

**Millipore®**

Preparation, Separation,  
Filtration & Monitoring Products

# Digital Transformation of Vaccine Manufacturing

Minh Tran  
Global Head of Bio4C Commercial

DCVMN International and Merck Workshop  
December 7, 2023

**Millipore®**

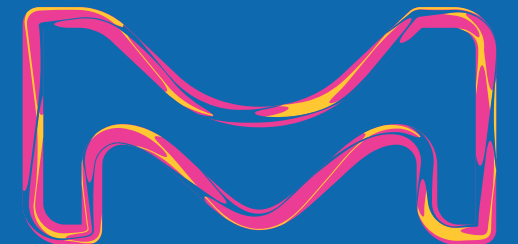
Preparation, Separation,  
Filtration & Monitoring Products

**SAFC®**

Pharma & Biopharma Raw  
Material Solutions

**BioReliance®**

Pharma & Biopharma  
Manufacturing &  
Testing Services



The Life Science business  
of Merck KGaA, Darmstadt, Germany operates  
as MilliporeSigma in the U.S. and Canada



# Agenda



Trends in Biopharma Manufacturing



Building Blocks and Enablers



Convergence of Technologies



Summary And Takeaways



# Our core businesses

Every day, our nearly **64,000** 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  
**MERCK**

## Impacting life and health with science

Cutting- edge technologies, products and novel services for diagnostics, research, development and the manufacturing of biological and novel therapies (mRNA). Focused on Pharma Biotech, Diagnostics, Academic and Government Research and Industrial

## Life Sciences

## As one for Patients

Biologics and small molecule prescription medicines for cancer, multiple sclerosis, fertility and general medicine. Research focus: Oncology, Immunology & Immuno-Oncology

## Healthcare

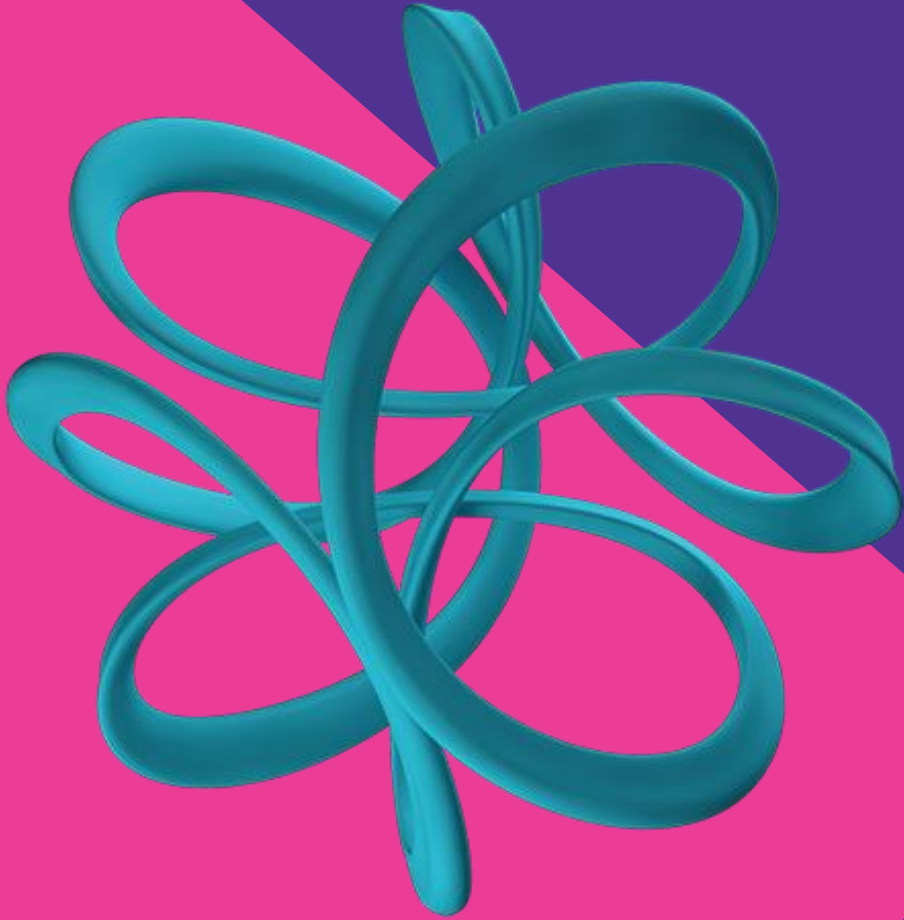
## Advancing Digital Living

Advanced solutions for the Semiconductor & Display industries focused on materials, equipment and services

