

# Addressing the Evolving Information and Automation Needs of Biopharma

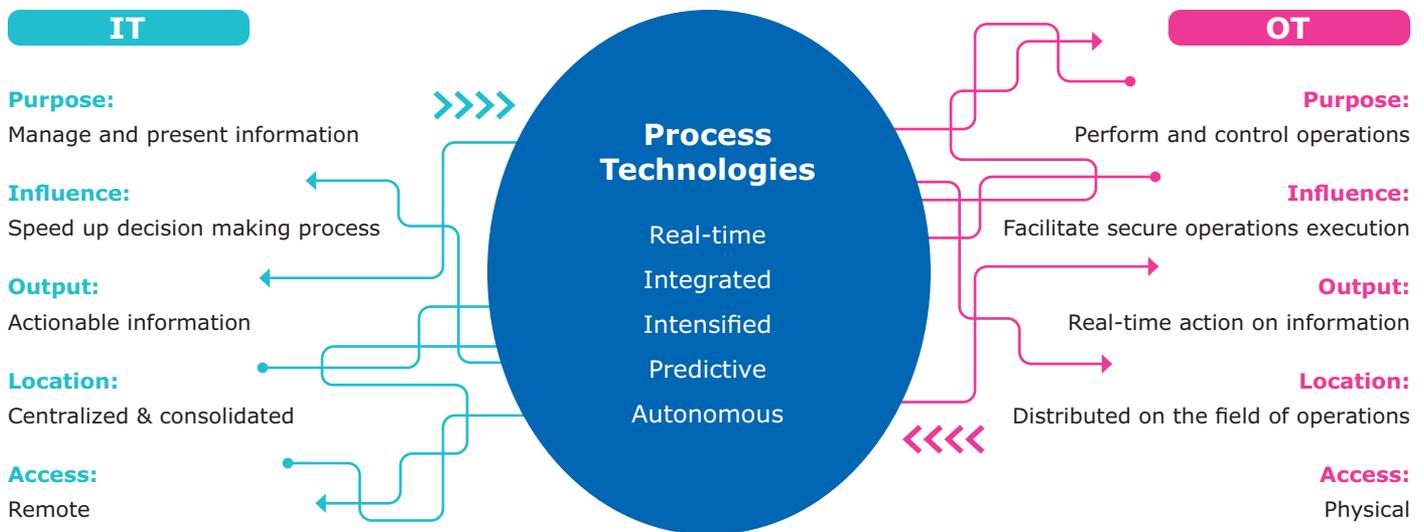
*Aniruddha Bose, Global Product Manager*

As the biopharmaceutical industry evolves and new opportunities and challenges rise, manufacturers must keep pace. For example, a dramatic increase in the amount of information that is available, in parallel with a reduction in the cost of obtaining, processing, and transmitting information, is changing the way biopharmaceutical manufacturers operate. Access to information, and more importantly, strategic use of it, can give a company a competitive advantage. Undoubtedly, the biopharmaceutical industry is collecting, interpreting and applying a vast amount of data to operations with a goal of increasing productivity, increasing operational flexibility, reducing costs, and assuring quality and patient safety.

