MODULAR AUTOMATION: THE PLUG-AND-PRODUCE OPPORTUNITY FOR LIFE SCIENCES

Honeywell

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EXECUTIVE
SUMMARY

Most manufacturing processes today have or are incorporating varying levels of automation in the quest for increased efficiency and productivity. In life sciences, where speed to market is the definition of competitive advantage, today's automation investments are decidedly modular, whether in the context of plant, process, or production.

Life science manufacturers have high expectations for versatile facilities such as modular cleanrooms as the market pivots away from a traditional stick-built approach. Early wins have come within biopharma, specialty, and fine chemicals in the form of speed improvements during project implementation and deployment, as realized by predesigned as well as turnkey facilities. The common factor? Standardization enabling integration and automation.

These wins are just the beginning for industries that build their strategies on flexible integration processes. Those that demand automation components have standardized plug-and-produce capabilities can also make product line updates easier. Those that understand the power of a leading-edge orchestration approach. Those that understand that success is measured in time to patient.

This whitepaper discusses the benefits of modular automation given the ongoing evolution to modular plants and what the industry dubs plug-and-produce processing. What standards should you be aware of as you make automation investments within the modular plant? How will modular technologies enable integration with component HMIs? What efficiency and cost impact can you expect to achieve?

LEVERAGING THE MOMENTUM OF THE MODULAR PLANT

Today's modular plant accelerates time to market through components such as single-use systems, prefabricated cleanroom units, and predesigned skids. The sooner the product gets to market, the more time the company has to recoup development investment before patents run out. This approach optimizes production in anticipation of the patent cliff for a blockbuster drug while simultaneously preparing the manufacturer for timely new launches to compete with generics or biosimilars.

Recouping investment before losing exclusivity creates an urgency for modular implementations. The momentum of implementation is impressive. According to Roots Analysis, the modular construction market for the biotechnology and pharmaceutical industry is estimated to be worth $2.5 billion in 2023 and is expected to grow at CAGR of 10% until 2035.[1]

The analyst further reports that modular facilities can be built 40% faster, as compared to conventional construction, which could take up to three years. Large-area, brick and mortar facilities dedicated to a sole product are giving way to versatile multiple product facilities. Solution providers are "catering to the needs of various players engaged in the development of therapeutics, including cell and gene therapy, biosimilars and vaccines."

Clearly it is an opportune time for manufacturers to explore new opportunities for the traditional physical plant and its components. A new era of manufacturing, certainly. However, speed to market cannot come at the expense of strategic interoperability and flexibility. The potential to aggravate what may already be a fragmented hardware and software landscape is real. The last thing manufacturers need is to increase siloed data and processes.

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1. https://www.rootsanalysis.com/reports/modular-manufacturing-market/178.html

THE TIME TO AUTOMATE IS NOW:
THE URGENCY OF MARKET DEMAND

Emerging on the heels of modular construction successes, modular automation is characterized by the industry need for standardized, integration-ready technologies to support a plant-level, plug-and-produce strategy. Modular automation is an industry goal driven by market factors including:

- **Personalized medicine** is driving smaller volume requirements, trending away from "one size fits all" toward production of a variety of products from a single, flexible facility that can accommodate faster changeovers and automated equipment utilization. According to the Tufts Center for the Study of Drug Development, several biopharmaceutical companies have doubled their investments over the last five years in precision medicine and are expected to increase their investments by an additional 33% over the next five years.[2]

- An increasing focus on **biologics** and their role in research and development and in turn, production strategies. Analysis from McKinsey & Company reveals that new modalities, such as cell and gene therapy and mRNA vaccine technology, have increased from 11 to 21 percent of the drug development pipeline—the fastest growth ever seen in the sector.[3]

- **Shifting capacity** requirements including small-scale production, scaling from lab to production, executing parallelization, or running single-use systems push the boundaries of many legacy platforms to the point where traditional automation approaches are simply not possible.

- **Talent constraints** are an industry-wide problem, with 45% of companies facing skills gaps amidst a pool of pharma digital talent that is currently at least 14 percent lower than demand.[4] The cost of siloed equipment with proprietary interfaces can be measured in the ineffectiveness of strained plant engineers and operators.

