

On Our journey from MANUFACTURING to SMARTfacturing!

Miss the shift – miss the future

European BioPharmafacturing summit

Düsseldorf, October 11-12, 2023

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- Prof. Dr. Michelangelo Canzoneri
- Global Head of Group Smart Manufacturing

- Dr. Michael Flannery
- Global Head of Smart Manufacturing and Digital Transformation, Life Science

MERCK

We are **MERCK**

A vibrant science and technology company

Every day, our more than **66,000 employees** work in **66 countries** to make a positive difference to millions of people's lives by creating more joyful and sustainable ways to live.



We are known as **Merck** internationally except for the United States and Canada, where we operate as **EMD Serono** in the biopharmaceutical business, **MilliporeSigma** in the life science business and **EMD Electronics** in the high-tech materials business.

Healthcare

- Pioneer in cancer treatment
- Advancing care in immunology
- Global market leader in **fertility treatments**
- Robust R&D pipeline
- We deliver **personalized treatments** for serious diseases









Life Science

- Trusted supplier and partner for the scientific community
- From research to large scale production with **>300,000 products**
- Novel technologies and world-class solutions driving discoveries

Electronics

- Innovations to change the way we access, store, process and display data
- Enabler of **new generation** electronic products for our everyday lives
- Supplier of innovative, functional and decorative pigments

We are a Science & Technology company Powered by Global Operations

-  120 manufacturing sites
-  100+ distribution centers
-  60+ process development labs
-  120+ QC labs
-  320,000+ products
-  1.5 million+ customers
-  100 Million+ patients
-  25,000+ employees

POW eRING

the 3 businesses of

MERCK

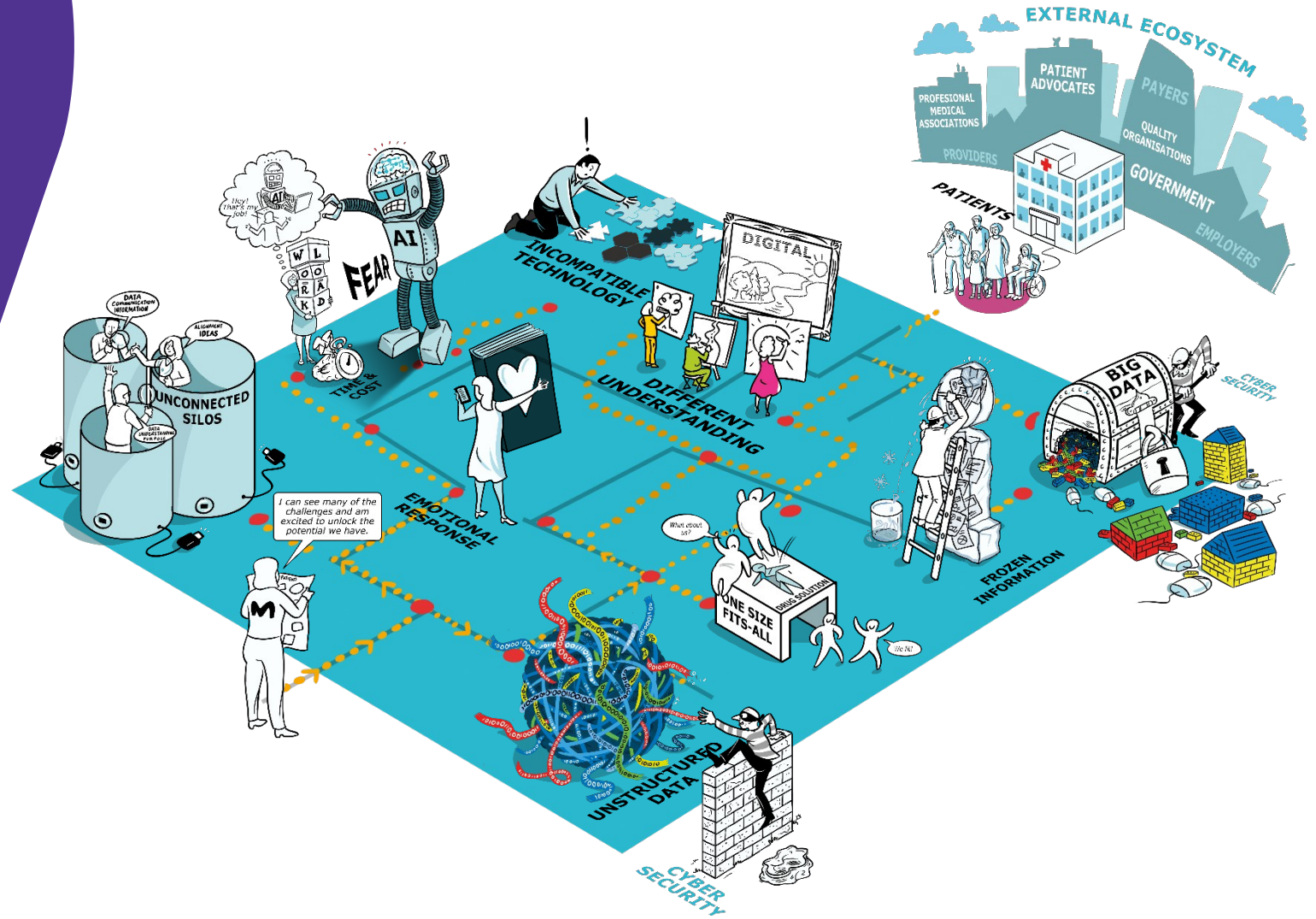
(Life Science, Healthcare, Electronics)