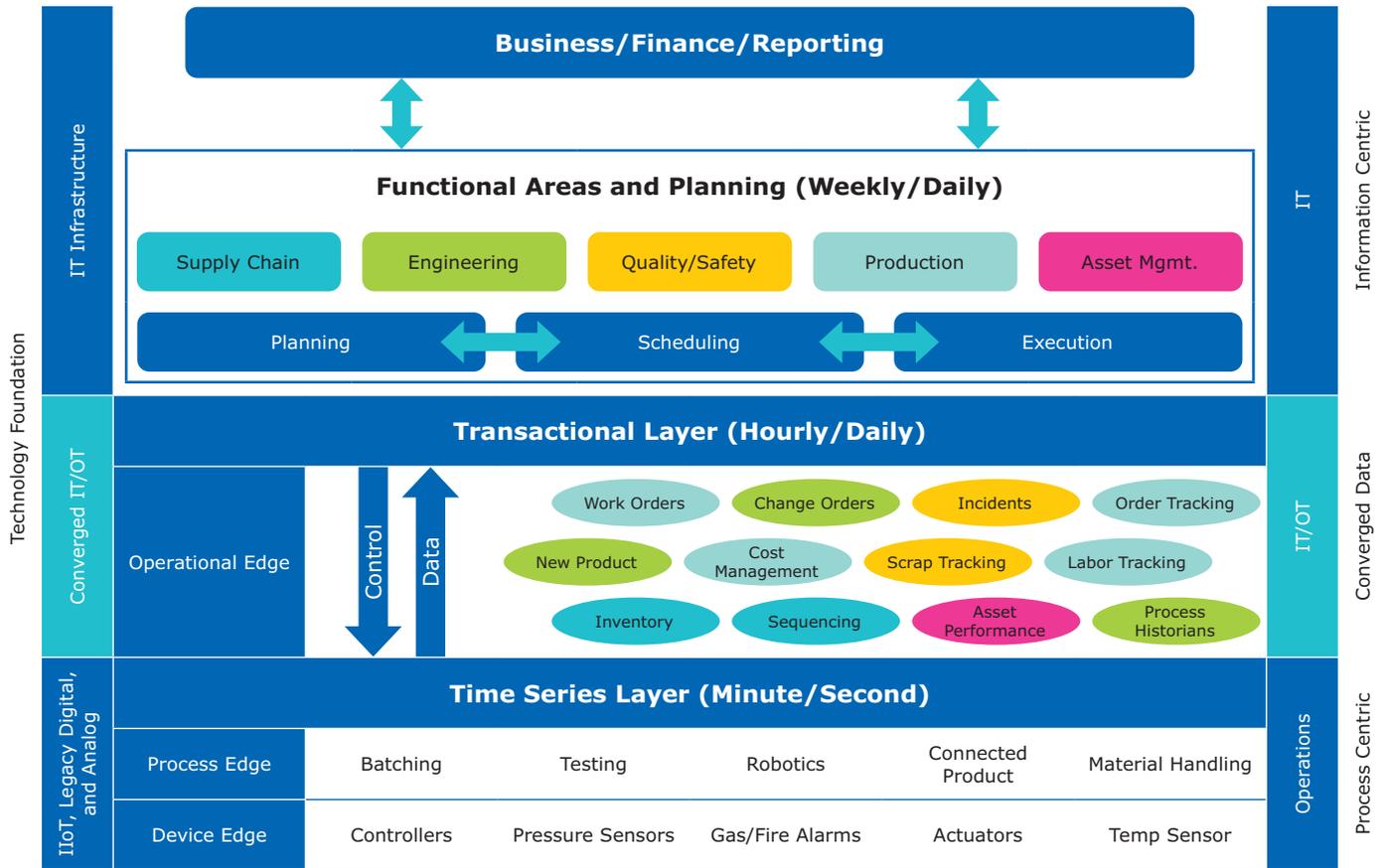
This unprecedented amount of information is increasing the need for a more effective convergence of information and operations technology (IT-OT; **Figure 1**).

As reflected in this schematic, the purpose of information technology (IT) is to manage and present information with a goal of accelerating decision-making, collecting actionable information in a centralized location and enabling remote access capability. The purpose of operations technology (OT) is to perform, control and facilitate secure operations. Processes should enable real-time action with the freedom of distributed control but also physical access to unit operations.

This white paper describes the conceptualization and development of a value-driven digital solution to support the evolving bioprocess information and automation needs of biopharmaceutical manufacturing facilities. Residing at the convergence of IT and OT, a real-time, integrated, intensified, predictive and autonomous solution has the power to transform workflows and deliver a competitive advantage over traditional, generic automation solutions currently on the market.



**Figure 1.** Process technologies reside at the convergence of information and operations.



Source: IDC, 2019

**Figure 2.** Three broad layers of IT/OT convergence are the device edge, the process edge and the operational edge.

## Enabling IT/OT Convergence

The power of convergence can be distilled into three broad layers as shown in **Figure 2**.

- The device edge, which encompasses the physical instruments performing a variety of tasks, having sensors, actuators and controllers
- The process edge directs execution at the device level
- The operational edge serves as a means to capture and communicate data about the fragmented operational processes

These layers are supported by the IT infrastructure which communicates to the business functions, empowers operations and help in the planning, scheduling and execution of batches. Given these layers, their interactivity and complexity, automation and digitization are essential to create a sustainable, responsive and future proof business model.