## Electronics

Pigments and active ingredients for the Automotive, Cosmetic and Industrial industries





# Bioprocessing

We anticipate and shape the future of biopharma manufacturing for **the betterment of our planet and its people.**

## A vision for the future

- Lead the acceleration of sustainable and digital solutions to enable better health outcomes globally
- Blaze new development and manufacturing paths to deliver life-enhancing biologics
- Emphasize quality. Always.

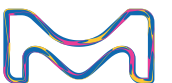
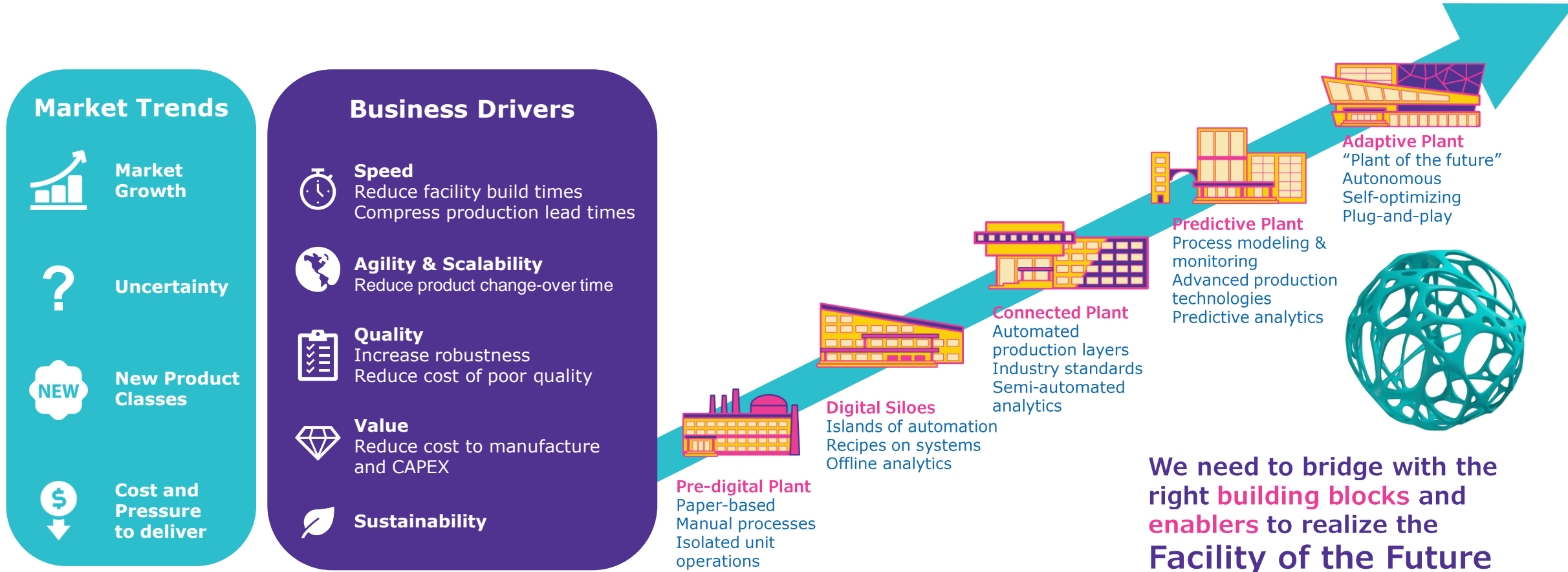