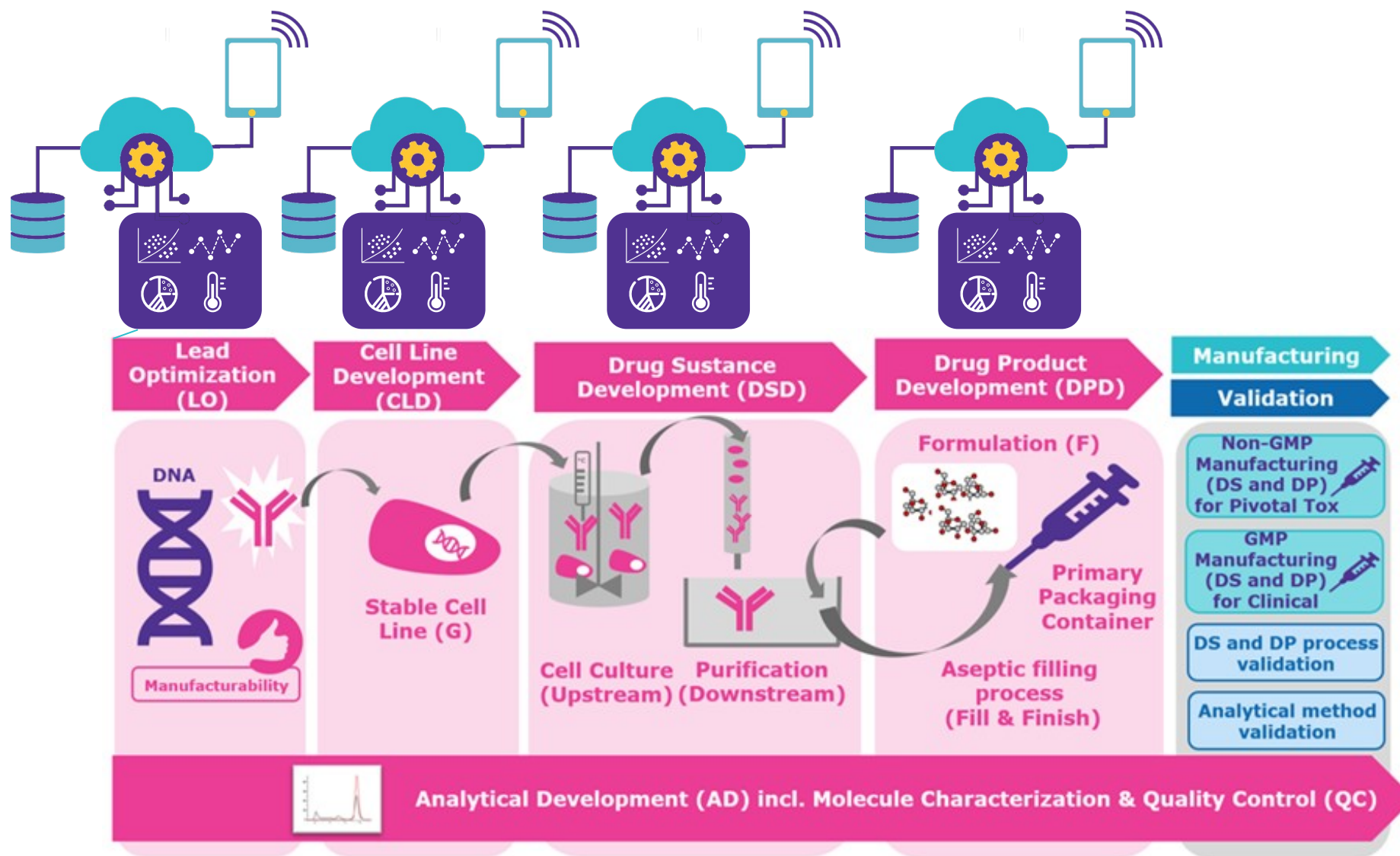
MERCK

Current state of industry

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

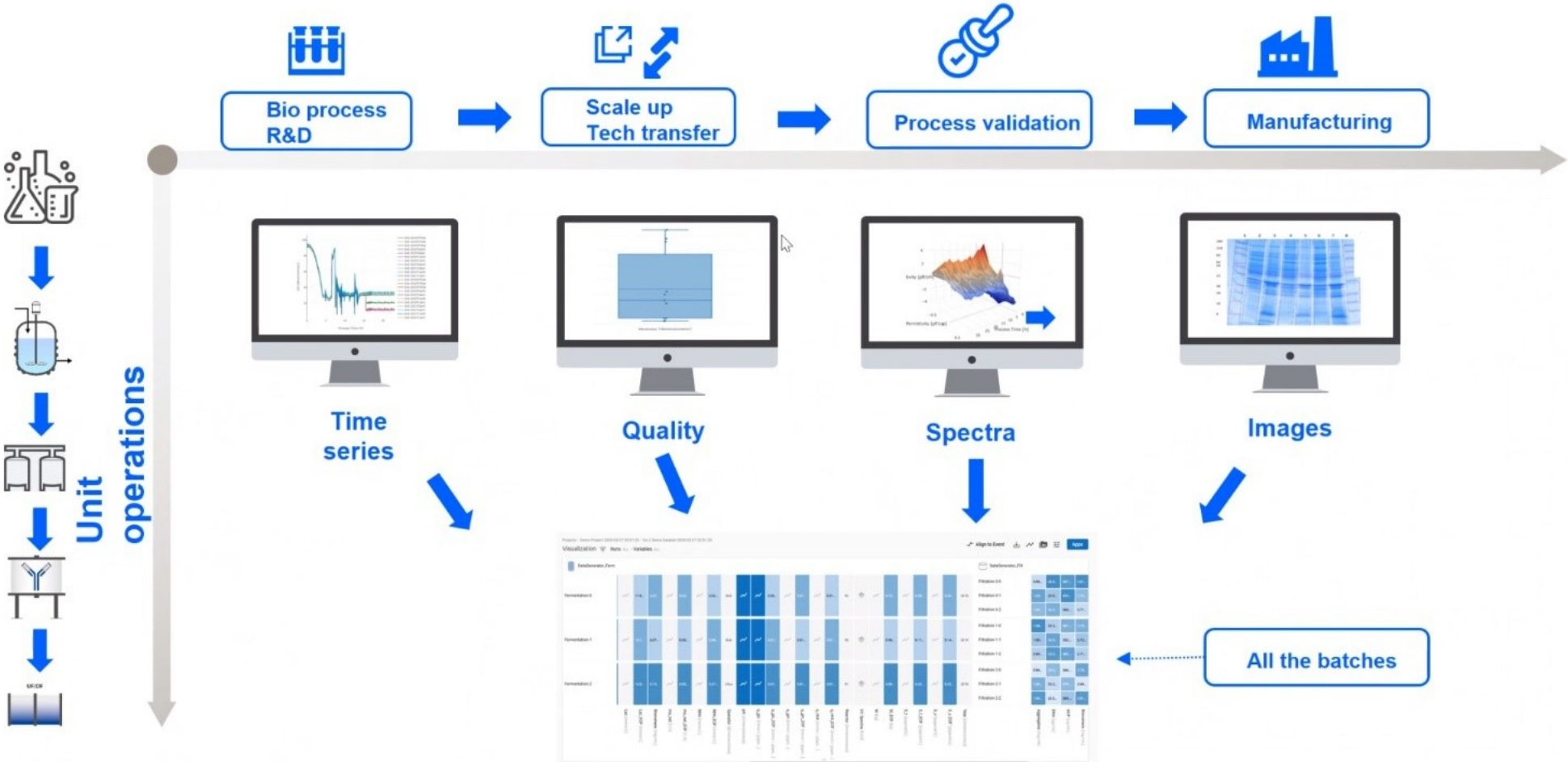


Ever-Increasing Data Along the Drug Development Life Cycle



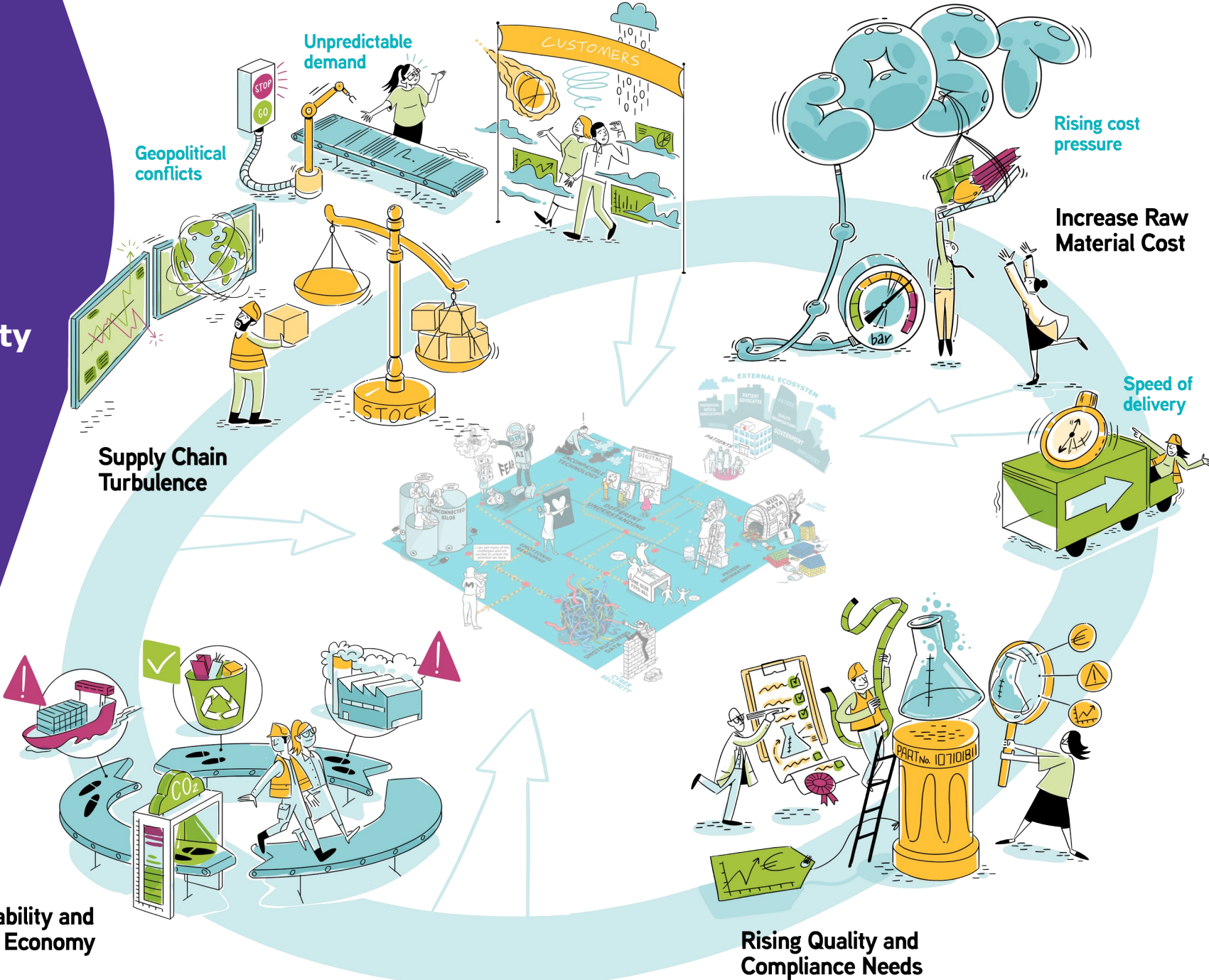
The holistic understanding of manufacturing processes

Data should be available from multiple dimensions



External Challenges

Manufacturers face rising costs, unpredictable demand, and growing sustainability and quality pressures, amplified by geopolitical risks