2. https://www.prnewswire.com/news-releases/global-precision-medicine-market-to-reach-14170-billion-by-2026-reports-bis-research-664364683.html

3. https://www.mckinsey.com/capabilities/operations/our-insights/emerging-from-disruption-the-future-of-pharma-operations-strategy

4. https://www.mckinsey.com/mgi/overview/in-the-news/automation-and-the-future-of-work

TOWARD INTEGRATION:
THE MODULAR EFFECT

Just as digitalization has revealed the advantages of componentization, interoperability, and reusability, so too will the modularization of process modules. Realized through XML-based Automation Markup Language (AML) principles and technologies, modular automation requires a new way of thinking about process lines. Segmenting, or designing process line tasks into smaller, more manageable "building blocks" is the goal. Consider the traditional versus modular plant and how the landscape of process line tasks evolves with a modular automation approach. The modular plant promotes interconnectivity and equipment interaction while allowing for process and equipment changes. The end game is to enable engineers to integrate skids with a variety of different control systems faster and with less expertise, easing the effect of talent constraints and ensuring repeatability. As a result, heavy customization is less of a burden to the ROI of interoperability and reusability possible with a more open, non-proprietary approach.

TRADITIONAL PLANT DESIGN
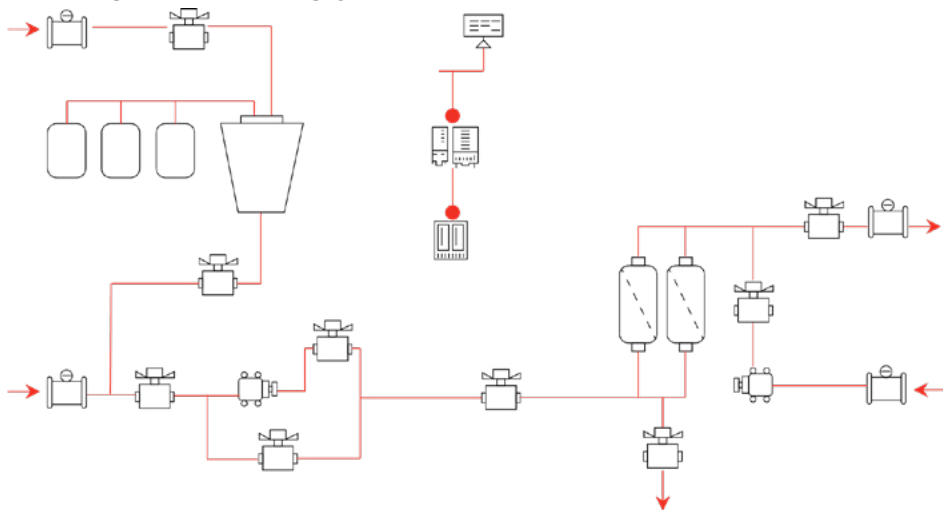
MODULAR PLANT DESIGN
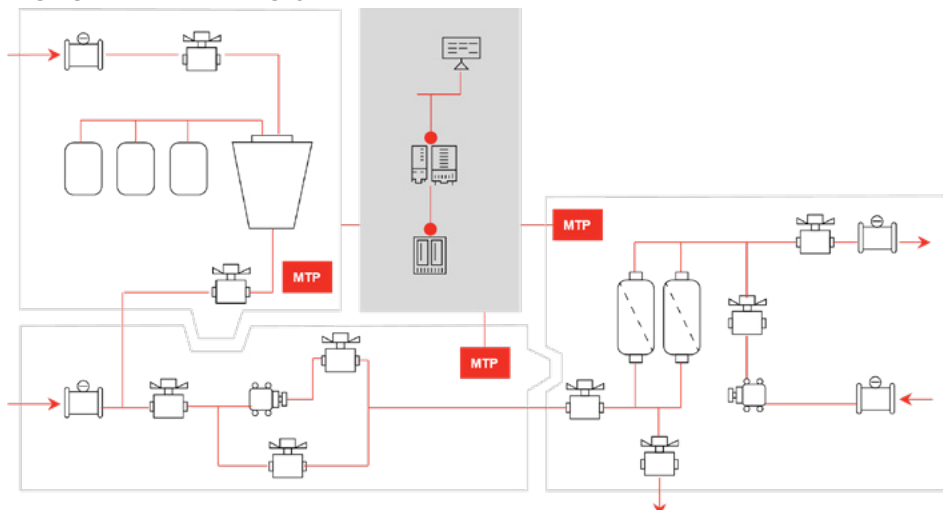
> Individual modules are pre-automated and then added together like building blocks, each with its own control functions and intelligence.