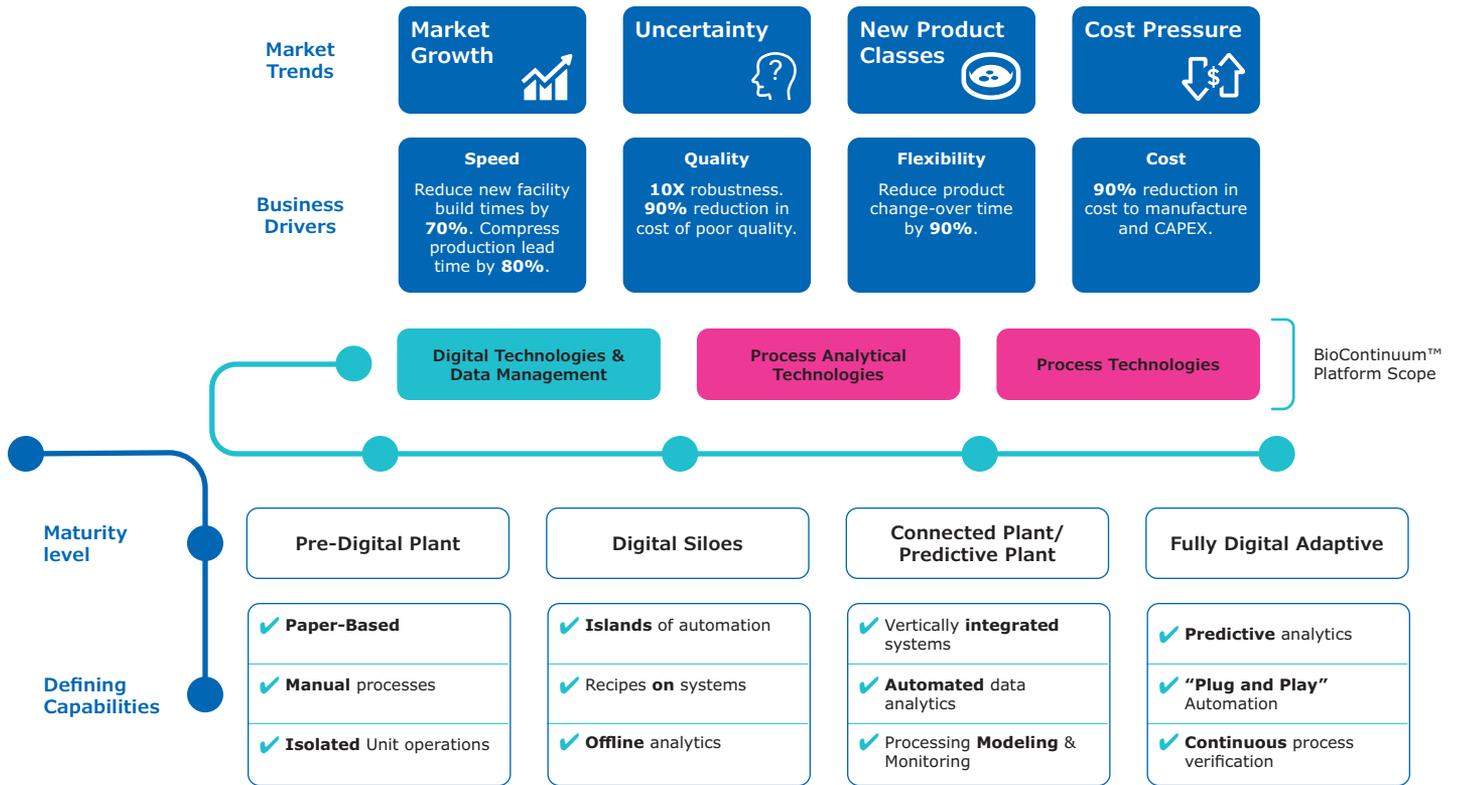
IT/OT convergence and the need for automation are driving biopharmaceutical organizations to explore how software can provide important benefits to the integrated manufacturing workflow. While vertical automation solutions have delivered greater productivity and efficiency in a range of specific tasks and unit operations, a more holistic approach is needed to support the facility of the future and access the benefits of “bioprocessing

4.0” – a reference to the fourth industrial revolution, a hallmark of which is the automation of traditional manufacturing and industrial practices.

**Figure 3** summarizes the digital evolution underway in the biopharmaceutical industry. Several key industry trends are accelerating this progression and include market growth, the need to address uncertainty, the need to support new product classes and reduce cost pressures. These, in turn, create business drivers centered on speed, quality, flexibility and cost, all of which can be positively impacted by investment in digital technologies, data management and automation. The facility of the future will be fully digital-adaptive, embracing predictive analytics, plug-and-play automation and continuous process verification.