From MANUfacturing to SMARTfacturing

The Next Generation Manufacturing Excellence

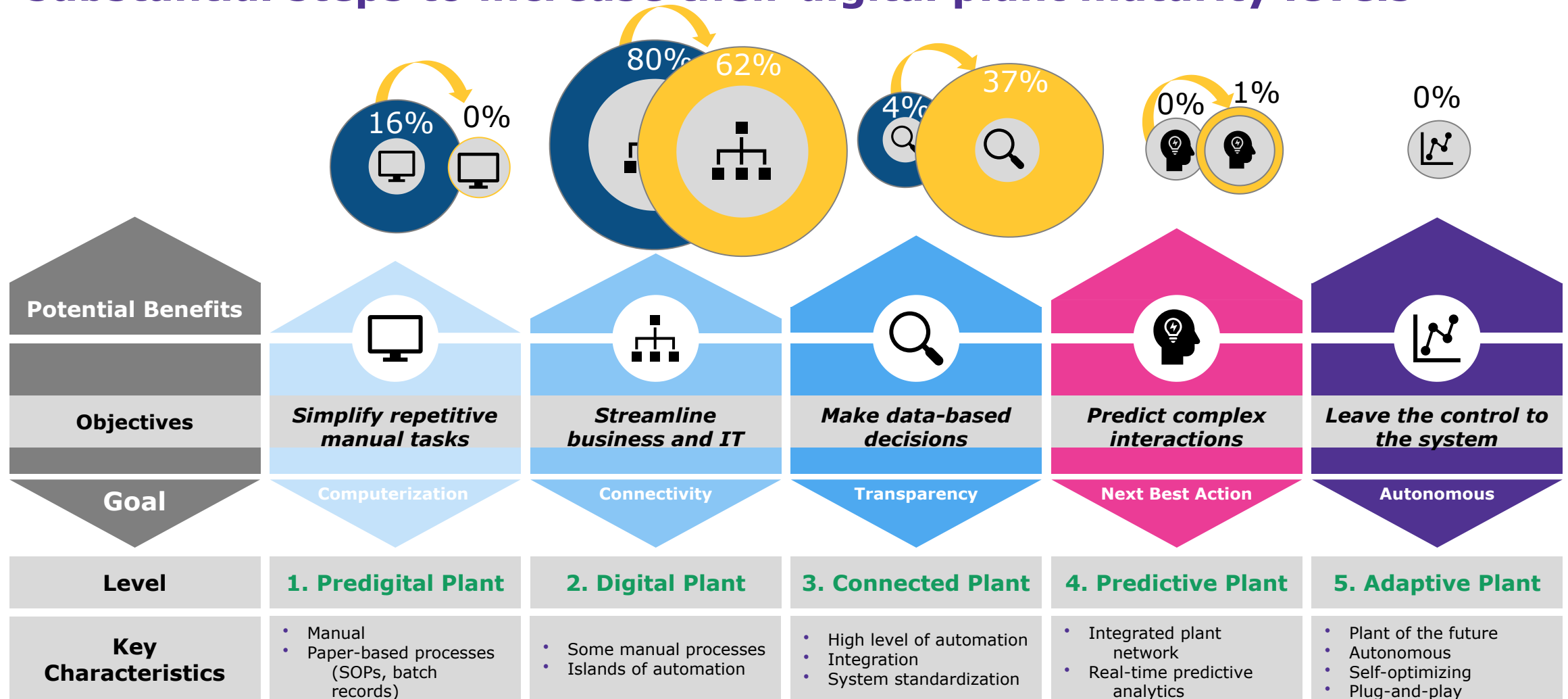


From MANUFACTURING to SMARTfacturing

The Next Generation Manufacturing Excellence

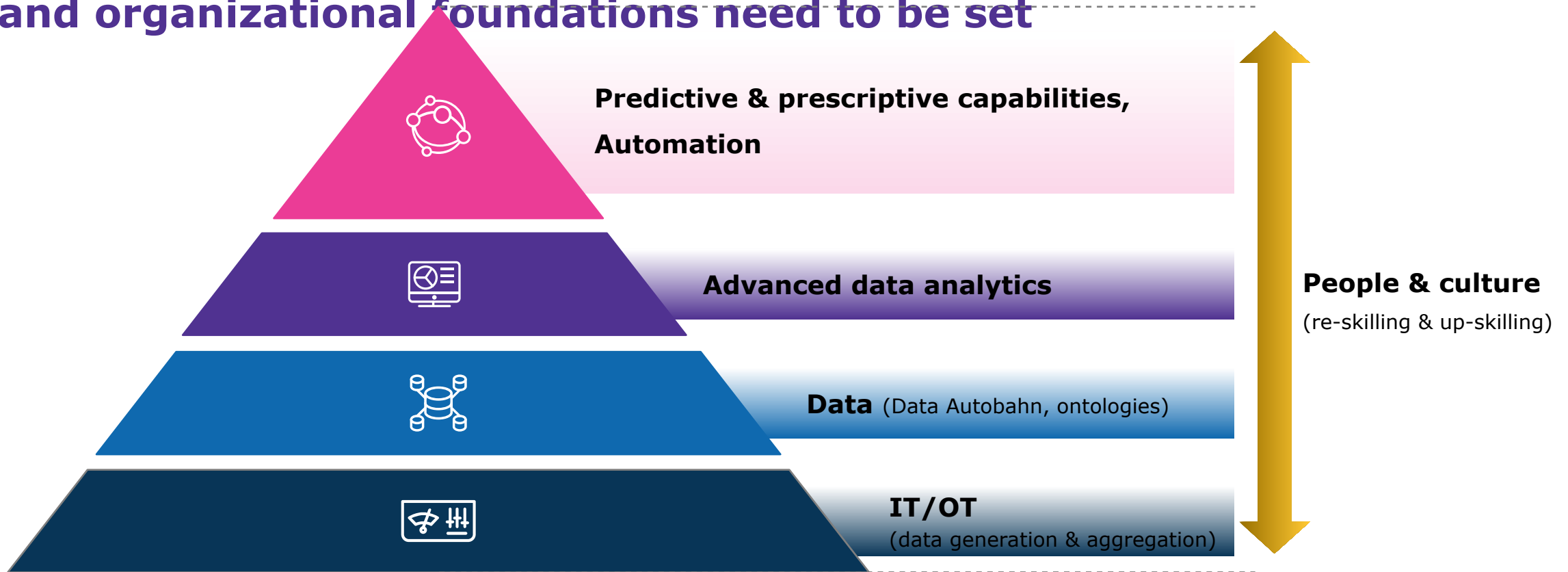


Between 2022 and 2024 the manufacturing industry has taken substantial steps to increase their digital plant maturity levels



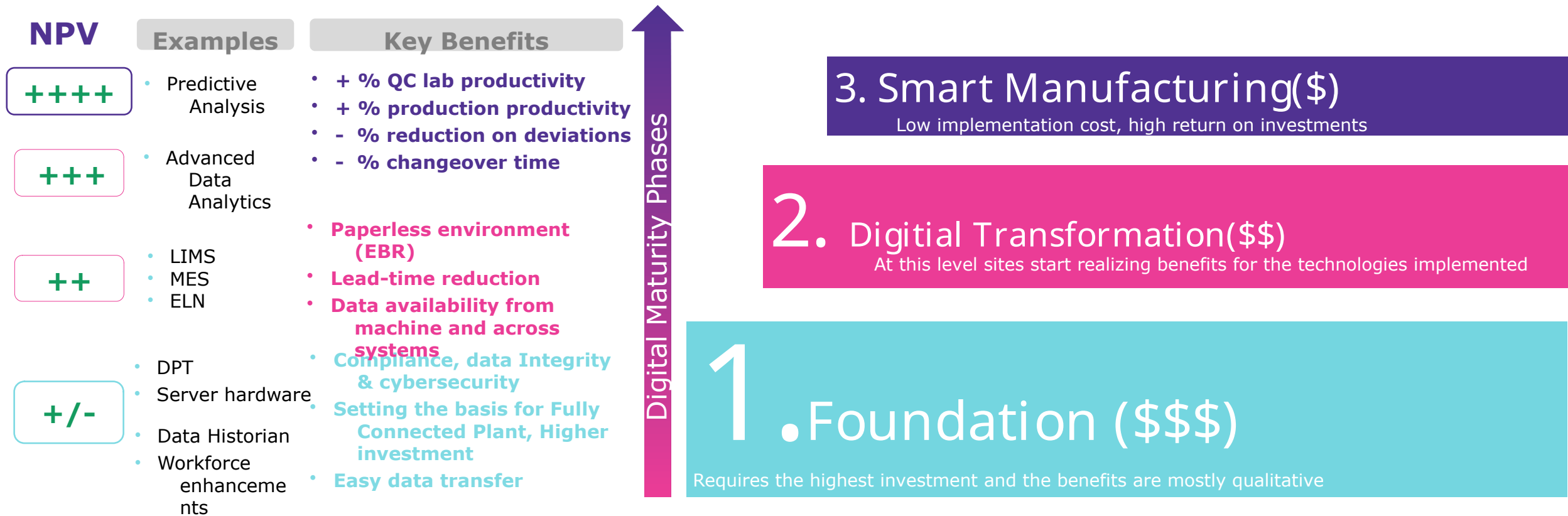
Enablers of Smart Manufacturing

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



Benefit realization requires infrastructural investments

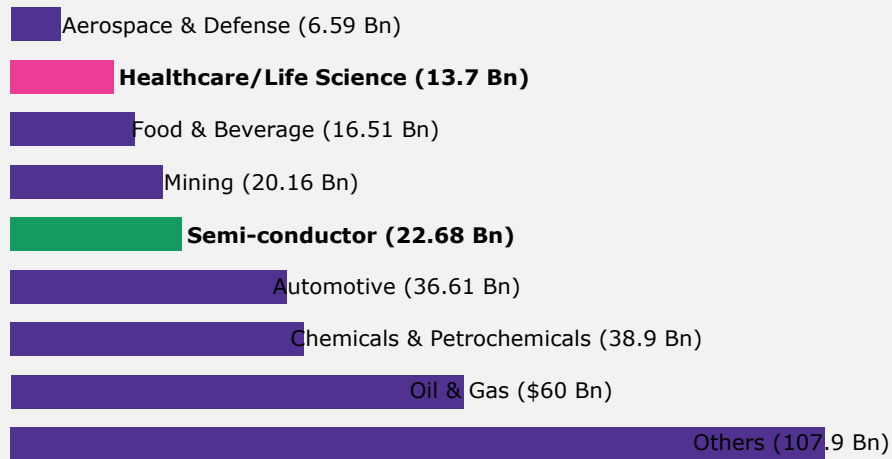
SMARTfacturing is a journey that requires long term strategic planning



