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 However, they face outdated, paper-based, and manual processes, which result in data loss, lengthy timelines, and high costs.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.

70%

OF DATA COLLECTED BY BIOMANUFACTERS IS NOT USED, DUE TO...

- Cultural and organizational barriers
- Difficulty aggregating and gaining insights from data
- Paper-based workflows

THE SOLUTION? THE DIGITAL PLANT MATURITY MODEL!

The global BioPhorum Organization has developed the Digital Plant 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 1 Pre-Digital Plant
- Paper-based
- Manual
- Minimal or no integration

Level 2 Digital Silos
- «Islands of Automation»
- Some manual processes
- Semi-electronic batch records

Level 3 Connected Plant
- Automated production layers
- Industry standards
- Semi-automated analytics

Level 4 Predictive Plant
- Advanced production technologies
- End-to-end supply chain visibility
- Integrated real-time process analytics

Level 5 Adaptive Plant
- Real-time, closed process verification and control
- Advanced production technologies are a standard
- Full end-to-end supply chain integration from suppliers to patients

THE DPMM HELPS BIOMANUFACTURERS ANSWER A NUMBER OF QUESTIONS...

- What is my manufacturing plant's current maturity level?
- How does my manufacturing plant compare to the industry benchmark?
- How can the capabilities of a digital manufacturing plant 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 ONE MATURITY LEVEL TO THE NEXT?

- Integrate digitalization to boost process automation and intensification
- Implement centralized systems to automate and orchestrate processes and workflows
- Incorporate real-time process monitoring and analytics to improve decision-making
- Deploy software systems for seamless data collection, monitoring, and analysis

COLLABORATE WITH A TECHNOLOGY PROVIDER TO PLAN YOUR DIGITAL TRANSFORMATION STRATEGY

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 the Future.

Our Bio4C™ Software Suite is an example of a digital ecosystem of products designed to empower biomanufacturers to achieve this."

Merrilee Whitney, Head of the BioContinuum™ Platform, Merck

INCORPORATING THE BIO4C™ SOFTWARE SUITE 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 evolving productivity, processes, and regulatory needs
- Data-driven decisions on a process and plant level
- Full data transparency and intelligence
- Real-time monitoring and reporting

BioContinuum™ Platform

The Bio4C™ Software Suite

Bio4C™ Orchestrator	ProCellics™ Raman Analyzer with Bio4C™ PAT Raman Software	Bio4C™ ProcessPad	Bio4C™ Customer Portal
Connects individual unit operations to a centralized platform	A process analytical platform for in-line and real-time monitoring	A data visualization, analytics, and process monitoring software	A secure, single location for all installed hardware and software service information

CONTROL the equipment → CONNECT the processes → COLLECT the data → COLLABORATE with stakeholders

CONVERGE → INTENSIFY → EVOLVE

Biomanufacturing Process

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 closer to developing more innovative, accessible, and 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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Sources:
- BioPhorum
- Merck
- Labiotech
- Factory of the Future
- Pharma's Almanac
- Genetic Engineering & Biotechnology News (GEN)
- The Future Factory
- International Society for Pharmaceutical Engineering

BioContinuum™ Platform
Convergin, Intensify and Evolve Together

To find out more about Merck's BioContinuum™ Platform, visit merckmillipore.com/biocontinuum

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