# TRENDS IN BIOPHARMA MANUFACTURING

01

# Industry is driving towards ambitious targets for output and flexibility

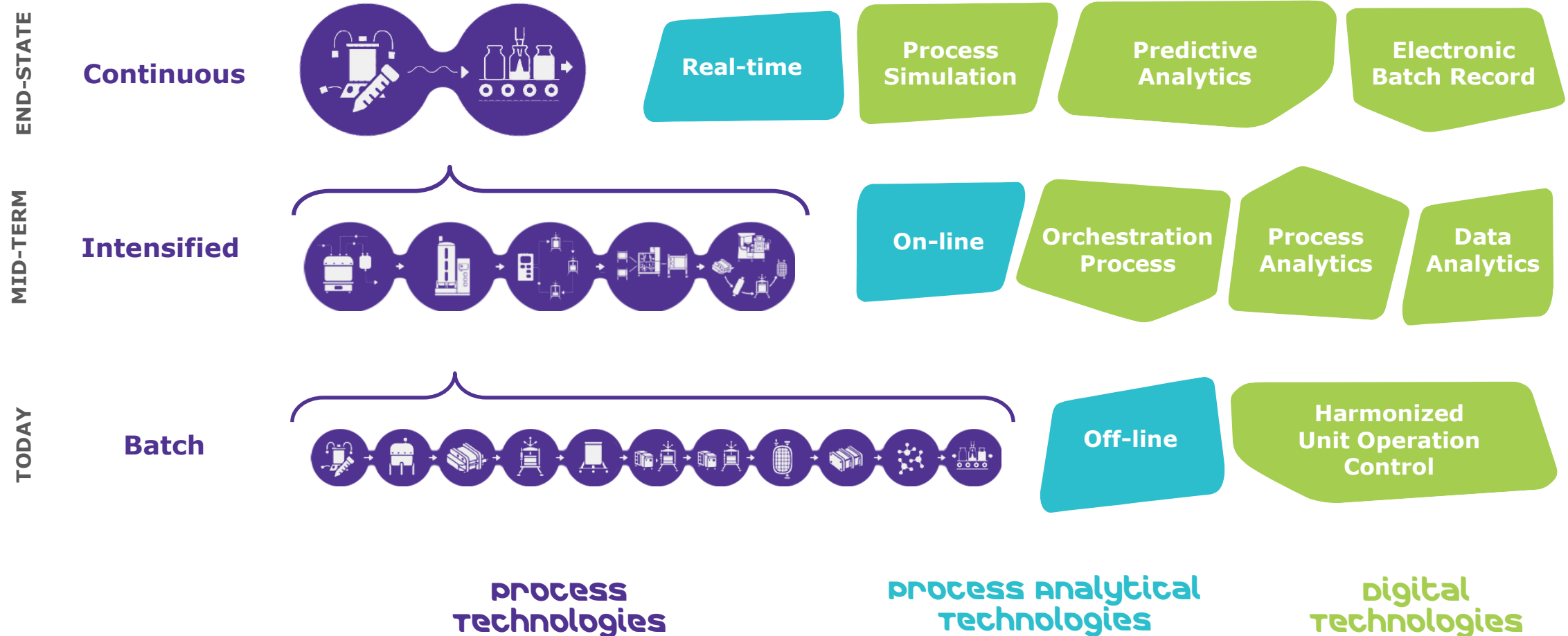
## Bioprocessing can drive transformation by focusing on key technology areas