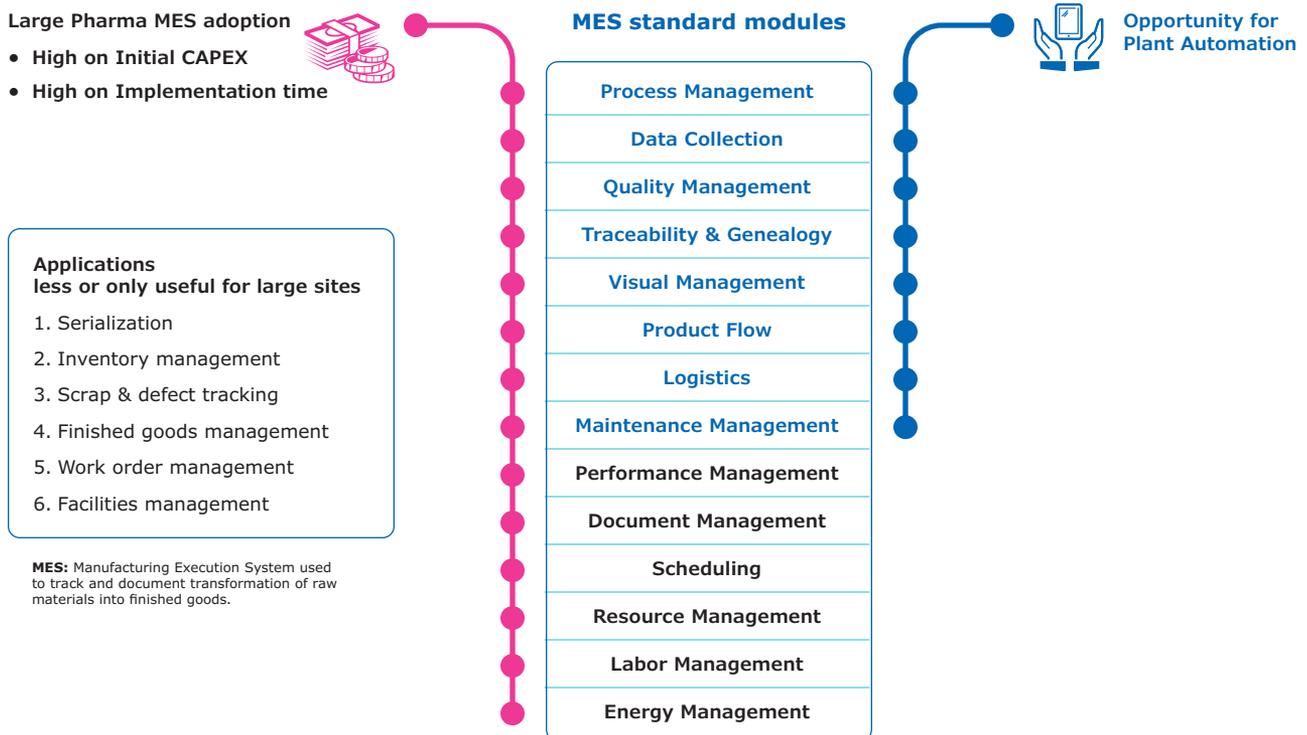
## Defining Biopharmaceutical Industry Needs

Many industries have adopted manufacturing execution systems (MES) to support automation initiatives. A typical full-stack MES solution requires several million dollars of investment and three to five years to implement. Unfortunately, about half of the standard MES modules provide little to no value-add for biopharmaceutical companies (**Figure 4**).