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

Investments in SMFG capabilities in 2022

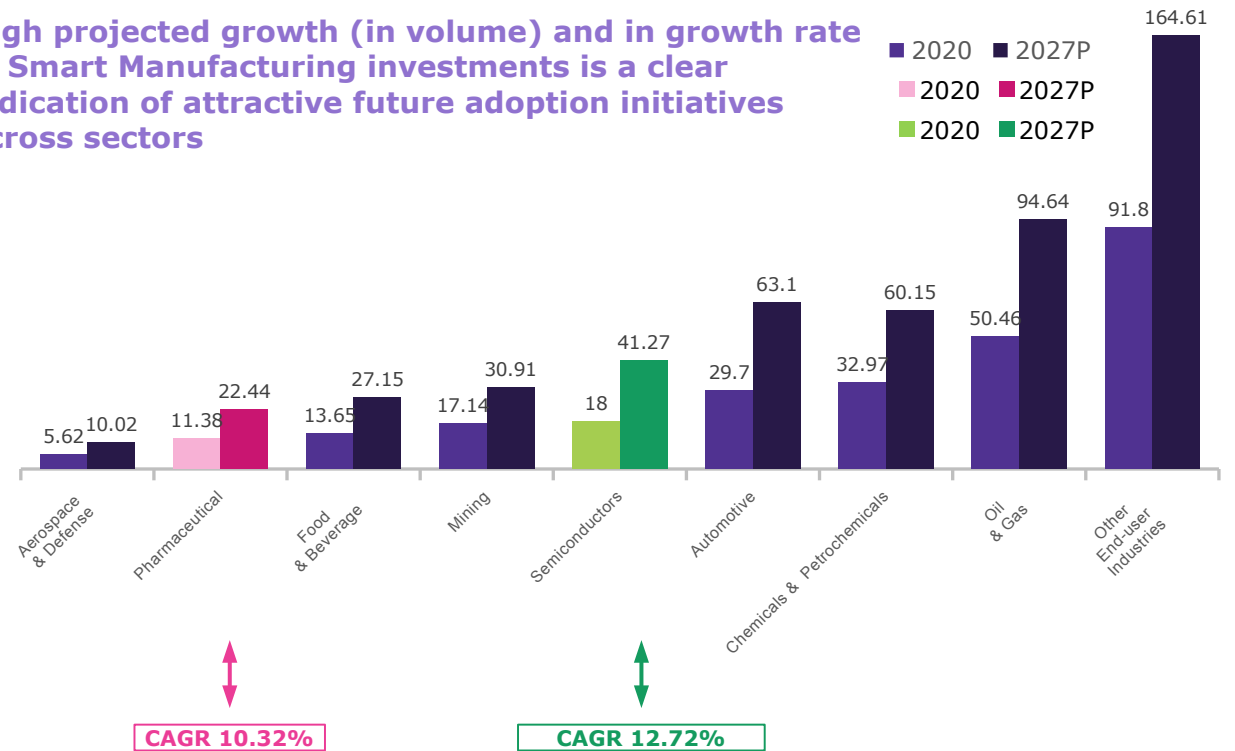
(in USD, 2022) - Cross Sector Analysis:



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:

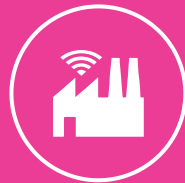
High projected growth (in volume) and in growth rate in Smart Manufacturing investments is a clear indication of attractive future adoption initiatives across sectors



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

41%

Global manufactures are adopting smart manufacturing technologies.



132

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

Source: Global Smart Factory Report - Mordor Intelligence 2021

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

Outcomes & Benefits

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

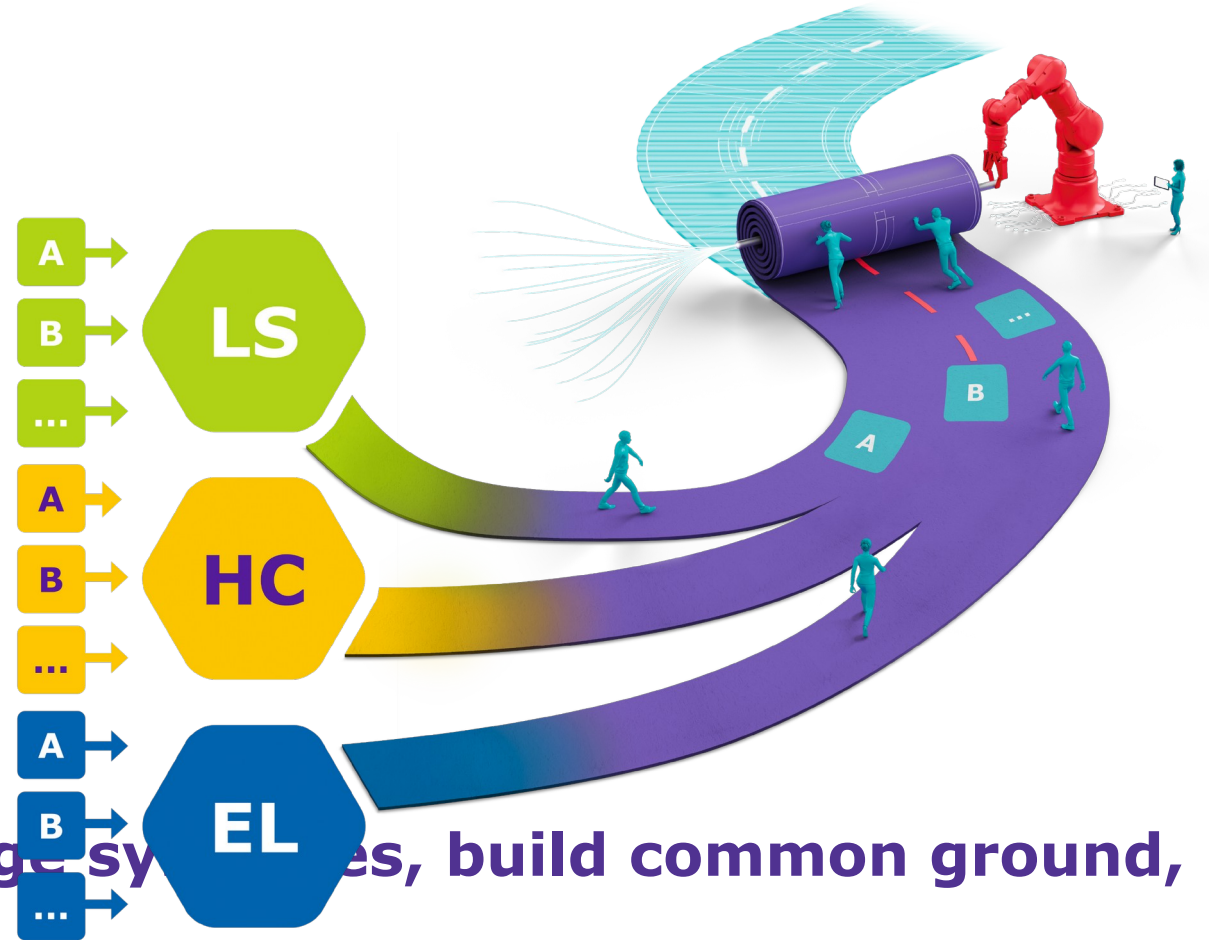
ONE Merck SMARTfacturing Journey

From...
Developing **individual, stand-alone capabilities** in each sector that are based on different technologies



...to
Driving **standardized capabilities** across Merck through coordinated workstream efforts with common technologies for high scalability

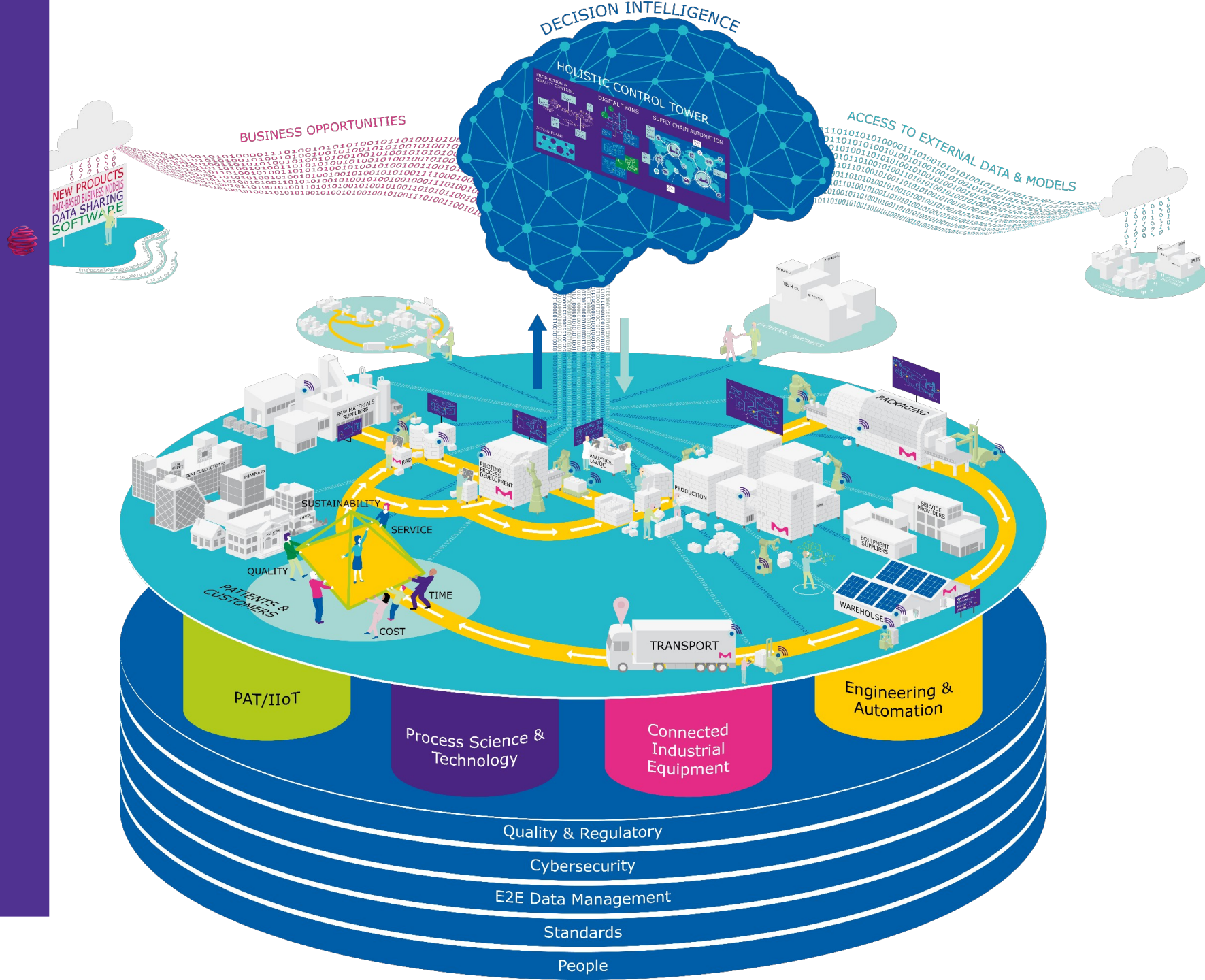
leverage systems, build common ground,



- LS capability
- HC capability
- EL capability
- Scaled ONE Merck capability



Envisioning Our future with SmartFacturing



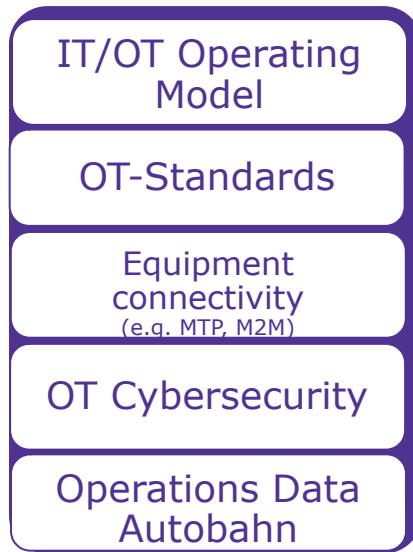
Merck has the ambition to enable the following **SMART**facturing Goals & Levers



