



# Digitally Enabling Manufacturing

*Simplify, Standardize, Digitize, and Sustain  
End-to-end across our network*

**Lori H. Canzanese**

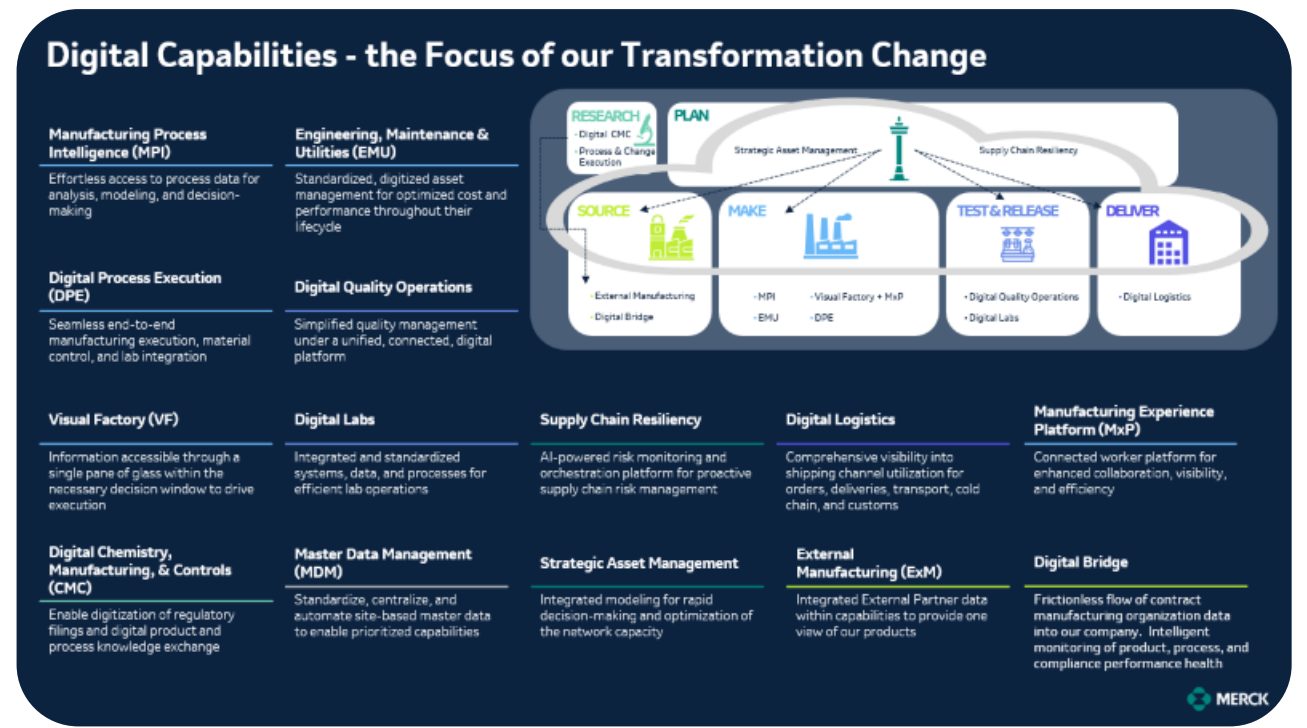
**Executive Director, Digital  
Manufacturing Operations**

**March 2026**

# End-to-End Evolution

## A Comprehensive Approach to Transformation

Pockets of Excellence	Our starting point
Bottom-Up	Conducted workload analysis; Collaborated with site and functional leaders to identify critical strategic opportunities
Top-Down	Validated through external benchmarks
One Network One Vision	Determined our digital maturity – current state and future state, capability by capability across entire network
How	In partnership, established True North and new ways of working



Methodical approach led to identification of interconnected initiatives, each with defined objectives and measurable key results.

