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Digitalization Moves Forward in Pharma Equipment and Processes

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What's Next for Life Sciences?

By Gagan Naeger

We explored the road ahead at Automation Fair 2021 and uncovered three ways to accelerate your digital transformation.

You know the life sciences industry inside and out. The trends, the challenges, the competition—it's foundational information that helps build a successful company.

It's no different for us. Whether we already earned your business or hope to someday, we can't serve you if we don't know the landscape. That's why we place a premium on listening. When we meet with customers, attend an industry trade show or organize an event of our own, we take every opportunity to understand the current state of the life sciences market as well as its future. That way, we can help you play a major part in both.

I had an opportunity to do a lot of listening (and a little talking) at Automation Fair 2021 while serving as moderator at the life sciences forum. Everyone in attendance shared their views of the industry—the panel as they traded ideas and the audience as they posed questions—and left with an improved perspective.

WHAT'S NEXT FOR LIFE SCIENCES?

The forward-thinking portions of our conversation really stood out to me, particularly when I asked the panel to share one thing our audience needs to consider when planning the future of their digital transformation project. You'll find a preview of that conversation below and a link at the bottom of the page so you can watch the entire forum on demand.

Artificial intelligence

With digital transformation being a major focus across so many industries, the tools associated with it have grown in familiarity: manufacturing execution systems (MES), the industrial internet of things, virtual and augmented reality, and so on.

Just like any tool, you want to find ways to make it work as effectively as possible. An MES solution, for example, can collect data enterprise-wide. But what do you do with all of it? How much is realistically usable through manual analysis? One of our forum panelists, David Hinkler of Thermo Fisher Scientific, suggested artificial intelligence as something to lean on more heavily in the future.

"We've come so far. But I think there's still so much ground to leverage artificial intelligence and bring that data back from the mainframe and start doing data correlation," he said. "There's so much to learn with artificial intelligence and how to apply it, not just to the connected worker, but the connected factory with the entire enterprise: to understand if there's a shortage in one area or another, maybe we can switch production to another facility.

"There's going to be so many dynamics behind that and an opportunity to look at machinery and the performance of machinery from one site to the next," he added. "It's something that's really going to help move us forward."

Control tower

The issue of what to do with the information available to us came up again with this aptly

named tool. Think about how an air-traffic control tower works—information from hundreds and even thousands of flights every day, delivered to individuals who need to understand how they relate while accounting for external factors like weather. Their goal: safety and efficiency.

It sounds very similar to what life sciences decision makers deal with every day. As Kalypso's Sachin Misra explained, applying the control tower concept to our industry would serve similar goals by giving leaders the same thing air-traffic controllers need to do their jobs — visibility.

"For the last few decades, everybody has been focused on how one single line is performing or how one facility is performing. Nobody's really thought about bringing together all of the views that you need to have effective manufacturing operations," Misra said in the forum. "That's really what the future's going to be about: having aggregated, composite views not only at an equipment level, but at a line level and a facility level, all rolled up into a digital performance management view.

"At the end of the day, if it's done well, what you can really enable is this notion of a dark facility that's fully autonomous, that really understands all of the complexities and variations that need to be dealt with to be able to produce quality, efficacious product."

Customer first

Some things never go out of style, right? If anything discussed during the forum is future-proof, I would choose this. It's the bedrock of successful, repeatable business results and something we prioritize with every project.

In fact, ensuring the customer is 100% clear about their objectives is one of the first things we do.

It's not about the technology or software or other solutions we can provide. The most important thing is building toward an optimal outcome.

Cytiva's Kevin Seaver said as much as we wrapped up our discussion.

"It all starts with the customer," he said. "We understand their needs, and then we apply the right technology to meet those customer needs. Certainly, those big pharma customers have totally different needs than the ones that are just starting off. And if we try to apply those fancy technologies and so forth to our smaller customers, it isn't going to work—and vice versa.

WHAT'S NEXT FOR LIFE SCIENCES?

"In either case, we want to be scalable," he added. "We want to be able to scale from small to large. So as these customers grow, we want to be able to grow with them. We don't want them to have to throw away what they have and do something entirely new. We want to start at the core and grow in a lot of different directions."

For more on these topics and others that could spark your next stage of business growth — from digital thread to single-use equipment — visit our life sciences homepage. Or contact us to share your objectives for your next improvement project.

Gagan Naeger

Global Vice President
Enterprise Accounts Life Sciences
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Gagan has spent her career as a global leader focused on accelerating digital transformation through a software value-based approach, helping customers integrate data silos to meet or exceed customer expectations in the life sciences industry. Her software background has been augmented by extensive sales experience leading and growing full end-to-end business dramatically outpacing the market. She has successfully navigated/built organizations by cultivating team-based inclusive/collaborative cultures that lead to game-changing innovation and elevating products/portfolio as best in class for the life sciences industry.