Manufacturing Excellence by Design



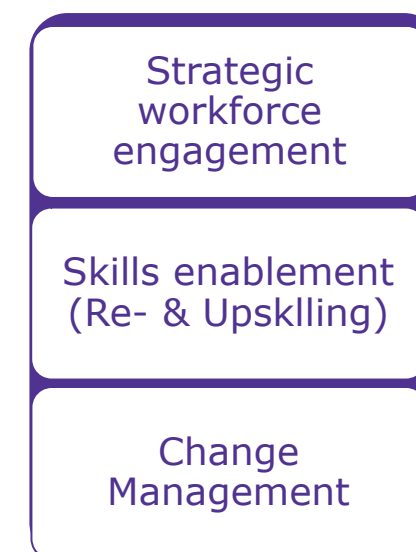
IT/OT convergence



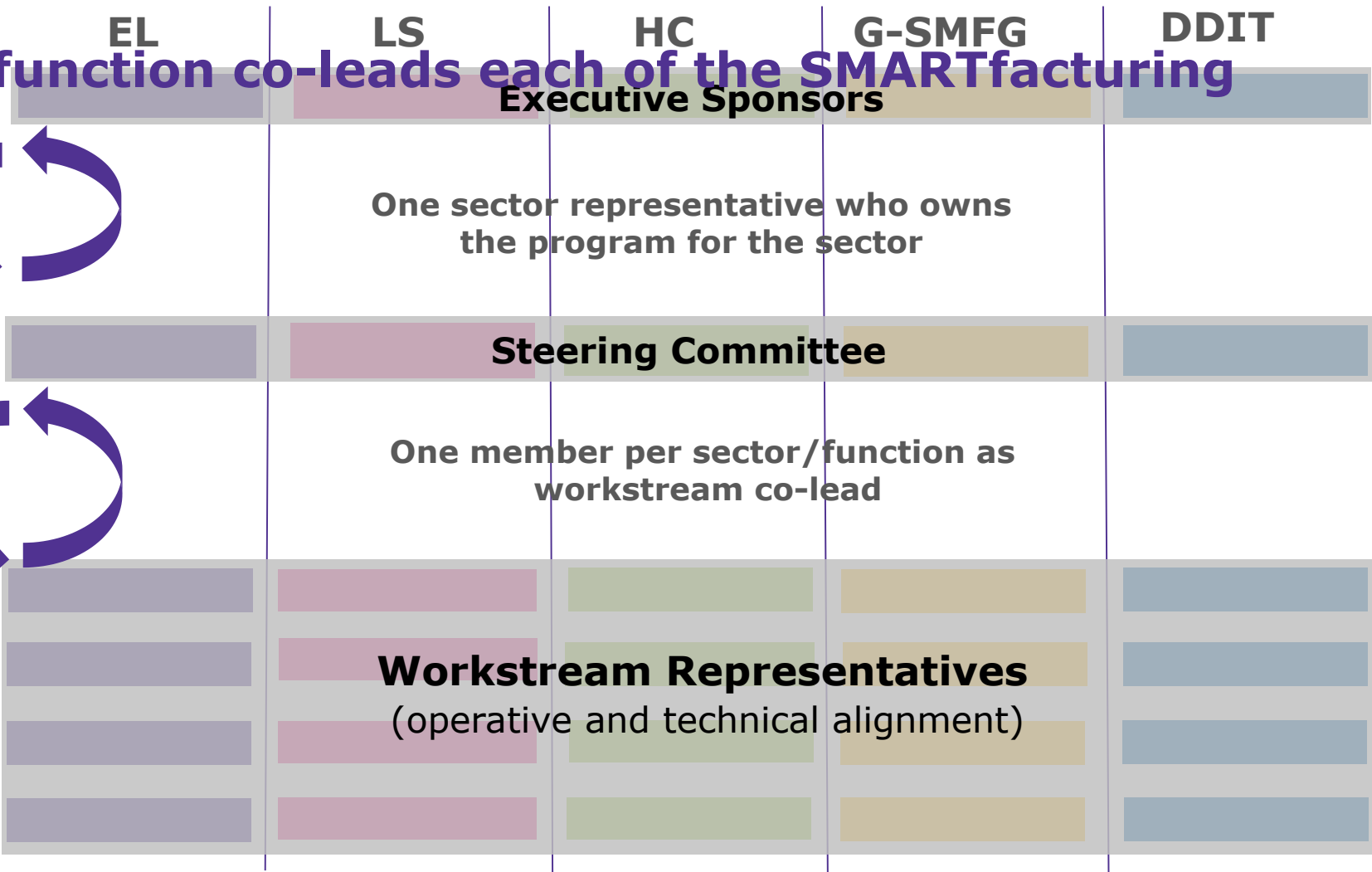
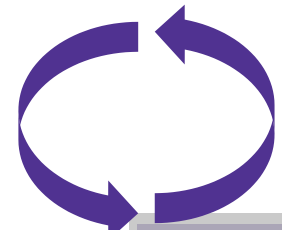
Supply Chain Intelligence



Workforce Readiness & Change Management



Each sector/function co-leads each of the SMARTfacturing workstreams




Executive Sponsors

X-sector SPoCs


SMARTfacturing Capabilities & Projects

Top a

Portfolio of SM



>130
Capabilities



25+
Capabilities
scaled across sectors

Capabilities include:

- Manufacturing Intelligence & Cockpits
- AI supported Deviation & CAPA management
- GenAI enabled Supply Chain Chatbot
- End-to-End Supply Chain Visibility Cockpit
- Demand Forecast Analyzer
- Advanced Planning and Scheduling
- Distribution Planning
- Modular equipment / Plug & Produce
- Predictive Maintenance
- GreenSpeed – Automated Sustainability process assessment
- Sustainability report and plastic tracking
- Automation & Robotics
- Paperless labs/eLabs
- AR/VR enabled trainings
- Digital Twins ...

60+

Capability Projects

started or in pilot phase



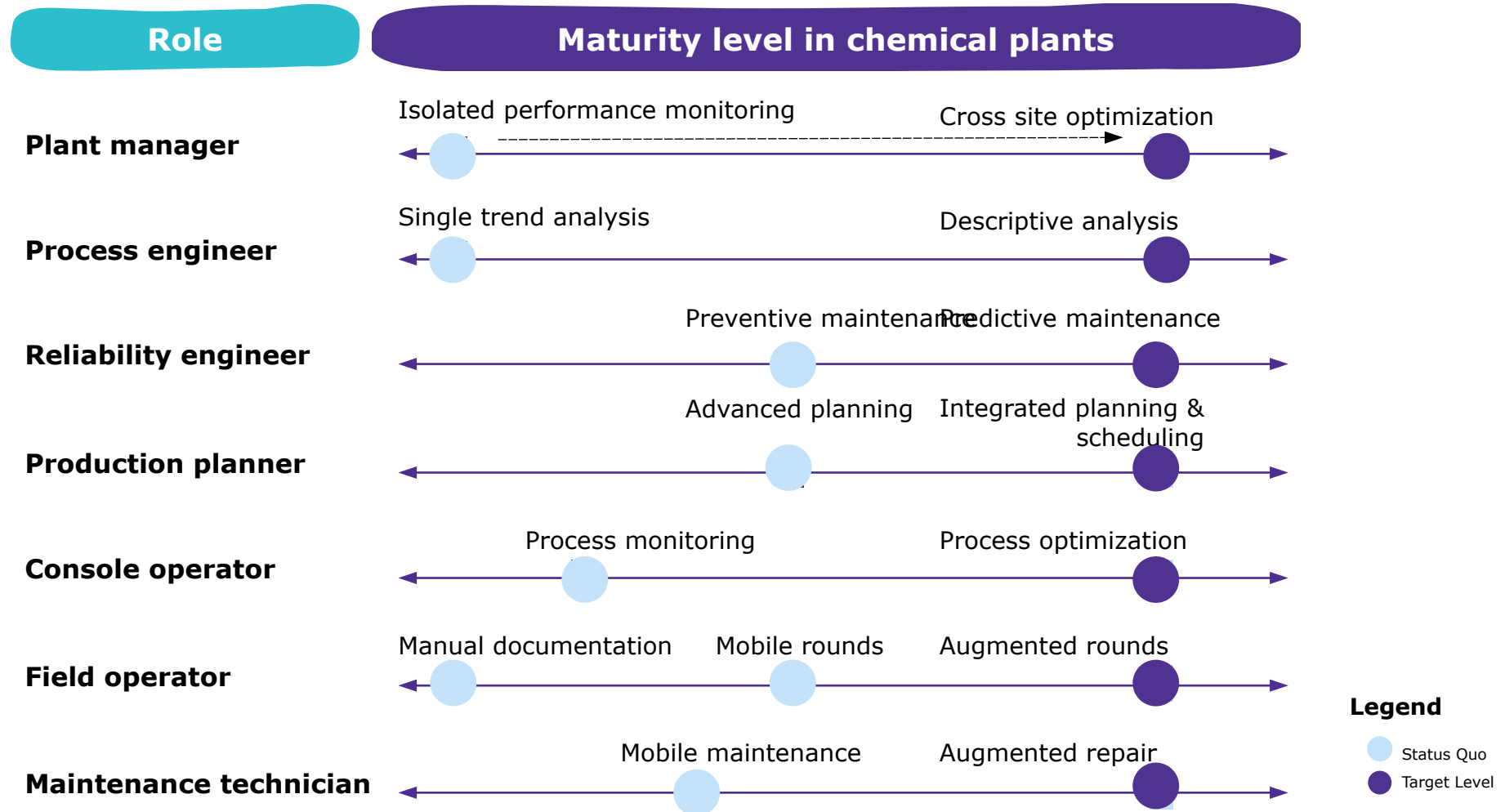
across all sectors
Work in progress

...but WHY do **9 out of 10**
digital transformation projects fail*?