# Digital Capabilities - the Focus of our Transformation Change

## Manufacturing Process Intelligence (MPI)

Effortless access to process data for analysis, modeling, and decision-making

## Digital Process Execution (DPE)

Seamless end-to-end manufacturing execution, material control, and lab integration

## Visual Factory (VF)

Information accessible through a single pane of glass within the necessary decision window to drive execution

## Digital Chemistry, Manufacturing, & Controls (CMC)

Enable digitization of regulatory filings and digital product and process knowledge exchange

## Engineering, Maintenance & Utilities (EMU)

Standardized, digitized asset management for optimized cost and performance throughout their lifecycle

## Digital Quality Operations

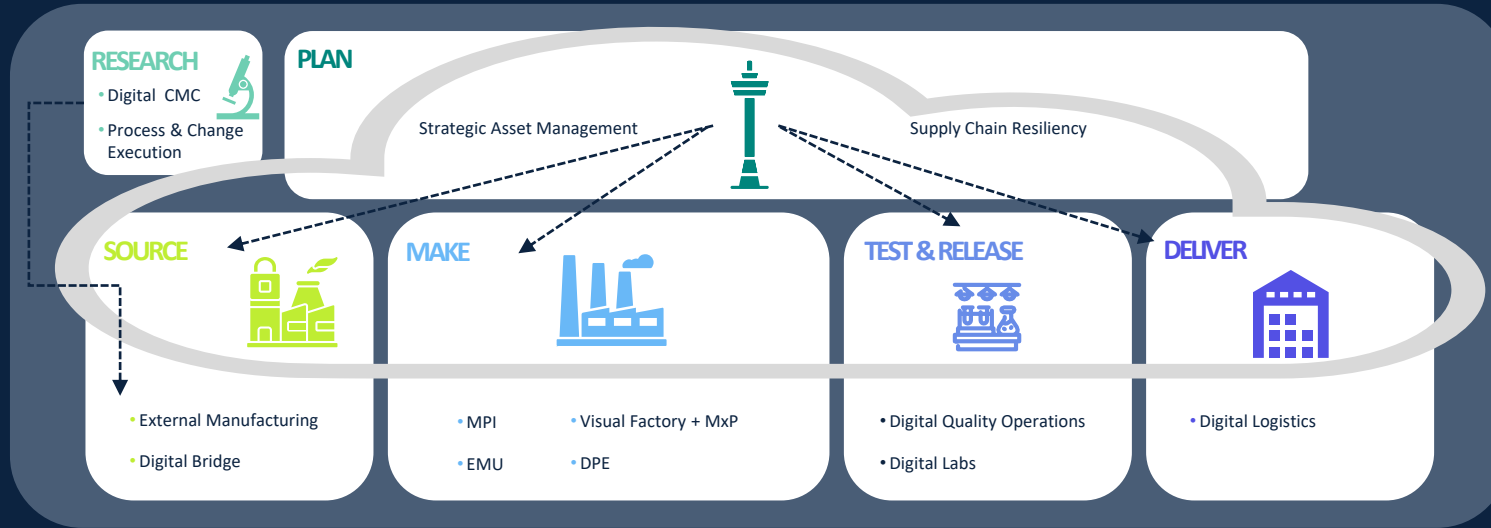
Simplified quality management under a unified, connected, digital platform

## Digital Labs

Integrated and standardized systems, data, and processes for efficient lab operations

## Master Data Management (MDM)

Standardize, centralize, and automate site-based master data to enable prioritized capabilities



## Supply Chain Resiliency

AI-powered risk monitoring and orchestration platform for proactive supply chain risk management

## Strategic Asset Management

Integrated modeling for rapid decision-making and optimization of the network capacity

## Digital Logistics

Comprehensive visibility into shipping channel utilization for orders, deliveries, transport, cold chain, and customs

## External Manufacturing (ExM)

Integrated External Partner data within capabilities to provide one view of our products

