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THE BIOPHARMACEUTICAL FACTORY OF THE FUTURE: WHY IS IT NEEDED AND WHAT WILL IT OFFER?

The biopharmaceutical industry is in the midst of a period of rapid growth. It is also experiencing increasing uncertainty, diversification of modalities, and cost pressure. The challenges associated with these market trends, which have accelerated in response to the Covid-19 pandemic, require a reconsideration of biologics manufacturing. To address these challenges, the industry will need to embrace the facility of the future – a new biomanufacturing paradigm.

MARKET TRENDS CHALLENGING BIOPHARMACEUTICAL COMPANIES

Market growth, driven by:

- Expanding indications for existing therapies
- New therapies to treat unmet needs
- Globalization of biotherapeutics

Uncertainty, relating to:

- Clinical trial success
- Unknown regulatory path for novel processes
- Fluctuating drug demand

Alternative approaches, including:

- New product classes
- New modalities
- Personalized medicine

Cost pressure, resulting from:

- Payer pressure
- Development costs
- Widespread affordability

Biopharmaceutical companies need to rethink their approach to biologics manufacturing. To address these trends and achieve sustainable biomanufacturing, four key business drivers have been identified.

IDENTIFIED BUSINESS DRIVERS TO MEET MARKET NEEDS

Speed

- Reduce new facility build times
- Reduce production lead and release times

Quality

- Increase manufacturing robustness
- Reduce waste

Flexibility

- Improve response to changes in demand
- Reduce product changeover time

Cost

- Reduce operational costs
- Reduce capital expenditures

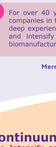
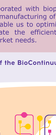
The Factory of the Future will transform biologics manufacture to overcome the challenges posed by the market. This factory will transform biologics manufacturing in four key areas.

THE FACTORY OF THE FUTURE WILL REQUIRE INNOVATION IN FOUR FACETS

PROCESS

Intensified	Connected	Continuous
Intensified production to increase unit operation productivity and alleviate bottlenecks	Multiple operations combined and **connected** in single units	**Continuous** processing with advanced automation and control

FORMAT

Single use	Closed	Sterile
		
Single use is quick to configure, assemble, and scale	Single use, **closed** processes reduce risk	Single use, closed, **sterile** processes enable increased flexibility

ANALYTICS

In-line	Real-time	Predictive
In-line and at-line monitoring for robust material characterization, process control, and assurance of quality	**Real-time** release testing of product quality	**Predictive** models, multivariate analysis, and closed feedback control loops

DIGITAL

Controlled	Integrated	Autonomous
Observation and **control** of process performance	Data collection to identify and **integrate** necessary improvements	Fully **autonomous** to reduce staff requirements and changeover time

Embracing this transformation drives the biopharmaceutical industry towards the Factory of the Future to address five aspirations of biomanufacturers.

ASPIRATIONS FOR THE BIOPHARMACEUTICAL FACTORY OF THE FUTURE

90% reduction in factory footprint

90% reduction in capital required for the same output

70% reduction in construction time

60% reduction in operating expenditure

90% reduction in the cost of quality

MERCK ENABLES THE BIOPHARMACEUTICAL FACTORY OF THE FUTURE

For over 40 years, we have collaborated with biopharmaceutical companies in the development and manufacturing of biologics. Our deep experience and knowledge enable us to optimize, automate, and intensify processes to facilitate the efficient response of biomanufacturers to patient and market needs.

Merrilee Whitney, Head of the BioContinuum™ Platform

BioContinuum™ Platform

Converge, Intensify, and Evolve. Together.

The BioContinuum™ Platform empowers biomanufacturers to make the Factory of the Future a reality. Within a single environment, it encompasses intensified and continuous processing, proven and novel technologies, connected software, applications, and expert support. By converging process technologies and digitization, the Biocontinuum™ Platform helps biopharmaceutical companies to achieve their bioprocessing goals.

KEY ELEMENTS OF THE BIOCONTINUUM™ PLATFORM

Process Intensification	Connected	Continuous
• Improved productivity, which enables more efficient operation, by incorporating novel technologies throughout the process • Increased cost-efficiency	• Systems communicate and collect information to coordinate steps in the manufacturing process • Ultimately, process deviations and failures will be anticipated and prevented	• Once the process has been set up and started, no human intervention is required until the product is ready • The process is closed to protect from contamination, as well as the exposure of operators to harmful compounds

BETTER BIOPHARMACEUTICAL DEVELOPMENT AND MANUFACTURING

The Factory of the Future will help biopharmaceutical companies to overcome market challenges in the biologics industry by delivering:

The BioContinuum™ Platform sets the foundation for the Factory of the Future by offering intensified, connected, and continuous bioprocessing with software, automation, analytical technologies, and services.

Want to work with us? Reach out to contact@labiotech.eu

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Sources:
- Biophorum
- Deloitte
- Merck/MilliporeSigma

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

*The life science business of Merck operates as MilliporeSigma in the US and Canada.

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