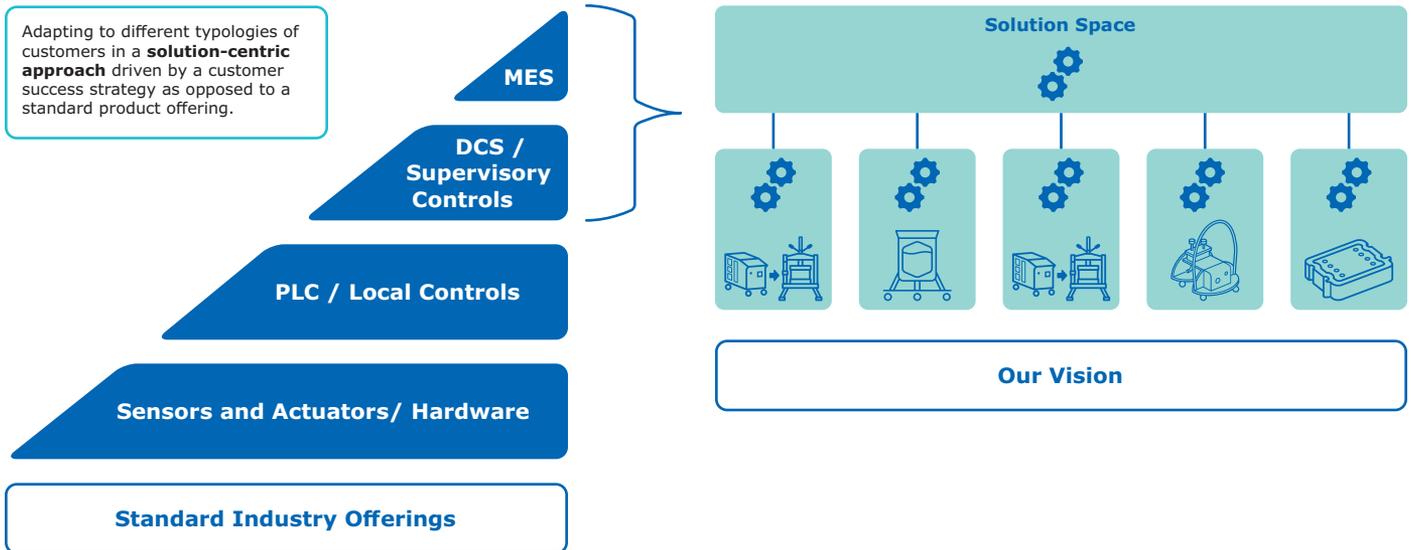
Source: BioPhorum (BPOG) <https://www.biophorum.com/category/resources/technology-roadmapping-resources/introduction/>

**Figure 3.** Bioprocessing 4.0 and the digital plant maturity model.



**MES:** Manufacturing Execution System used to track and document transformation of raw materials into finished goods.

**Figure 4.** Approximately half of the standard MES modules provide little to no value-add in the biopharmaceutical manufacturing setting.



**Figure 5.** A comparison of conventional, vertical automation solutions (A) and a horizontal, lean approach (B).

Alternatively, a lean, purpose-built automation solution for the biopharmaceutical industry can offer significant value. Instead of being standardized across many industries, the modules would be bioprocess-centric, offer significant business value and include management of bioprocessing runs, process data capture, quality modules, traceability and genealogy modules, process monitoring, product workflow, logistics management and maintenance.

A recent market assessment and voice-of-customer research confirmed the need for a lean, solution-based, bioprocess-centric approach to automation. The following bullets summarize the key requirements an automation strategy must address.