# Achieving Manufacturing Success Requires a Paradigm Shift

## Evolution: Batch → Intensified → Integrated & Continuous

### Convergence of Evolving Process, Analytics & Digital Technologies







# Building Blocks and Enablers

02

# How can we enable a Paradigm Shift?

## Building blocks and enablers of Biopharma 4.0

### building blocks

Digital Technologies & Data Management

Process Analytical Technologies

Process Technologies

### ENABLERS FOR the FUTURE

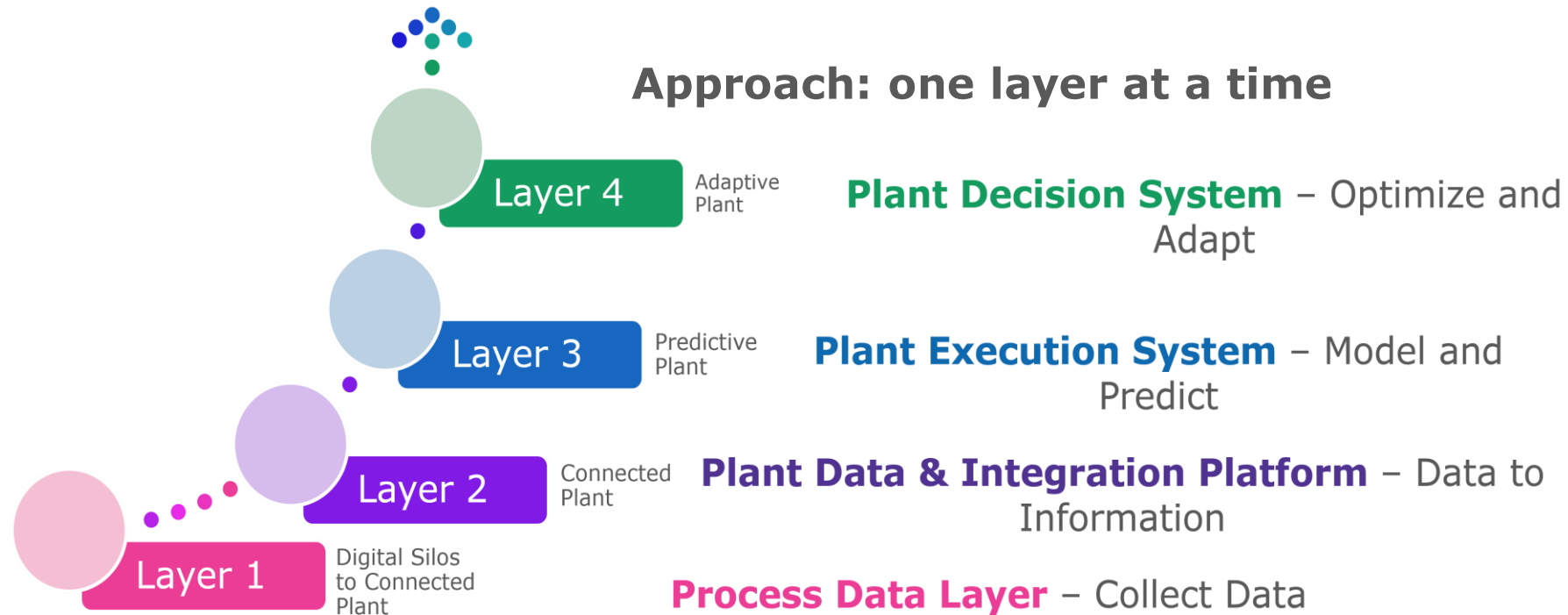


Convergence of technologies and enablers create an ecosystem for BioPharma 4.0 Manufacturing Execution Success