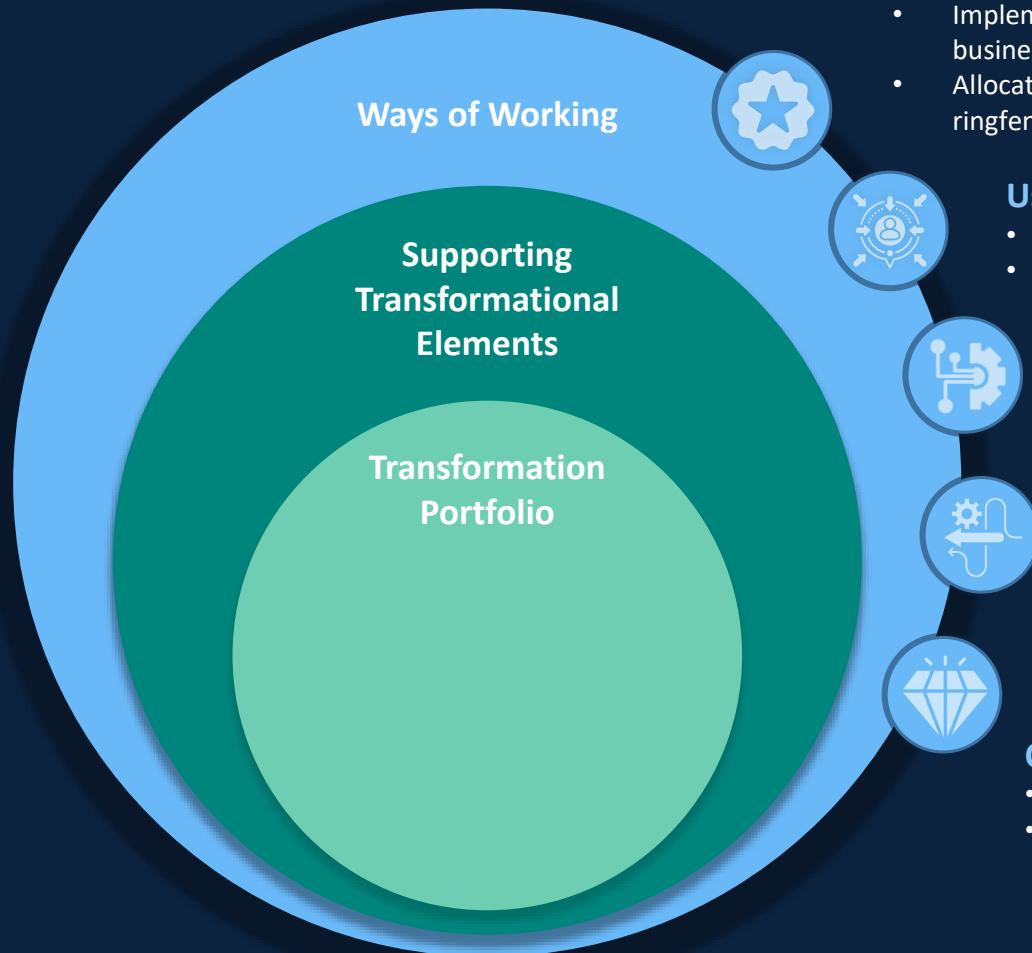
## Manufacturing Experience Platform (MxP)

Connected worker platform for enhanced collaboration, visibility, and efficiency

## Digital Bridge

Frictionless flow of contract manufacturing organization data into our company. Intelligent monitoring of product, process, and compliance performance health

# Our Digital Transformation Portfolio and Ways of Working



## World Class Execution

- Implement agile and disciplined project management focused on business outcomes.
- Allocate dedicated Subject Matter Expertise (SME) resources for ringfenced support.

## User-Centric Innovation

- Embed user experience as a core element in solution development - Designed by SMEs, for SMEs.
- Prioritize change management to ensure user adoption.

## End-to-End Digitization

- Address foundational gaps to strengthen core operations.
- Build interfaces to R&D through digital Chemistry, Manufacturing, and Controls (CMC) and product master data.

## Streamlined Business Processes

- Integrate Op Ex support to deliver and sustain our digitally enabled production system.
- Eliminate optionality.
- Transition from highly customized site-based solutions to enterprise solutions for greater benefits.

## Clarity in Digital True North

- Establish clear sponsorship and support for the defined True North.
- Ensure digital literacy and fluency among key roles across manufacturing.



Simplify +  
Standardize +  
Digitize

# Transformation Impact beyond Operational Efficiency

## Deviation Management Streamlined

incident closure time reduced by ~70% and investigation closure reduced by ~40%

Eliminating deviation backlogs, supporting batch release and enabling focus on proactive right first time and robustness

## Change Control Less Complex

>50% reduction in change processing time

Enabling faster implementation of improvements and corrective actions

## Complaints Simpler Intake

Defect photos available in 1-2 days vs weeks

Enabling rapid focus on high risk, impactful complaints

## End to End Batch Disposition Easier

30—40% reduction in activity to complete batch disposition review

Eliminating bottlenecks in batch release and supporting downstream customer service

## Maintenance Transformation Optimized

Elimination of 15-20% of preventative maintenance activity, equipment break-ins and high-risk work