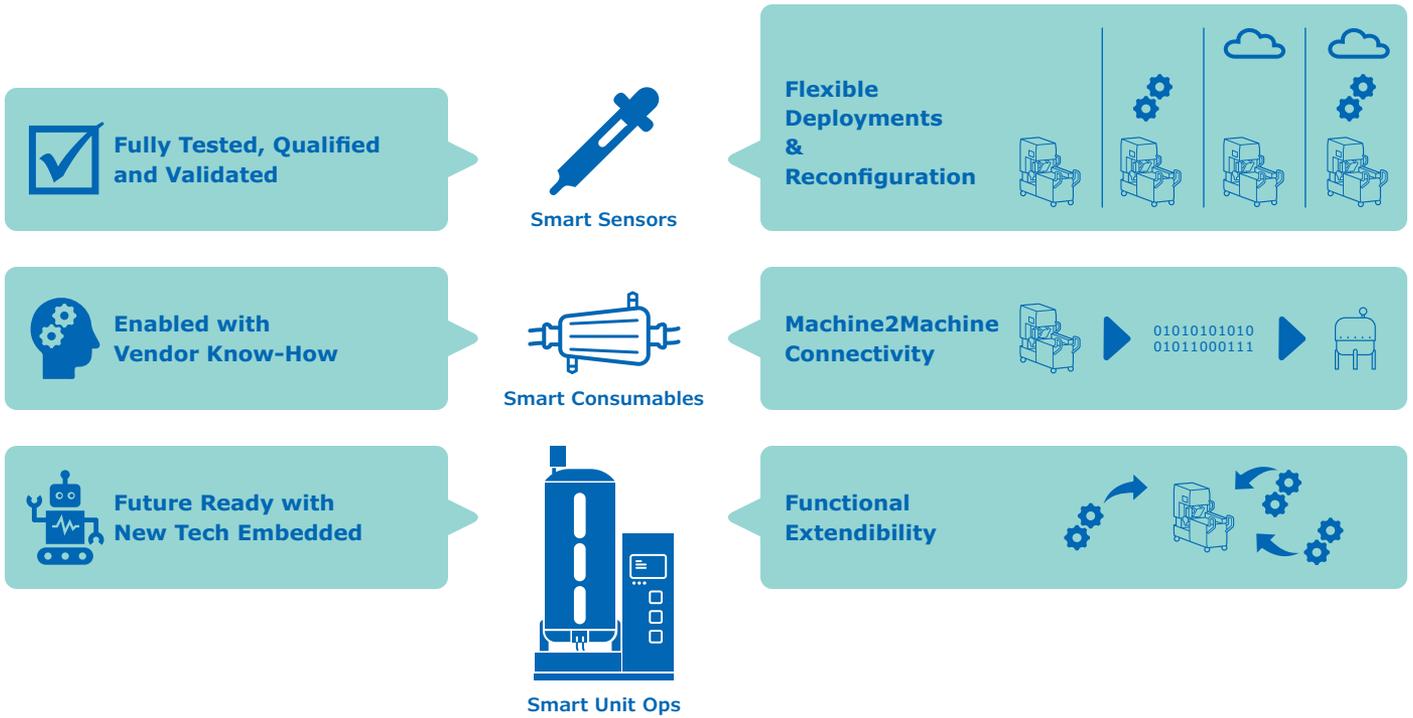
- Connect multiple pieces of equipment on the manufacturing floor
- Monitor and visualize real-time status of process runs
- Centralized data integration and consolidated reports
- The systems on the manufacturing floor must talk to each other
- Remote monitoring for process issues or system-related alerts
- A single centralized login to assess multiple pieces of equipment
- Reduce paperwork needed to support manufacturing and audits
- Efficient and accurate translation of requirements from bioprocess engineers to automation engineers

## Breaking the Mold of Standard Industry Automation Solutions

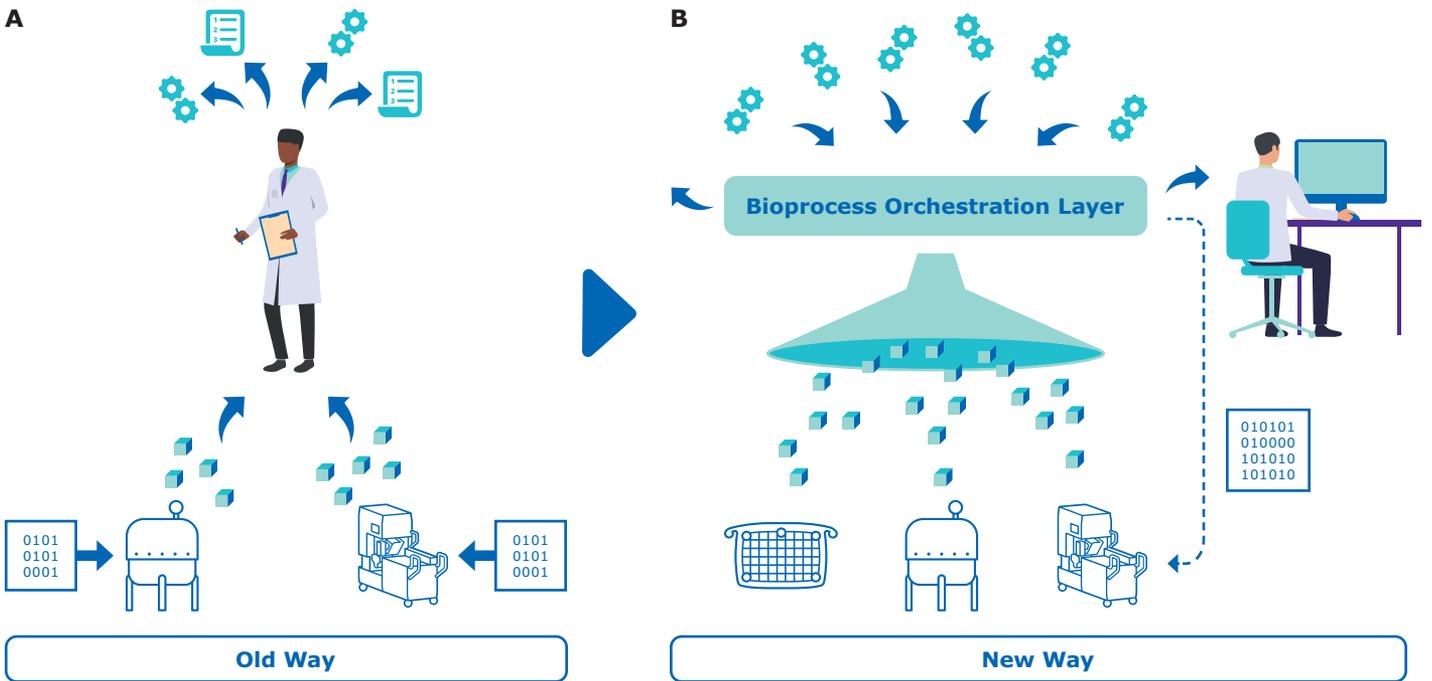
A standard industry offering for plant automation starts with the hardware layer and adds the programmable logic controller (PLC) layer above that (**Figure 5A**). The distributed control systems (DCS) and MES reside at the top of the pyramid. In contrast, our vision is to pull up the best from the DCS and MES layers, while remaining connected to the bioprocessing equipment (**Figure 5B**). This approach is horizontal and lean in nature as compared to vertical-stacked standard solutions.