Figure 1: Traditional versus modular plant design

GETTING TO KNOW MTP: INTEROPERABILITY FOR MODULAR AUTOMATION

Standardization is integral to modular automation strategies. In turn, industry alignment and adoption are critical for widespread adoption. AutomationML (IEC 62714[5]) provides the automation-specific XML data format for the foundational information required for automation processing, expressed through Module Type Package (MTP).

A non-proprietary emerging standard in the modular automation landscape, MTP is characterized by what authors refer to as the three Ps – pre-engineered, pre-manufactured, and pre-automated. Developed by the User Association of Automation Technology in Process Industries (NAMUR), MTP represents the interests of over 150 member companies and several thousand process control technology specialists.[6]

MTP contains necessary information to define a process module, including an HMI template, connectivity information, and communication services (alarms, data, events, etc.). Its intent is to facilitate the rapid deployment of modular equipment in product development and production environments by:

- Reducing the time required for engineering commissioning through simplified validation.

- Establishing manufacturer-independent connectivity of equipment modules.

- Enabling standard configuration of data transfer.

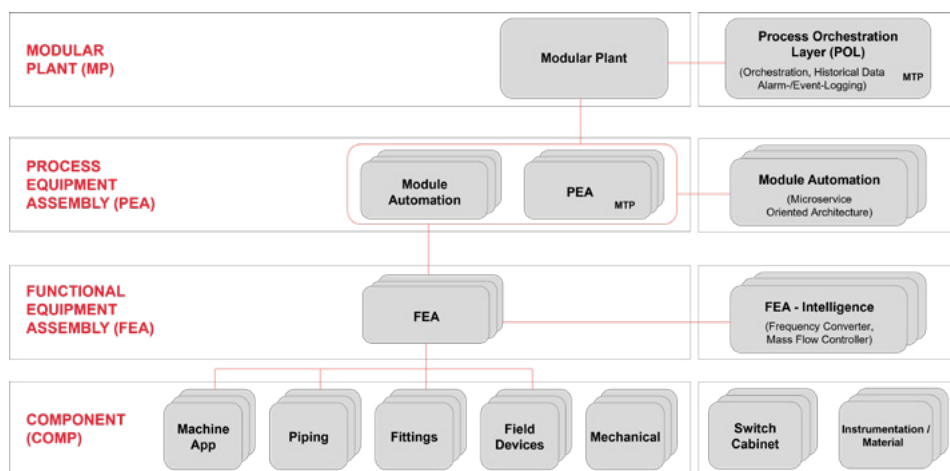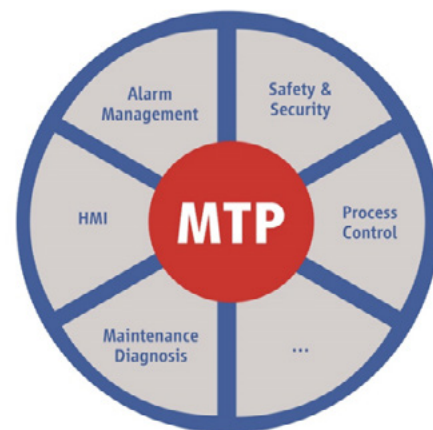It aligns well with the modular plant approach, as shown below.