# The Digital Transformation Journey

## A Step-Wise Approach



**Process Data Layer:** What happened? Why did it happen?

**Plant Data & Integration Platform:** Where did it happen? Where else can it happen?

**Plant Execution System:** What can happen and when?

**Plant Decision System:** When it is predicted to happen, how can I adapt and continue?





# CONVERGENCE OF TECHNOLOGIES

03

Digital  
PAT  
Process

## Enterprise Portal



Reporting



Analytics

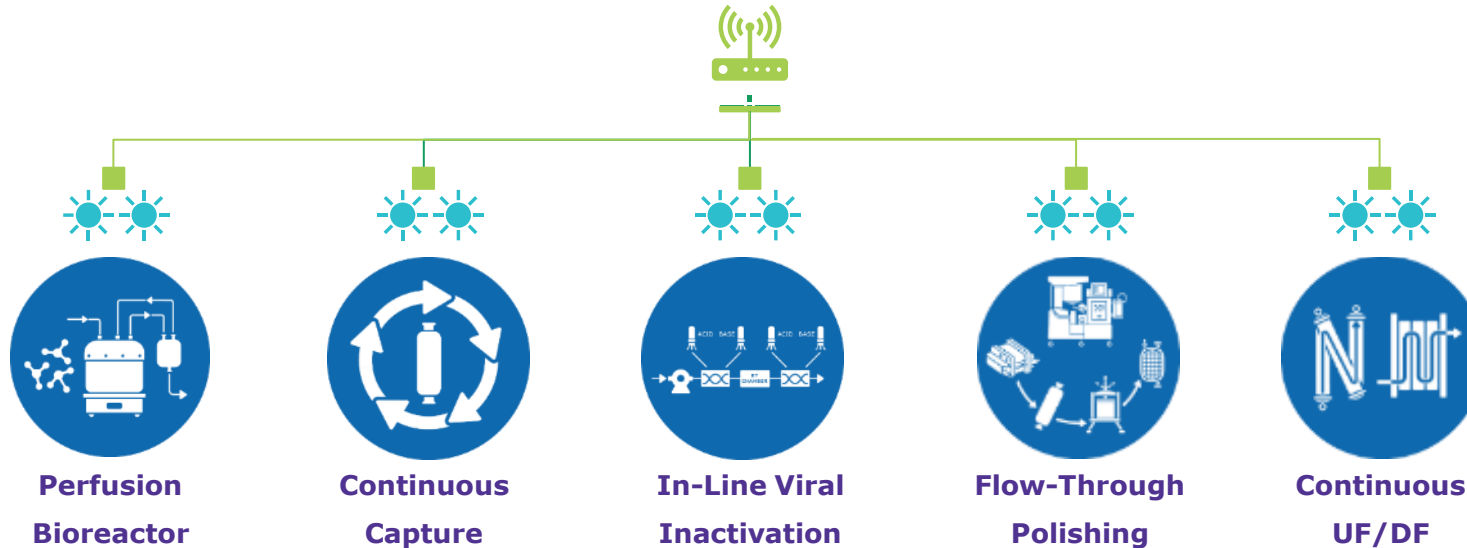


Sharing



ML/AI & Digital Twins

## Process Data Layer (Historian +)



### Bio4C ProcessPad™ Software

- Data integration, management and analytics and visualizations

### Bio4C Orchestrator™ Software

- Equipment connectivity
- User, recipe management
- Reporting and approvals

### Bio4C ACE™

- Equipment control

### ProCellics™ Raman Analyzer & Bio4C® PAT Raman Software

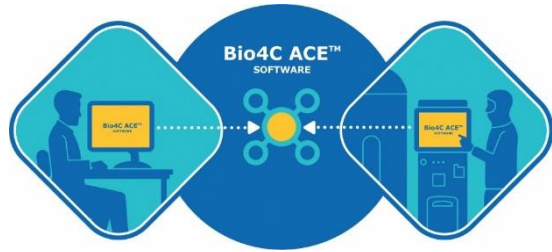
- In-Line/on-line sensors
- Chemometric modeling software to analyze Raman spectra for real-time process analytics

### MAST® Autosampling

### Processing Technologies

- **Hardware Systems**
- **Consumables**
- **Single-Use Technology**

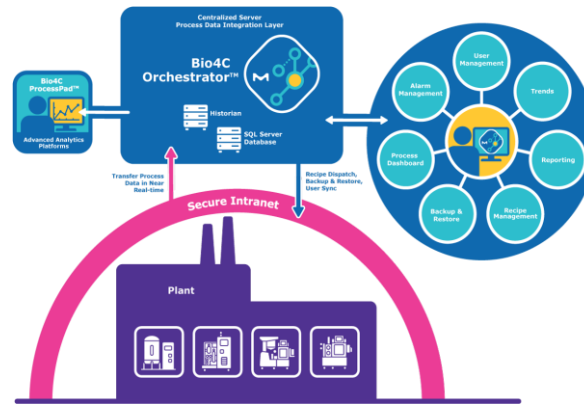




Control unit operations from anywhere

## Bio4C ACE™ Software

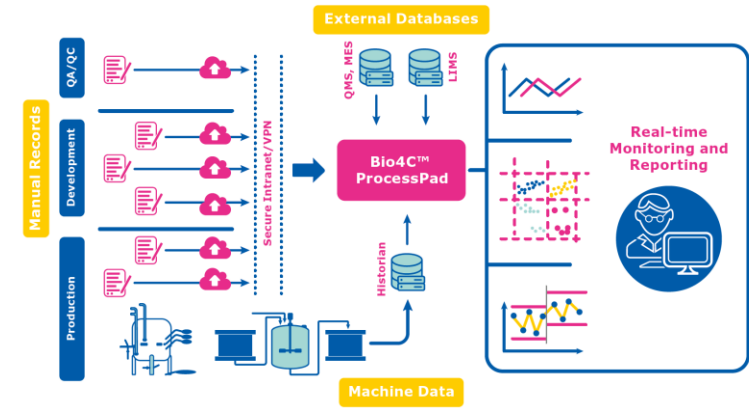
- Remote control and automation software
- Built on Industry 4.0 principles
- Supports easy and fast integration – vertical and horizontal