In our solution space, we are building future-ready flexible, deployable and reconfigurable elements which enable connectivity among equipment (**Figure 6**). All elements are tested, validated, and qualified and become the building blocks for smart systems and smart controls.

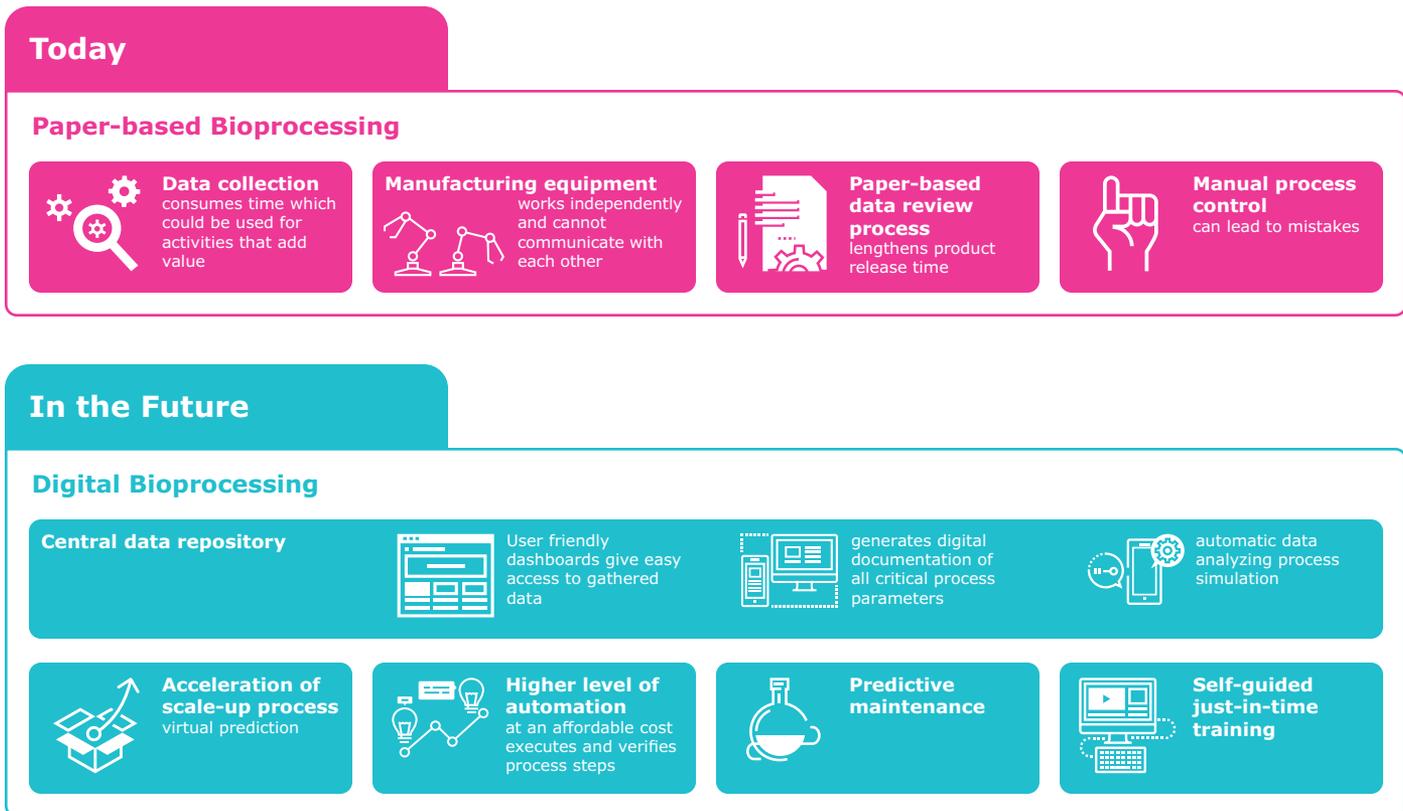
In conventional approaches to automation, the operator runs multiple systems, with individual logins, collects reports and, most importantly, operates via multiple, individual human machine interfaces (HMIs; **Figure 7A**). With our digital approach to automation, smart controls and the solution layer enable a centralized approach to data collection, monitoring critical to bioprocessing parameters, reporting, user management and backup/restoration of data where the operator can work through a single HMI, yet monitor and control multiple pieces of equipment (**Figure 7B**). The operator can manage every piece of equipment centrally, on a single system, providing complete oversight of bioprocessing, through central connectivity of disparate manufacturing systems.



