



HOW DIGITAL SOLUTIONS ARE TRANSFORMING BIOMANUFACTURING

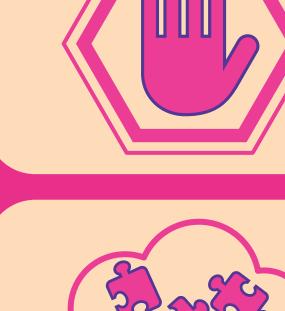
THE DIGITAL PLANT MATURITY MODEL: A JOURNEY TO BIOPROCESSING 4.0

Today, biomanufacturers are encountering immense pressure to increase productivity and deliver biotherapeutics to market faster. However, they face outdated, paper-based, and manual processes, which result in data loss, lengthy timelines, and high costs.

Consequently, the sector is looking to optimize and innovate its processes by building an end-to-end process where all systems are digitally enabled and connected in the Facility of the Future. A new era in biomanufacturing, known as Bioprocessing 4.0, creates these new facilities built on digitalization, software integration, and automation.

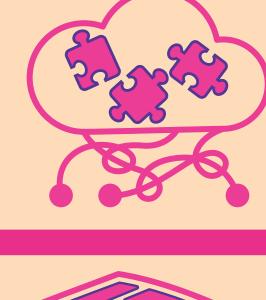
OF DATA COLLECTED

BY BIOMANUFACTERS IS NOT USED, DUE TO...



organizational barriers

Cultural and



and gaining insights from data

Difficulty aggregating



Paper-based workflows

THE DIGITAL PLANT MATURITY MODEL! The global BioPhorum Organization has developed the Digital Plant

THE SOLUTION?

Maturity Model (DPMM), as a roadmap for biomanufacturers to follow along their journey towards Bioprocessing 4.0. This guide lays out each step and milestone in the digital transformation to a paperless, automated plant in which analytics are used in every process...

DIGITALIZATION

Level 3

Connected Plant

production layers

• Industry standards

Semi-automated



- Paper-based
- Manual
- Minimal or no integration

Level 2 **Digital Silos** Automated

 Semi-electronic batch records

«Islands of Automation»

Some manual processes

- THE DPMM HELPS BIOMANUFACTURERS
 - ANSWER A NUMBER OF QUESTIONS...
- Advanced production technologies

Level 4

Predictive Plant

End-to-end supply

chain visibility

- process analytics analytics
- Real-time, closed process
 - verification and control Advanced production technologies are a standard

Level 5

Adaptive Plant

- Full end-to-end supply chain integration from suppliers to patients

• Integrated real-time

What is my manufacturing plant's current maturity level? How does my manufacturing plant compare to the



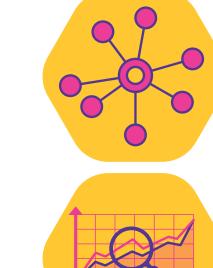
be defined, measured, and implemented at a sector, site,

and department level? What should my digital strategy and future goals look like to reach the Facility of the Future?

HOW DO ORGANIZATIONS PROGRESS FROM

automation and intensification

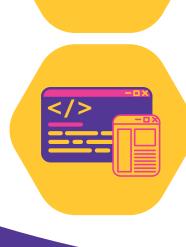
ONE MATURITY LEVEL TO THE NEXT?



and orchestrate processes and workflows

Integrate digitalization to boost process

Implement centralized systems to automate



the Future.

Deploy software systems for seamless data collection, monitoring, and analysis

Incorporate real-time process monitoring and analytics to improve decision-making

At Merck, we are developing solutions to help manufacturers gain the greatest benefit from next-generation bioprocesses and help them overcome the challenges that come with this type of change.

Collaborating with a vendor offering a wide portfolio of

manufacturing options, coupled with deep technical expertise,

enables manufacturers to tailor processes to meet user needs and

help them welcome the era of Bioprocessing 4.0 and the Facility of

Our Bio4C® Software Suite is an example of a digital ecosystem of

COLLABORATE WITH A TECHNOLOGY PROVIDER

TO PLAN YOUR DIGITAL TRANSFORMATION STRATEGY

products designed to empower biomanufacturers to achieve this." Merrilee Whitney, Head of the BioContinuum™ Platform, Merck

INTO THE BIOMANUFACTURING PROCESS

Created by bioprocess experts specifically for bioprocessing, the Bio4C®

Software Suite is part of Merck's BioContinuum™ Platform. The Bio4C®

Software Suite creates a digital environment enabling...

Adaptability to Data-driven Full data Real-time evolving decisions on a monitoring and transparency

BioContinuum[™] Platform

Bio4C Orchestrator™ software Connects individual unit operations to a centralized platform

CONTROL

the equipment

productivity,

processes, and

regulatory needs

The Bio4C® Software Suite **ProCellics™ Raman Analyzer with Bio4C® PAT Raman Software** A process analytical

platform for in-line and

real-time monitoring

CONNECT

the processes

process and

plant level

Bio4C ProcessPad™ software A data visualization, analytics, and process monitoring software

and intelligence

Bio4C® **Customer Portal** A secure, single location for all installed hardware and software service information

COLLABORATE

with stakeholders

reporting

CONVERGE INTENSIFY

Facility of the Future

Merck helps biopharma manufacturers in their digital transformation by providing smart software that enables the core competencies of the Facility of the Future. In the near future, Bioprocessing 4.0 will take drug manufacturers

affordable biotherapeutics. Are you interested in learning more about Merck's Bio4C® Software Suite and how it supports your journey to Bioprocessing 4.0? Contact the experts at Merck or check

out the website for more information! Want to work with us? Reach out to contact@labiotech.eu

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- Merck Labiotech

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- Factory of the Future
- Pharma's Almanac • Genetic Engineering & Biotechnology News (GEN) • The Future Factory

• International Society for Pharmaceutical Engineering

Converge, Intensify and Evolve. Together.

BioContinuum™ Platform, visit merckmillipore.com/biocontinuum

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accessible resources. Created with love at labiotech.eu **f** in **y**

COLLECT the data

EVOLVE Biomanufacturing Process

closer to developing more innovative, accessible, and

BioContinuum™ Platform To find out more about Merck's

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