Reducing equipment downtime, shopfloor complexity and increasing capacity

## Digital Process Execution Simplified Process

50% reduction in approvals and 48% reduction in lead time to update a digital batch record

Enabling batch record updates “as needed” versus every 6 months to support faster implementation of improvements

## Manufacturing Process Intelligence One-Stop

Contextualized data from multiple systems available in a single platform

Enabling proactive performance oversight and improved process robustness

## Visual Factory Radical Transparency

Near-real time visualization of standard key performance indicators from shopfloor to end-to-end value chain

Providing right information at right time to right people for radical transparency and responsiveness

# Digital Process Execution (DPE)

Making it easier to make medicine

DPE has standardized processes and developed digital solutions, so users spend more time executing the process and less time documenting the process.

**Vision Statement** To create user-centric, end-to-end shopfloor processes that are integrated to enable seamless and agile manufacturing

**Challenge Statement** By the end of 2027, DPE systems are designed around the user; no manual transcription between systems; 80% of batch records auto-close.

## DPE's Four Active Workstreams

### MES Digital Record Lifecycle

**Purpose:** Increases efficiency of MES digital records update process

**How?** One-way simplified process leveraging MES configuration by reducing signatures, documents, and thus handovers

**Resulting in** 48% capacity increase for the MES design hub resources

### Sterile Supply 2.0

**Purpose:** Streamlines documentation of processes enabling auto-close records

**How?** Integrates data, allowing system to review records due to quality by design

**Savings:** ~21,000 hours/year in execution and review of records

### Room Cleaning

**Purpose:** Simplifies and standardizes cleaning documentation with smarter, digital, compliant system

**How?** Incorporates visualizations and eliminates risk of manufacturing product in a dirty room

**Est. savings:** ~7400 touch time\*

### Instrument integration

**Purpose:** Removes manual transcription to create a frictionless flow of data from instrument to MES batch record

**How?** Implements middleware to capture data, automatic flow to MES

**Est. Savings:** Reduces time by 50% in execution and 100% in review

Future required workstreams

DPE's efficiencies create value for 10,000+ shopfloor operators and quality.

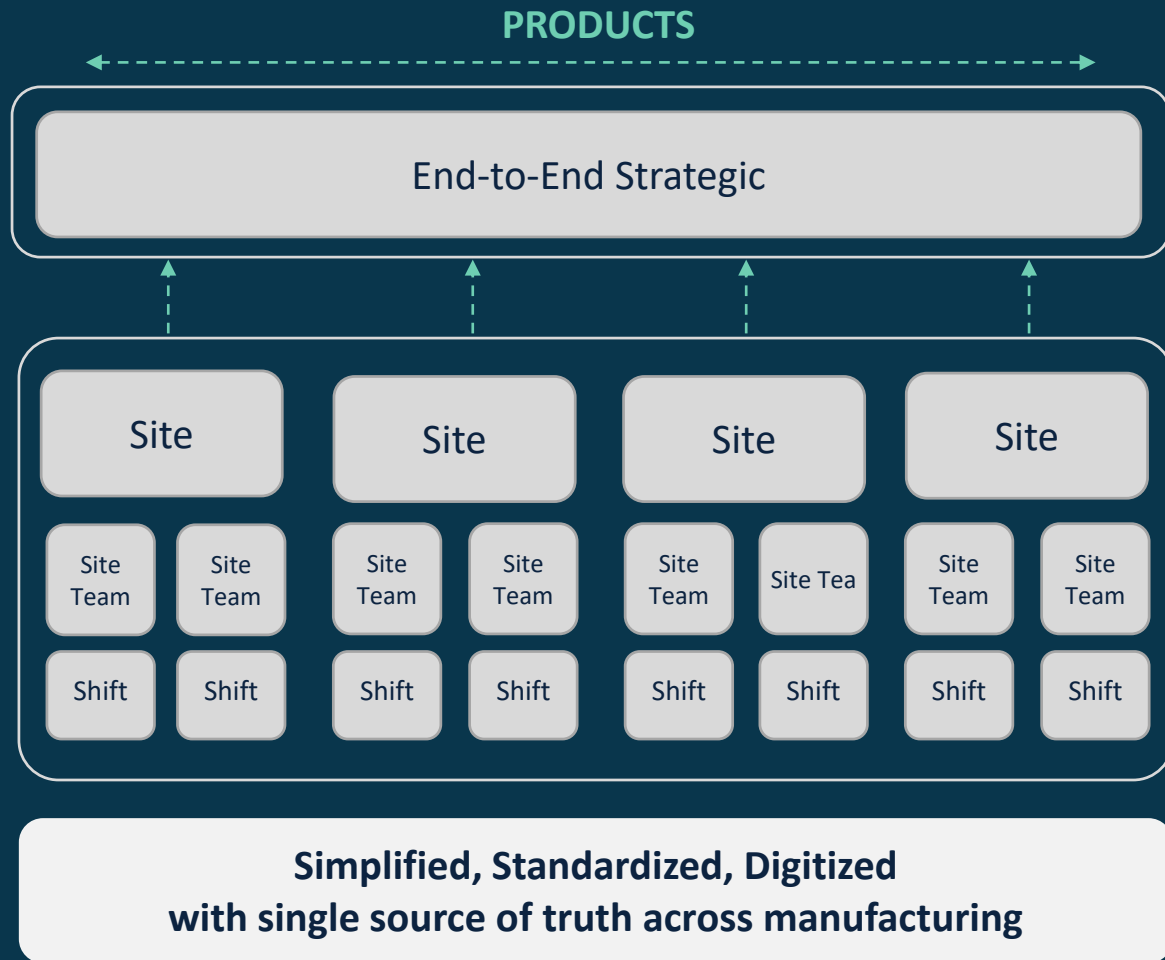
# Visual Factory: an easy-to-learn, efficient foundational solution providing the right information, at the right level (shop floor, site, strategic), to the right people for timely action