It's more than just a technological task!

Talent & Culture

Operating digitally enabled plants and plant operations requires additional skills and capabilities across majority of roles

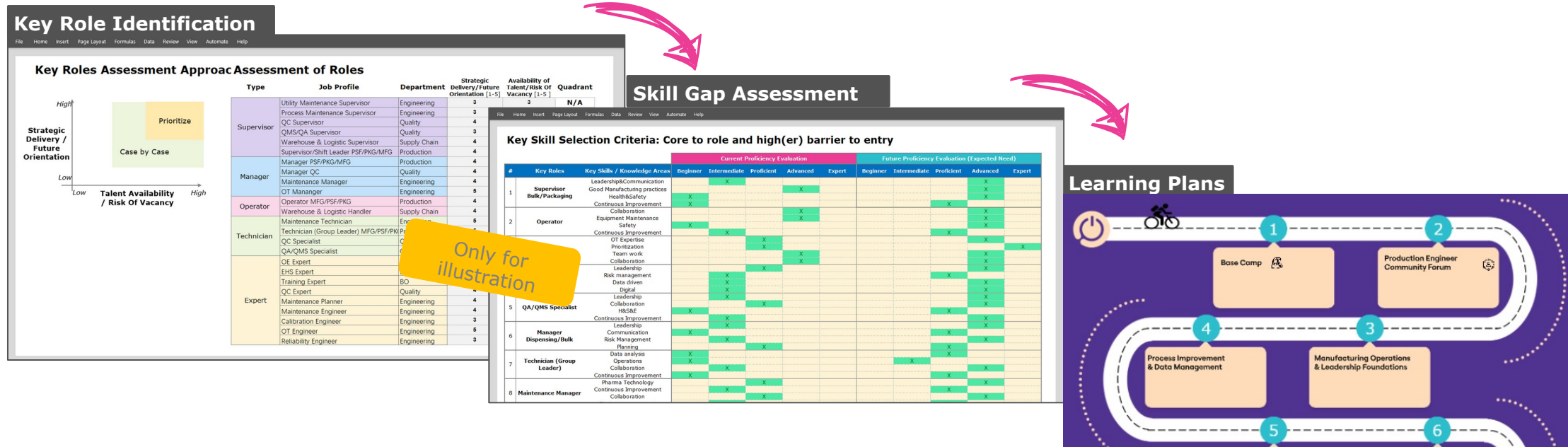


Workforce Readiness & Change Management

Ensure our workforce is well equipped to meet the smart manufacturing and digital plant ambitions defined by the sectors

Our Upskilling Approach for Operations

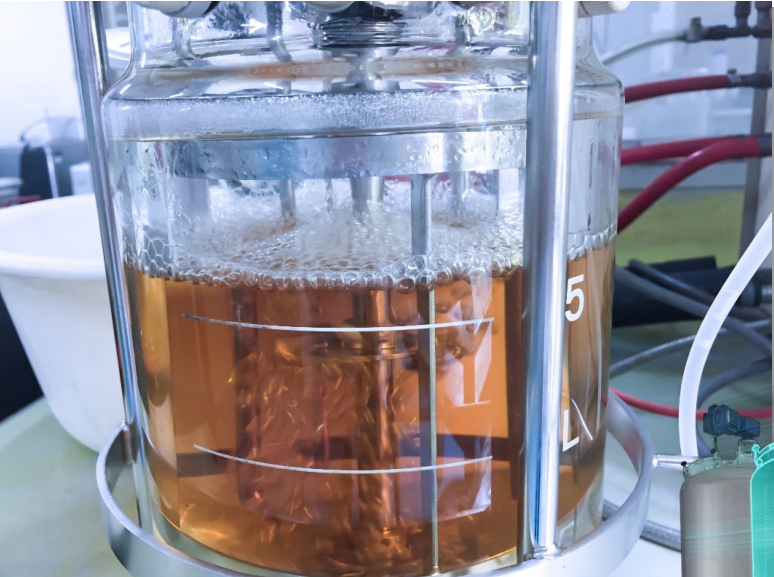
- We partner with local site teams and HR **to assess and close foundational (digital) skills gaps**
- **Training curricula and Learning sprints** are currently being developed in 3 pilot sites for high-priority roles with the intention to scale this in the following years



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

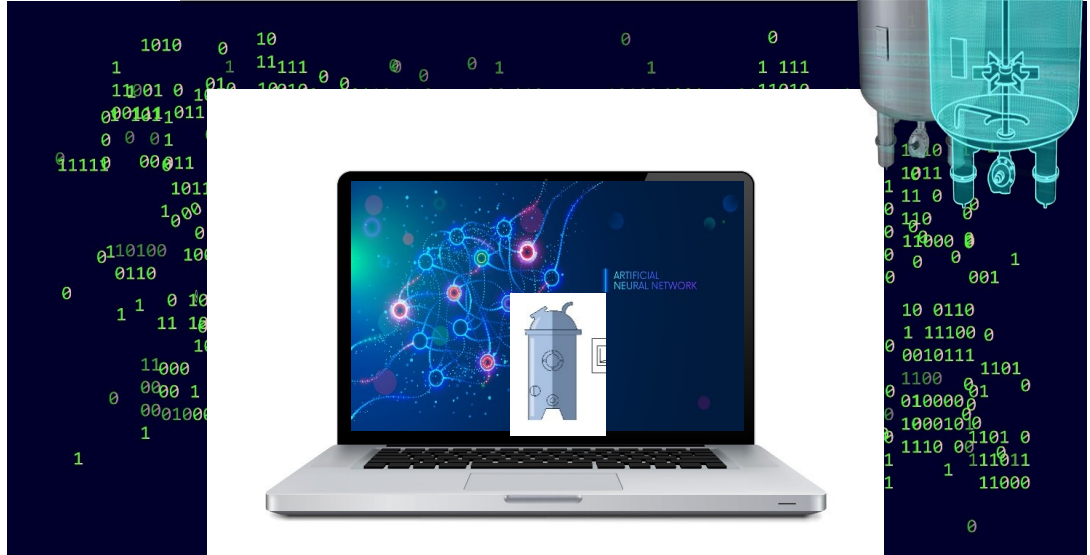
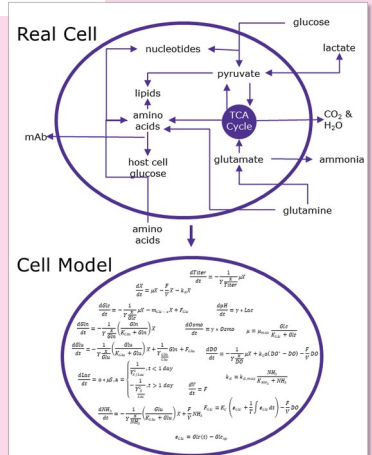


3D digital twin

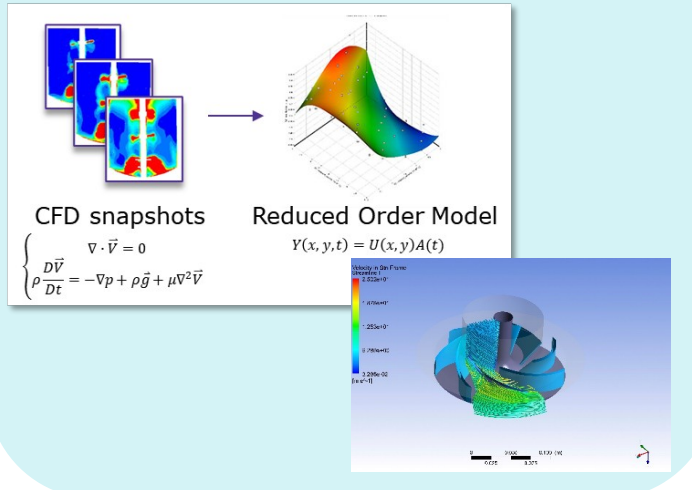
- Based on 3D computer graphics and AR/VR
- Used for equipment design, SME training, navigation in the plant...



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



Computational Fluid Dynamics (CFD)



AI Energy Saving @ Nantong LS & HC

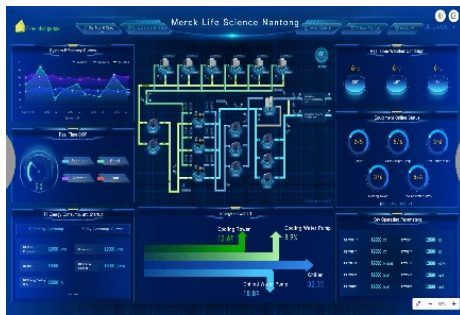
Demonstrated effectiveness of pilot and scaled solution with our preferred partner Siemens



Current energy management systems in industrial cooling stations are **inefficient, costly, and environmentally detrimental** due to lack of advanced technology integration.