Figure 2: MTP Components[8]

Figure 3: The modular plant approach

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5.   https://webstore.iec.ch/preview/info_iec62714-1%7Bed2.0.RLV%7Den.pdf

6.   https://www.namur.net/en/about-us.html

The Process Orchestration Layer (POL) connects and coordinates multiple process units or Process Equipment Assemblies (PEAs) into a modular plant. It is here that the investment in standards and modular automation has the potential to shine, depending on the breadth and depth of POL capabilities. In fact, a manufacturer's vision of plug-and-produce manifests at the orchestration layer, whose capabilities should fully leverage autonomous PEAs by supporting MTP throughout the overarching solution framework and provide a single consistent interface to the end users.

- A market-leading orchestration layer enhances the investment in MTP standardization by using OPC Unified Architecture (OPC UA) for data connectivity in anticipation of Industrial Internet of Things (IIoT) products and services.

- An outstanding POL seamlessly imports the MTP files from various skids to form the base of a plant-level visualization system that monitors and controls these skids. The design and capabilities of this environment set the stage for both efficiency and innovation gains as operators leverage a single consistent interface to identify exceptions and address issues before they impact yield or delay production.

- The exceptional orchestration layer enables operators to execute a full ANSI ISA S88 batch model in the process controller for direct batch automation with multiple production skids. Standardized recipe management, regardless of vendor or skid functionality, is the norm. Operators begin to transition from reactive responses to plant floor issues to proactive, insightful business decisions because of standardization, interoperability, and data transparency.

This kind of comprehensive investment in standards can deliver the plug-and-produce promise while extending its business impact with a framework for the future. According to the BioPhorum Operations Group, the potential impact of plug-and-produce technology on cost savings for manufacturers is significant.

ACTIVITY/FUNCTION	ESTIMATED PERSON-HOURS SAVED	ESTIMATED SCHEDULE REDUCTION	ESTIMATED COST SAVINGS
Interface integration design, development, implementation, and testing	300+ hours	2–3 months	$60–80k
Tools to help detect, diagnose, or help facilitate communications	20–60 hours	2–6 weeks	$5–25k
Troubleshooting communications	30–80 hours	3 weeks	$15K
Workarounds and diagnostic tools	20–40 hours	2 weeks	$8k
License cost of third-party solutions	16–20 hours*	1 week*	$2–8k

* Time estimation for a validated environment under change management control

Figure 4: Plug-and-play potential cost savings[7]

7. https://www.biophorum.com/external-resource/value-of-plug-and-play-october-2019/

CONCLUSION:
THE HONEYWELL PERSPECTIVE

Honeywell is at the forefront of technologies that advance the automation megatrend happening in life sciences and across industries. We are positioned to meet and exceed customer expectations for interoperable modular automation as the industry aligns around standardization. Achieving reduced speed to market through shorter product lifecycles is the overriding incentive for our community's adoption of modular automation approaches. Together, we're focusing on specific business problems with concrete outcomes. There's an urgent need to:

- Eliminate the approximately 30 percent of staff time spent on documentation-related activities, including product dossiers, machine logs, batch records, and more[8], plus the time engineers spend integrating equipment during project automation, including custom interfaces.

- Increase the availability of plants by quickly replacing defective modules with equivalent ones without manual reconfiguration.

- Increase flexibility for production of multiple products on one line with a seamless transfer from laboratory to production.

- Initiate quicker response to product variants and manufacture multiple products with available assets.

- Improve efficiency through re-utilization of engineering work and physical equipment, and including the ability to easily switch unit operations.

- Reduce the time and resources needed for qualification and validation.

Honeywell is helping to transform the future of Life Sciences by delivering exceptional solutions for modular automation for both the PEA and POL layers. Our foundational visualization technologies enable operators to identify and troubleshoot process issues with less expertise today. The advent of MTP-enabled equipment brings a wealth of AutomationML-based metadata to enhance visualization and enable integration, delivering the means for a plug-and-produce approach.

Honeywell's complete portfolio of solutions offers Manufacturing Execution Systems (MES), process control systems, building and energy management systems, batch control, environmental monitoring, and OT cybersecurity solutions to round out a complete automation solution for life sciences.

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8. https://www.mckinsey.com/capabilities/operations/our-insights/operations-can-launch-the-next-blockbuster-in-pharma

For more information

Learn more about how Honeywell's Batch Historian, visit hwll.co/LifeSciences or contact your Honeywell Account Manager, Distributor or System Integrator.

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