**End-to-end Strategic Visualization**  
 Build digital visualizations that enable proactive decision-making across the end-to-end value stream through one version of the truth

**Site Level**  
 Enable site level access to end-to-end value stream information through a standard, "one-stop-shop" interface

**Shopfloor Visualization**  
 Connect workers across functions to visualize real-time conditions, enabling the right decision



**Benefiting 10,000+ employees**



**Radical Transparency**  
 Near real-time performance data in sites and across our supply chains



**Efficiency**  
 Increased visibility and responsiveness, enabling supply robustness and product efficiency, to benefit our patients

# Manufacturing Process Intelligence

Manufacturing process data accessibility and analytics



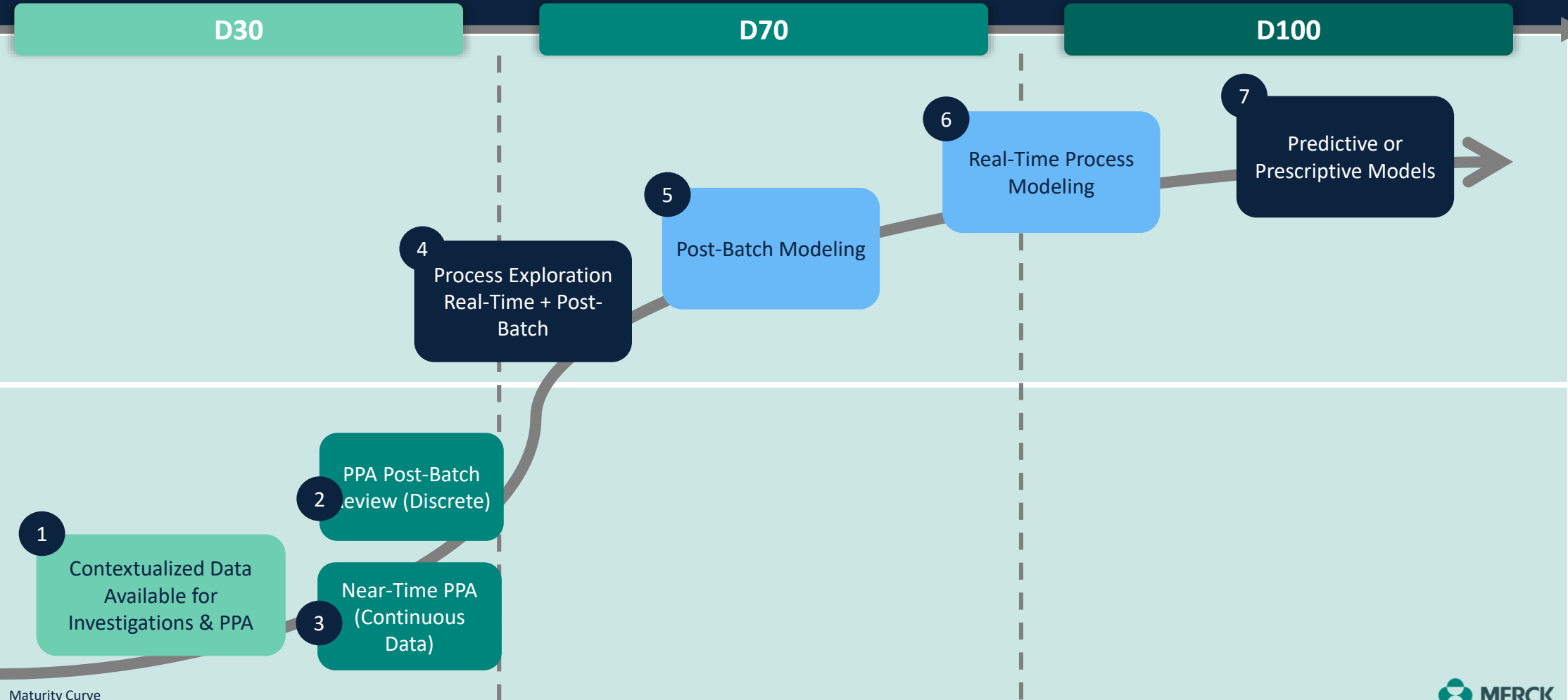
## Business Outcomes

Drive reduction in time spent accessing, manipulating, and visualizing data for investigations. Proactive process analysis (PPA) and advanced analytics improves process robustness and yields; reduces discards and quality notifications (QN)

Challenge Statements

Process Performance

Data Availability



# Deviation Management (DM)

Standardize processes and reduce time and effort for incident management and investigations



New tool uses GenAI to assist end-users with data assimilation and interpretation

Custom-made tool removed non-value add DM work for our users and generates rich data insights