Centralize and digitize workflows for efficiency and error reduction

## Bio4C Orchestrator™ Software

- Centrally connects disparate Merck & 3<sup>rd</sup> party bioprocessing systems
- Gathers machine data into a Centralized Historian – A Process Data Layer
- Enables real-time monitoring and visualization



Acquire, Aggregate, and Analyze Bioprocessing Data

## Bio4C ProcessPad™ Software

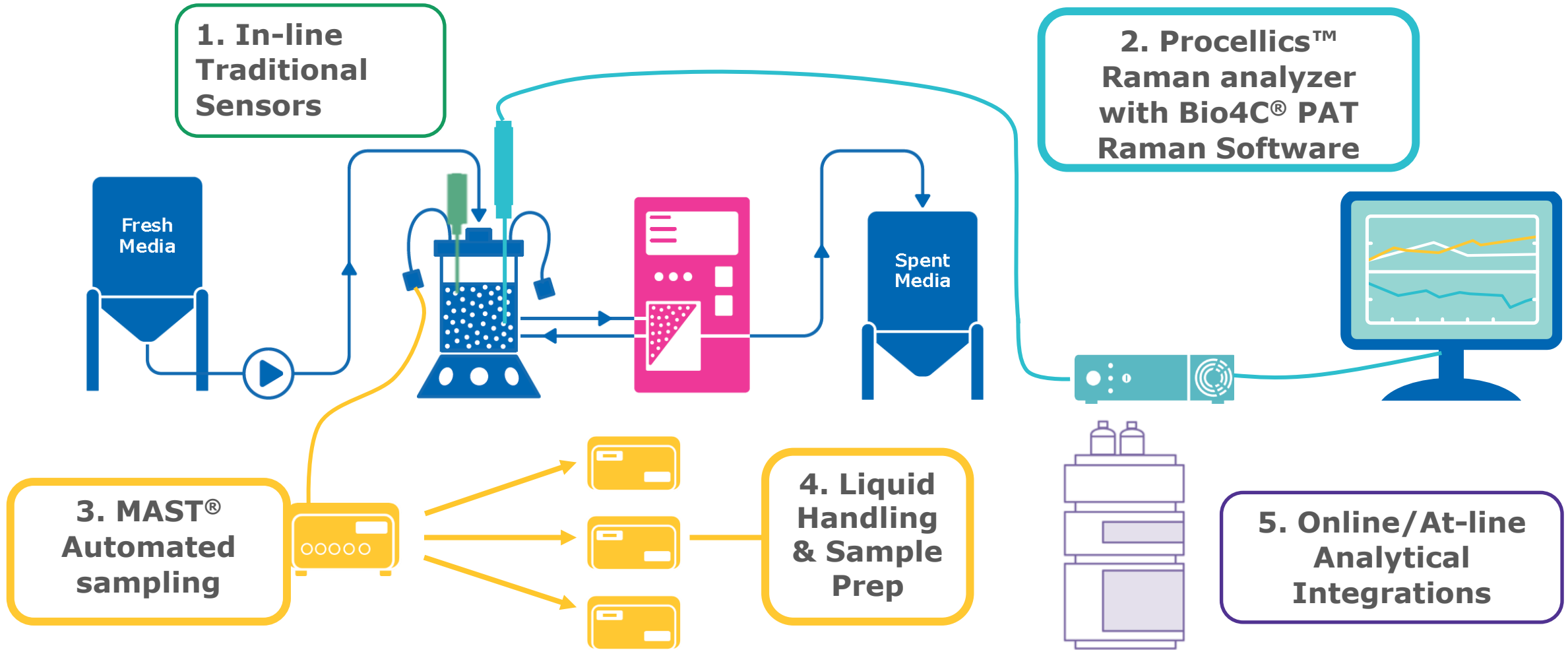
- Data management and analytics platform
- Offers bioprocess monitoring, lifecycle management, reporting, investigations, and continued process verification (CPV)
- Enables forecasting, prediction and process improvement