**Figure 6.** Applying bioprocessing 4.0 principles to smart control systems.



**Figure 7.** The conventional approach to automation requires an operator to run multiple systems via individual HMIs (A) in comparison to our platform which enables an operator to engage via a single HMI (B).



**Figure 8.** Digital bioprocessing and automation will deliver significant benefits to the biopharmaceutical manufacturing facility.

While manual, paper-based, vertically-independent functioning systems continue to lose relevance in the near future, digital bioprocessing is providing a competitive advantage and helping employees focus on their core experiments and process runs (**Figure 8**). In the future, digital documentation and data analysis will enable faster scale-up and lean and efficient automation, backed by predictive maintenance and just-in-time strategies to further streamline bioprocessing.

### The Way Forward

The amount and velocity of information available to support biopharmaceutical manufacturing are increasing faster than ever. Digital bioprocessing and industry-centric automation solutions are essential for managing this information and getting the most from it. As manufacturing facilities become smarter through these approaches, costs will be reduced, timelines accelerated and flexibility increased, along with improved compliance.

## Bio4C™ Suite and ProcessPad Software

The Bio4C™ Suite, part of our BioContinuum™ Automation & Analytics Platform, is comprised of stand-alone, but seamlessly compatible software products. Intuitive interfaces and easy access enable a broad user base to collaborate with global teams across boundaries to control, monitor and analyze equipment, processes, results, and data in near real-time. Based on our core 4C's (Control, Connect, Collect, Collaborate), the Bio4C™ Suite offers a convergent, open digital environment, adaptable to your changing productivity, process and regulatory needs. It allows for full transparency and intelligence leading to data-driven decisions for total mastering on a process and plant level.

Bio4C™ ProcessPad software is a data collection visualization, and analytics software platform that facilitates FDA 21 CFR Part 11 compliance and enables bioprocess monitoring, lifecycle management, reporting, investigations and continued process verification (CPV). Bio4C™ ProcessPad intelligently combines process data from disparate data sources such as batch records, quality control results, standard databases, QMS, MES, LIMS and data historians into a single, contextual, integrated data source. In doing so, the platform ensures process information is current, complete, and accessible throughout the product lifecycle. Intuitive out-of-the-box data visualization and analysis tools allow users to easily explore and analyze their data.

## BioContinuum™ Platform

**Converge, Intensify and Evolve. Together.**

An expanding environment of advanced processing, software, automation and analytic technologies, unlocking the potential of Bioprocessing 4.0 and empowering biomanufacturers to achieve greater speed, flexibility and quality.



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