- ➔ **Integrate Advanced Technologies**
IIOT, AI, and cloud computing to enhance energy management.
- ➔ **Optimize Energy Consumption**
Systematically control and reduce energy usage in cooling stations.

User Interface



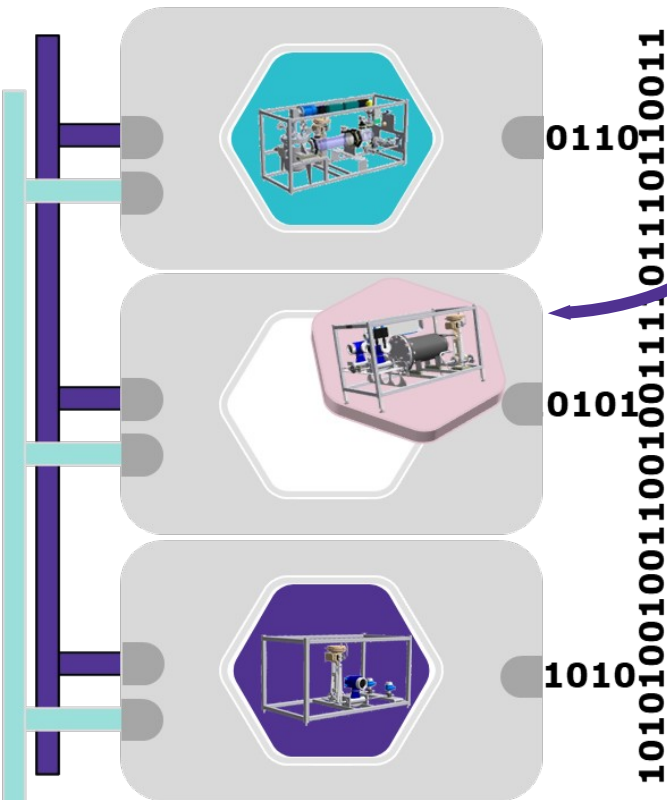
Outcome

- **Energy Reduction**
Cut cooling station energy consumption by at least **20%**
- **Environmental Impact**
Annually reduce CO₂ emissions by **435 tons**

Modular Plant concept enabled by Modular Type Package (MTP)

Highly automated platform

Pool of **specifically optimized** modules



universal backbone



Low conversion cost

Flexibility

Over 300 modules built

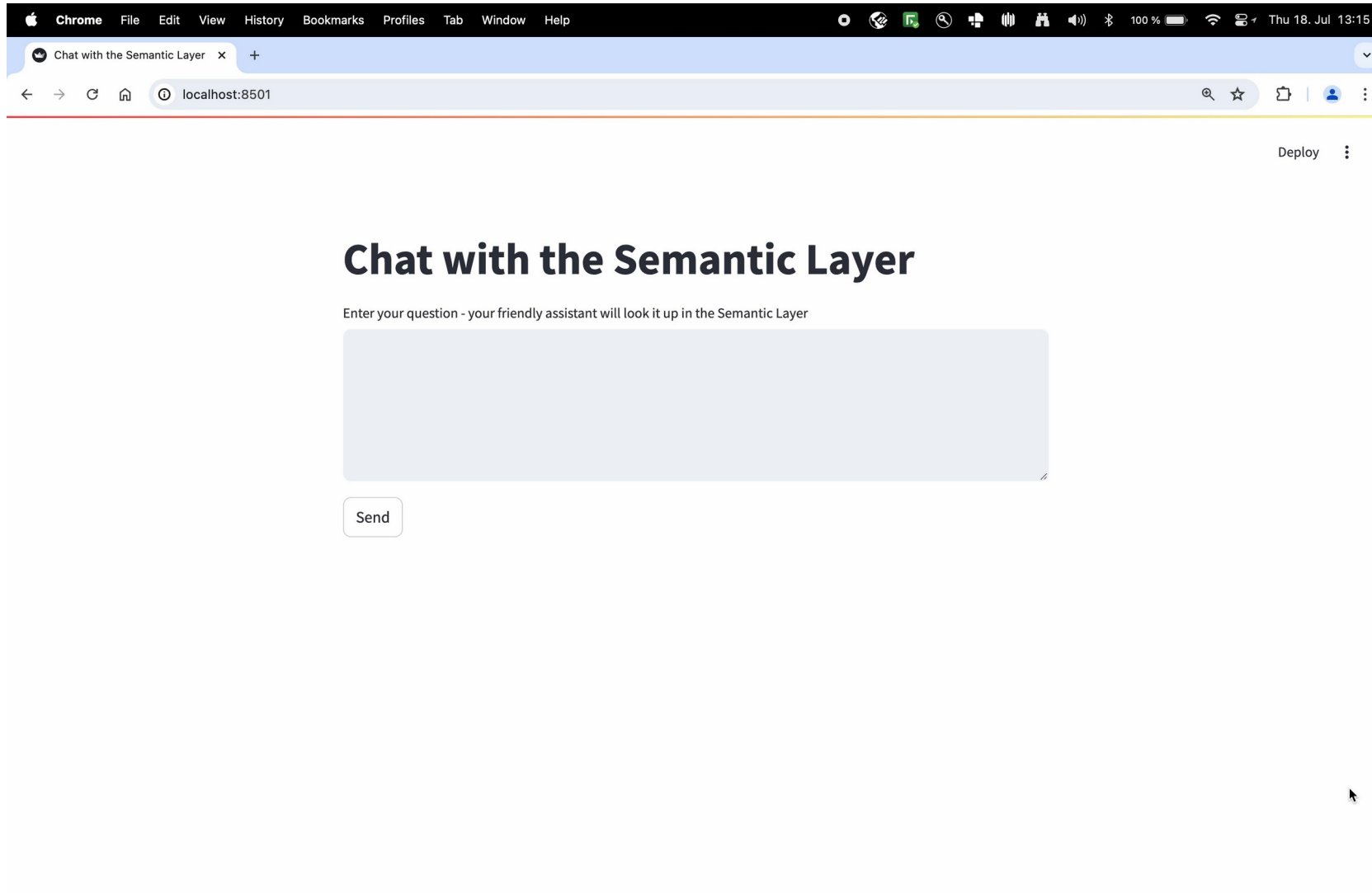
Break the paradox

between **flexibility** and **efficiency**.

pre-qualified modules are hooked into the production eco system

SMARTFACTURING

Interconnect sources of data and processing tools





SMARTfacturing Studio

Scope

“Show me, tell me, let me”

A **testbed of real manufacturing technologies** that are used at Merck **today**, as well as those we aspire to use in the **near future** through true **cross-sectoral collaboration**:

Predictive Maintenance (LS), PAT¹ (HC), Digital Twin (EL)