## What are the Benefits?



Leverage structured and unstructured data from numerous sources



Accessible data from closed QNs with AI-enabled 'smart' search capability



Ability to gain insights and search data without QN creation



Streamlined drafting and documentation of investigations



Developed by business SMEs from DM world



Performs better than limited current system search

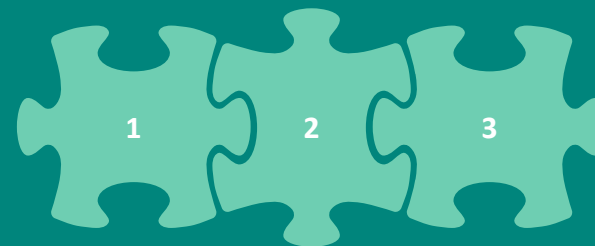


Enhances DM network knowledge sharing as data is pulled from all sites



Removes non-value add admin work allowing for focus on problem solving

## What are the Next Steps?



*Pilot Sites*



**April – June**

*Soft launch to 26 users at pilot sites*

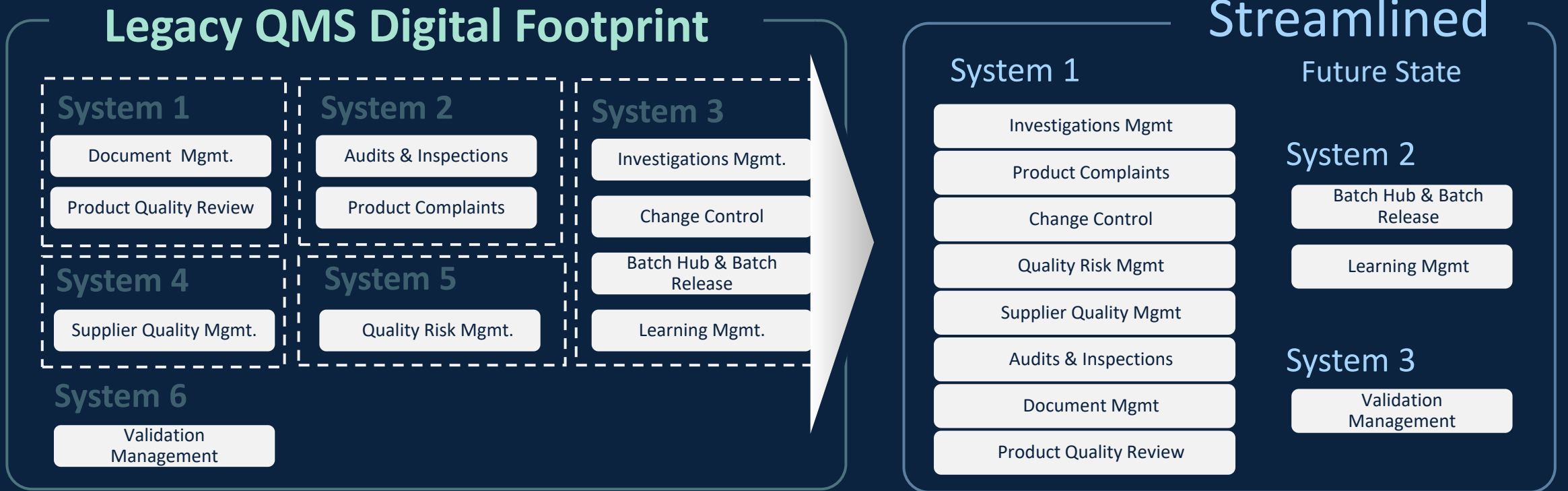


**June**

*Full site deployment at pilot sites*

# Quality Systems

Strategically rationalizing digital quality footprint across manufacturing, research and labs, and rest of enterprise, simplifying data flow and providing more real-time and proactive insights into product quality, patient safety, and data integrity.



# Supply Chain Resilience: transforming manufacturing risk management framework towards protecting supply amidst uncertainty affecting global supply chains

We're establishing a robust resilience framework, connecting the complete manufacturing risk ecosystem



Improved inputs to manufacturing through supply business continuity planning, proactive integrated risk management, and enhanced supplier visibility

