days



Q. For the data you typically process as part of your role, what is its 'shelf life' or period within which it loses its value?



Source: Global Data Valuation Survey, IDC, December 2022, N = 1,014 (% of respondents shown)

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At Merck >15 use cases contribute to Predictive Inventory management

Exemplary ongoing initiatives:

- Applying machine learning to provide highly accurate **short-term demand forecasts**
- Leveraging external data sources with AI/ML to enhance **demand planning effectiveness**
- Integrated business planning to **enable E2E value chain transparency, SC planning and optimization**
- Combining digital twins and reinforcement learning in sales and operations planning to **ensure appropriate inventory levels**



ON OUR JOURNEY FROM MANUFACTURING TO SMARTFACTURING!

1. Resilience as Strategic Imperative

Adopting Smart Manufacturing and Supply Chain Intelligence ensures our operations are not only efficient but also robust against disruptions. The seamless integration of IT and OT, supported by a skilled workforce, equips us to anticipate, respond, and adapt to challenges rapidly, securing our business continuity and protecting our market position in any scenario.

2. Driving Industry Advancement Through Collaborative Innovation

Embracing this transformation catalyzes not just internal improvements but propels the entire industry forward, setting new standards for operational excellence and sustainability by collectively pushing the boundaries of what's possible

3. Cultural Transformation for Sustained Success

The journey towards comprehensive digital integration demands more than technological investment; it requires a shift in corporate culture towards continuous learning, agility, and cross-functional collaboration.



Thank you for
your attention