Mission

INCUBATE

capabilities within a testbed of our operations technology stack



SHOWCASE

capabilities that already exist and will soon be coming to the shop-floor



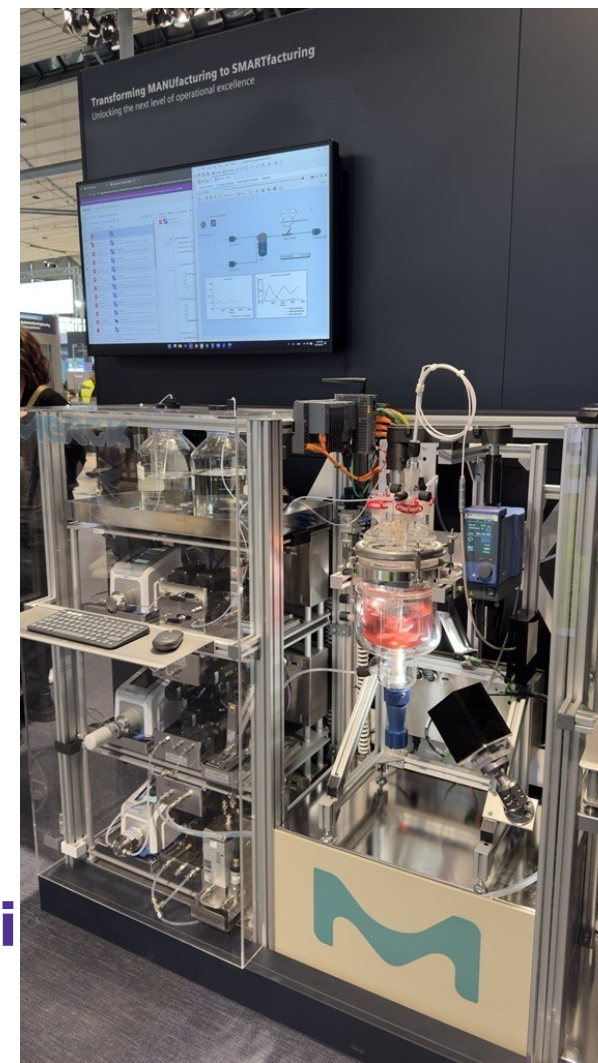
EDUCATE

the workforce with hands-on examples and trainings



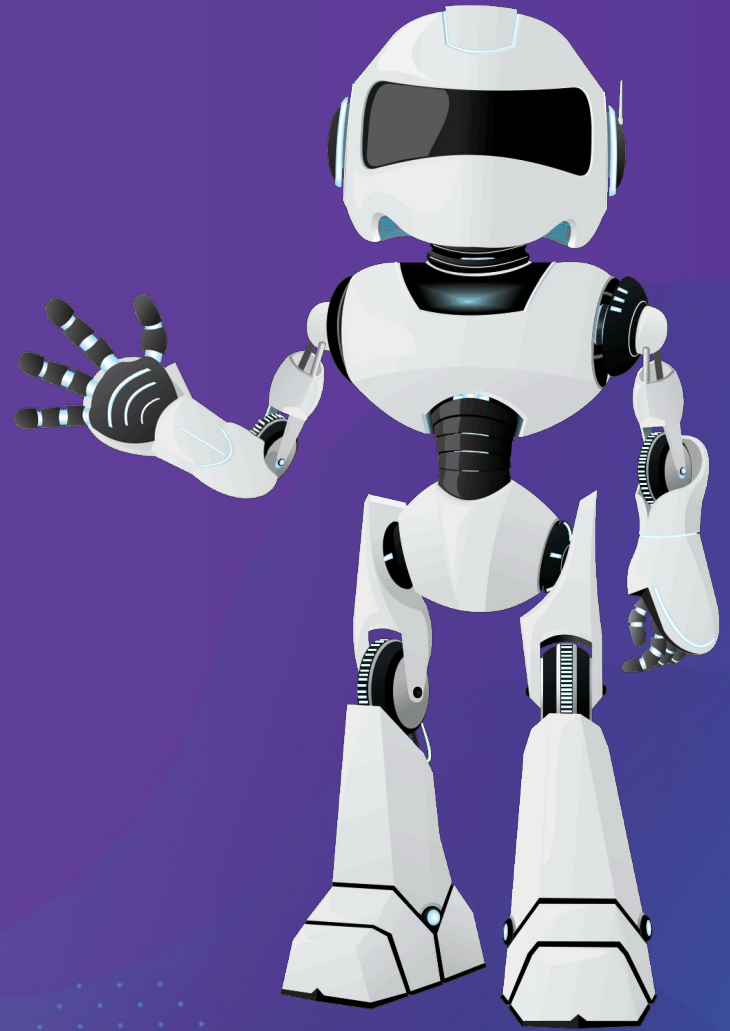
CONNECT

people, projects, and standards through cross-functional teams

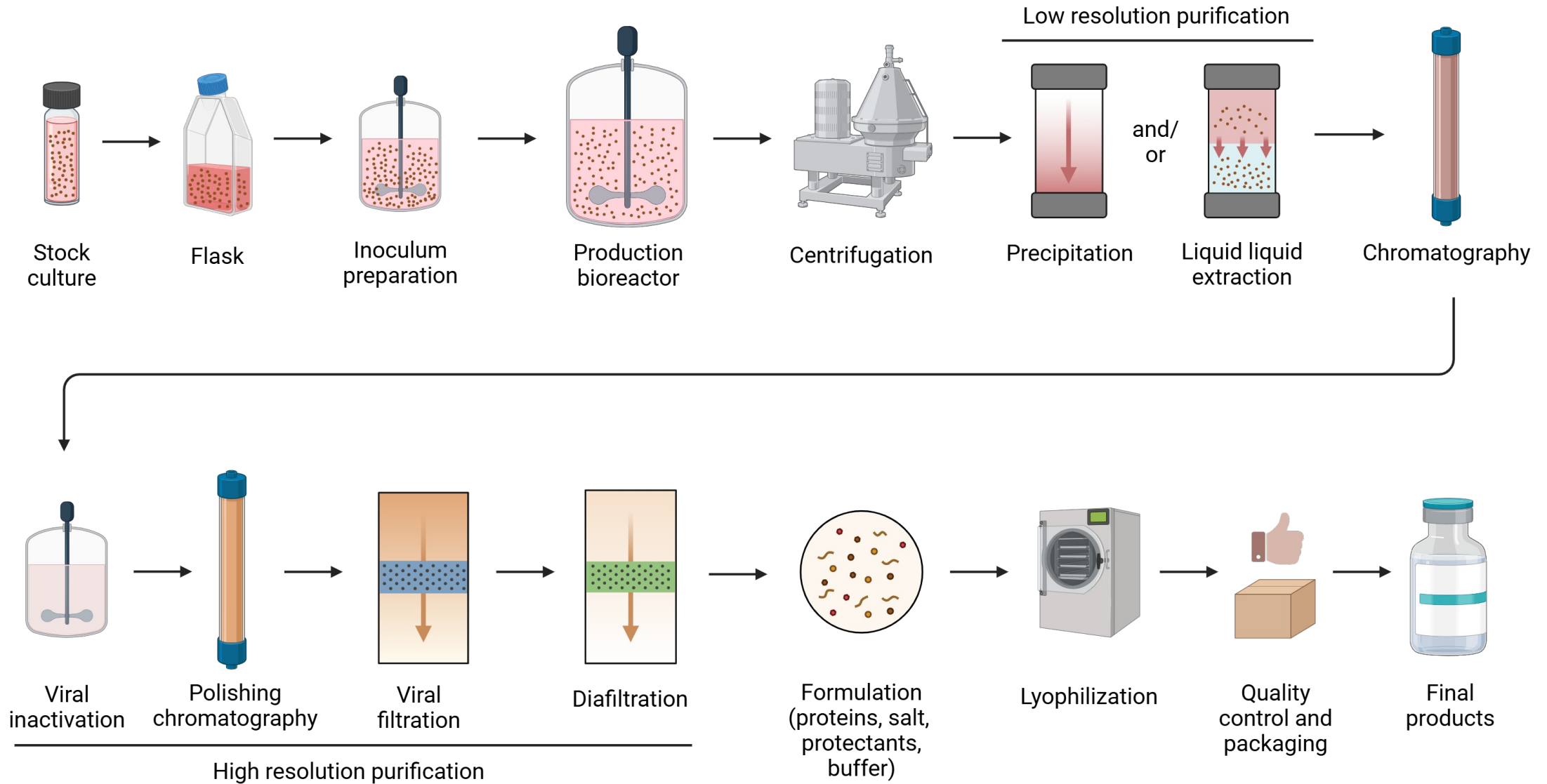


¹ PAT: Process Analytical Technology

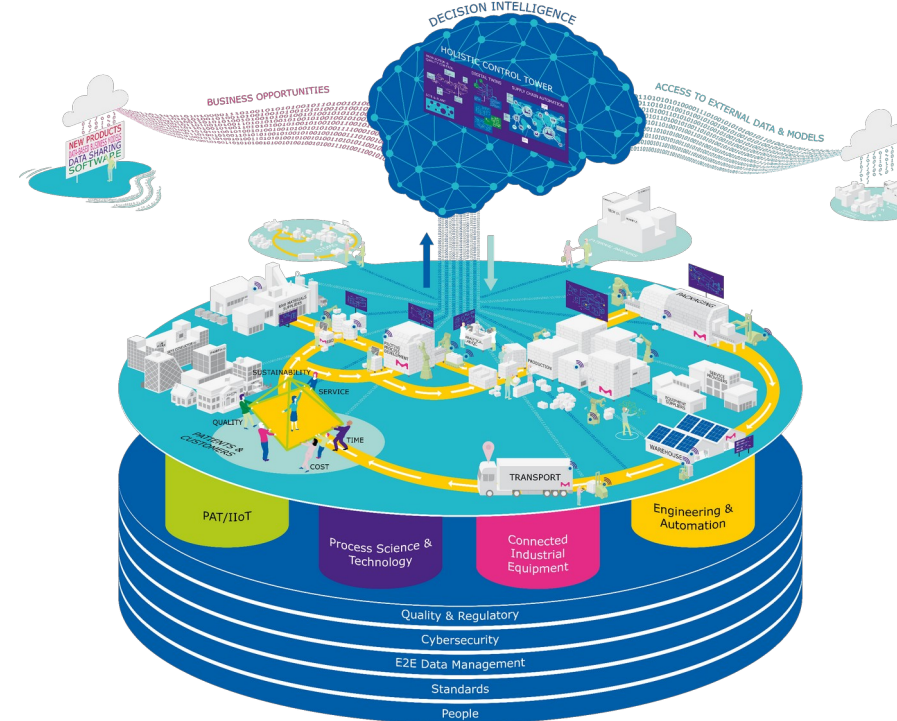
Thank you!



mAb Biopharmaceutical Manufacturing Example



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

- **Supply Chain Planning**
- Customer Collaboration
- Demand Planning
- Inventory Mgmt.
- Production Planning
- Sales & Operations Planning (S&OP)
- Supply Chain Analytics
- Supply Chain Strategy
- Supply Network Planning

- **Master Data Mgmt.**
- Manage Customer Master
- Manage Equipment Master
- Manage Material Master
- Manage Recipes Master
- Manage Vendor Master
- Manage Material Inspection Plan

- **Artwork Mgmt.**
- Product Artwork

Source

- **Collaboration**
- 3PL Integration
- Supplier Collaboration
- Procurement Distribution
- Customer Collaboration
- Daily Management

- **Trade Regulations**
- Export & Import
- Customs Regulations

- **Supplier Quality**
- Supplier Qualification

Make

- **Manufacturing**
- Detailed / finite Production

Make

- **Product & Sample Testing**
- Laboratory Data Mgmt.

Deliver

- **Logistics**
- Distribution Operations
- Warehouse Mgmt.
- Execute Transportation
- Track & Trace
- Waste Mgmt.

- **Environment, Health & Safety Mgmt.**
- Compliance & Fraud Mgmt.
- Occupational Health Mgmt.
- Label mgmt. & Printing
- IS Reporting & Risk Assessment
- Data Mgmt. / Dangerous Goods Data Mgmt.
- Distance Registration (Chemical Reg. Affairs)
- Invoice Volume Tracking & Reporting
- Incident Management
- Budget Planning & Execution

Return

- **Reverse Logistics**
- Returns Mgmt.

- **Customer Affairs Mgmt.**
- Complaint Handling
- Customer Communication/Inquiry Mgmt.
- Customer Notification Mgmt.