Digital Islands

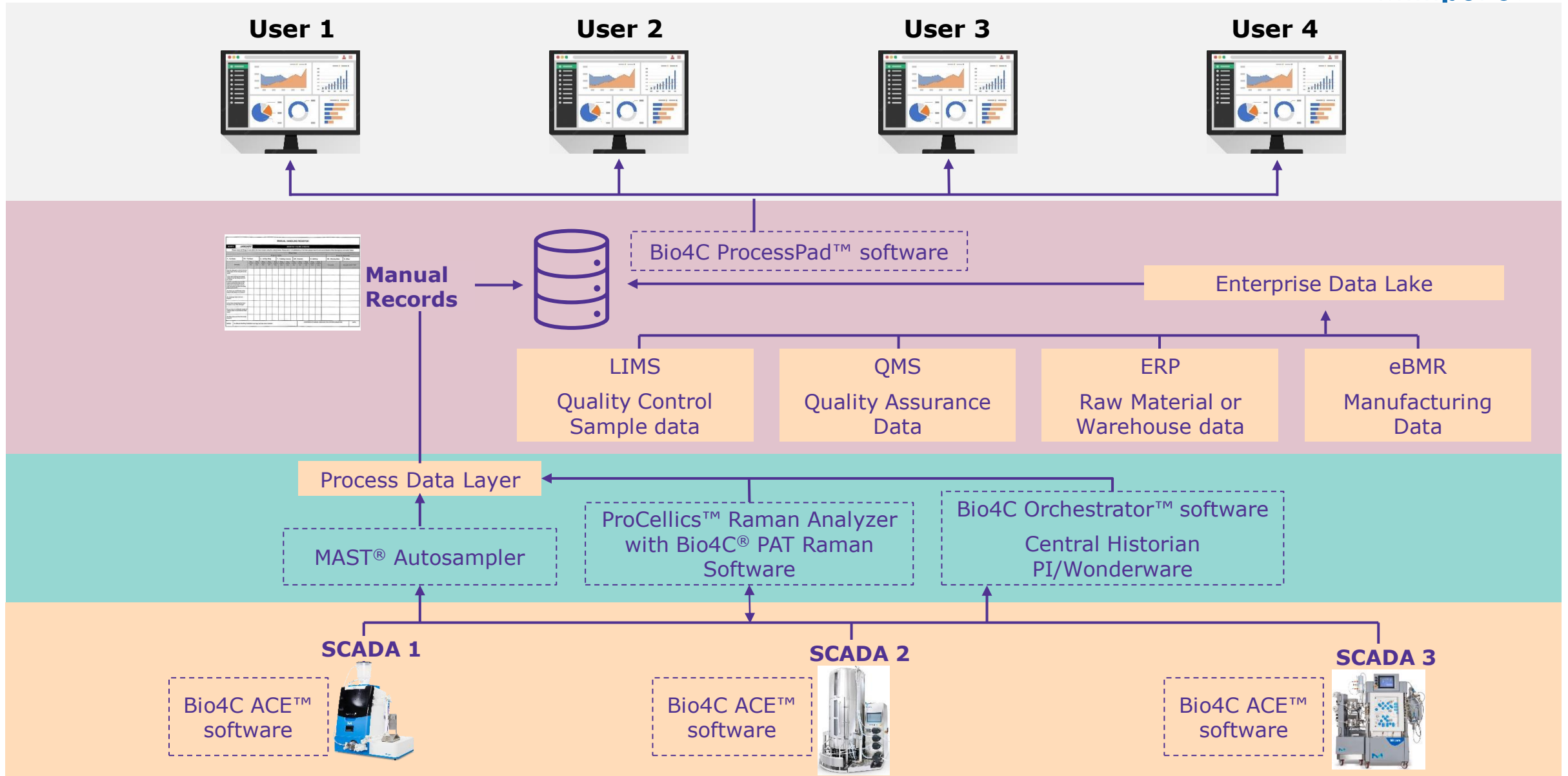
Connected Plant

Predictive Plant

## Enables real time feedback, modeling and optimization



# IT/OT Convergence: Towards Adaptive Plant



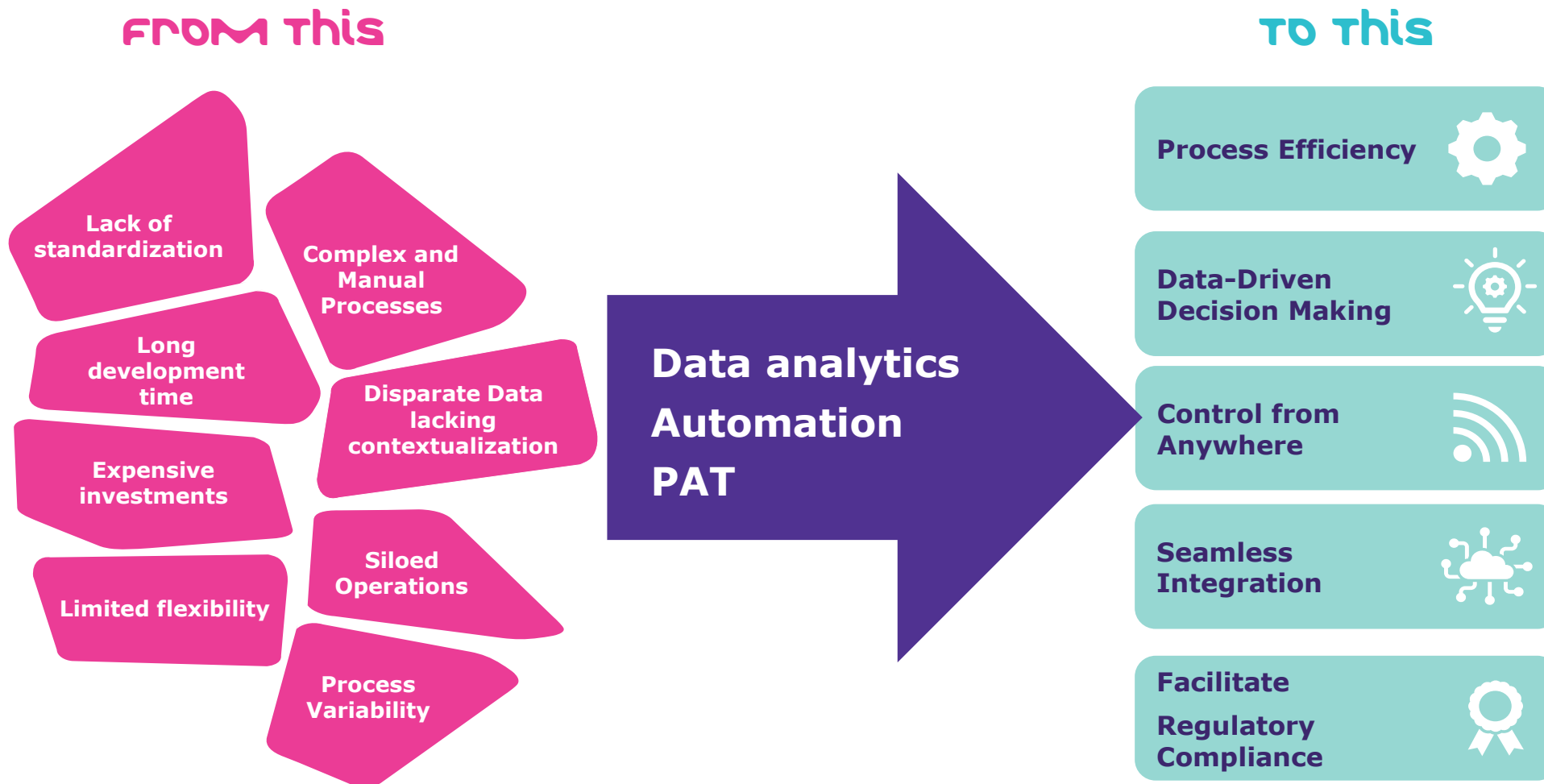




## SUMMARY & TAKEAWAYS

04

# Summary and Takeaways



## Contacts

Minh Tran

BioContinuum™ Platform

Minh.Tran@merckgroup.com

# Thank YOU!

Merck, MilliporeSigma, Millipore, SAFC, BioReliance, Bio4C, Bio4C ProcessPad, Bio4C Orchestrator, procellics, BioContinuum, and the vibrant M are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

© 2023 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.