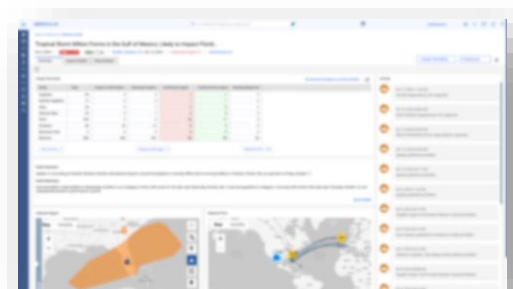
Enhanced last-mile resilience through digital logistics interventions and a focus on supply chain security

Network monitored 24/7 and risk events identified with real-world data

Compliance events in the upstream network monitored continuously

AI-powered assessment in real time

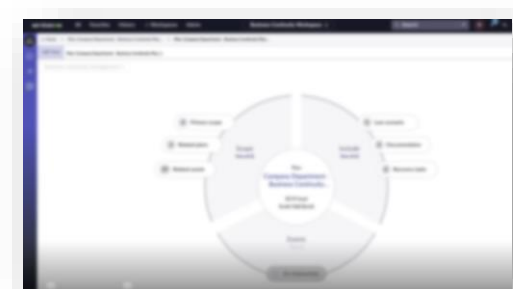
Supply Chain Resilience is harnessing the power of AI to ensure that no potential threat goes unnoticed and to gain comprehensive visibility across the entire risk landscape, enabling manufacturing to navigate uncertainties with confidence.



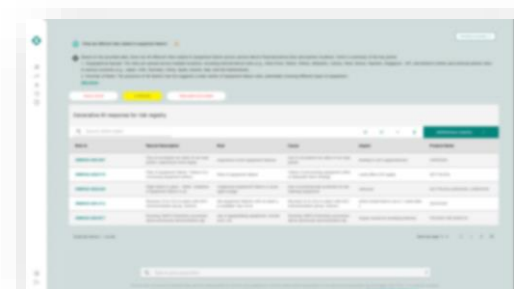
Applications track risk events in real time (disasters, human made, compliance, etc.)



Integrated Risk Management (IRM) system enable a forward look to our manufacturing, quality and supply risks



Business Continuity Plan (BCP) system structures manufacturing's continuity planning, disaster recovery, crisis response



Orchestration platform leverages AI to integrate the risk framework as one element

We're enabling standard-based, state-of-the art, AI-powered digital capabilities

# Foundational & Sustainable

By adopting a "simplify first, then standardize, and then digitize" approach, we ensure that our processes are efficient and cohesive before leveraging technology.

This strategic method enables us to build a robust foundation for digital transformation, fostering sustainable ongoing performance.