For some of the biggest challenges life sciences companies face,

there's a

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Staying Ahead in Life Science Manufacturing – Current Trends and Urgent Needs in Digital Transformation

Interview with Sachin Misra, Principal and Global Practice Leader at Kalypso (a Rockwell Automation company)

Sachin Misra

Principal and Global Practice Leader at Kalypso

Against a pre-existing background of financial and regulatory pressures to accelerate and improve the efficiency of drug development and manufacturing, the global pandemic has highlighted as never before the need to rapidly scale up both pharmaceutical R&D and production. What do you feel are the major lessons for the industry in terms of pharmaceutical development and manufacturing practices, and what are organizations now doing to improve their approach?

SACHIN MISRA: To remain one of the world's most lucrative industrial sectors with the highest return on assets (ROA), the pharmaceutical industry has needed to adapt to changing consumer behavior, pricing pressures and greater, more complex regulatory scrutiny. Drug discovery and development is lengthy, high-cost and risky. In the current environment, with expiring drug patents and regulatory conservatism, many companies are focused on reducing development and manufacturing costs and accelerating time to market, while maintaining quality, efficacy and patient safety.

STAYING AHEAD IN LIFE SCIENCE MANUFACTURING –
CURRENT TRENDS AND URGENT NEEDS IN DIGITAL TRANSFORMATION

The COVID pandemic has highlighted important lessons from recent years. Gaps exposed at the beginning of the pandemic in health systems, manufacturing capacity and drug products supply led to rapid capacity building. Now many pharma organizations face the dilemma of how best to utilize the excess capacity and optimize acquired or organically developed capacity. This points out some key lessons for the industry.

Firstly, identify an organization's capability, limitations and strengths in development and manufacturing. Complement these by creating effective partnerships with academia, governmental, research, development and manufacturing organizations. This enables companies to meet demand in an elastic fashion.

Second, invest in a distributed network of partners who can quickly ramp up manufacturing capacity. Undertake longer-term contingency planning and strategic coordination to maximize the resilience of manufacturing networks. Companies need a broad and reliable community of trusted and qualified partners.

Third, invest in inventory reserves, supported by large networks of suppliers. Develop plans for stockpiling, and expand collaboration channels with trusted partners.

Fourth, plan for the unexpected, including geopolitical driven protectionism. Countries tend to address their own issues first, potentially impacting global supply chains with implications for raw materials, manufacturing supplies, critical manufacturing automation and controls technologies.

Fifth, embrace digital information creation and the sharing of structured data to improve value chain alignment and reuse of digital data. While human effort and regulatory waivers helped address the recent situation, this is not sustainable.

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What are the key challenges in bringing new drugs to market? Is there any one standout challenge?

SACHIN MISRA: Drug development is lengthy, complex, costly and uncertain. Each development, commercialization or tech transfer delay risks increasing costs and reducing revenue. The growing influence of third-party payers is adding pricing pressures, while emerging therapies are targeting smaller patient populations with complex needs. Overall, developing and executing a commercial strategy is increasingly challenging.

There is also a question of market access. Most products that miss their first-year forecasts have market access issues, such as unfavorable placement or formulary

exclusion, formulary restrictions, high price and patient cost sharing, weak health-economic evidence, or unexpectedly high expenses on discounts and rebates.

Supply chain risk or disruption is a major issue. While many pharmaceutical companies have acquired additional capacity, its use has been impeded by disrupted materials supply chains. Better supply chain risk management is crucial.

Having a qualified workforce is critical to ensuring a pharmaceutical company performs well. The sector as a whole depends on a knowledgeable, skilled and experienced workforce and must increase its investment if progress is to continue. The current mature workforce will ultimately be replaced by younger workers with expectations of digital technology aids. Leveraging technologies like extended reality (XR) to capture existing workforce knowledge and using that to train incoming recruits will support continued growth.

Tech transfer, the capture and transfer of knowledge generated across a long development lifecycle into manufacturing organizations, remains elusive. This can mean multi-year latencies in ramping up manufacturing operations.

A further challenge is the need to collect and analyze huge amounts of data, defined in the pharmaceutical industry as all the information entered by operators or generated by machines. Data collection and data integrity form a key pillar of Pharma 4.0. Of greatest importance is a pharmaceutical company's ability to not only collect data, but to perform analysis that guides decision making, thereby turning data into insight. Every pharmaceutical company can collect data at several levels, and digitalization is essential for its easy exploitation.

It is generally acknowledged that the life sciences industry has been slower than others to adopt digital technologies, but now the term 'digital transformation' is very widely used. Beyond the buzzword, what does this really mean for a company, why is it important and how does it fit into the current push for manufacturing improvement?

SACHIN MISRA: The pharmaceutical industry is likely to see big change as a result of digital transformation in the coming years. Digital transformation is a broad business strategy aimed at solving traditional business challenges and creating new disruptive opportunities using digital technologies. This strategy can take different forms depending on the processes, functions and organizations concerned, and the challenges and opportunities being addressed.

Digital transformation in pharmaceuticals manufacturing is essentially the use of established, emerging and disruptive

technologies to accelerate time to market, reduce costs, improve quality and increase flexibility. Technologies such as artificial intelligence (AI), big data analytics and machine learning (ML) are already helping improve efficiency, accelerate latency-ridden processes and make data-driven decisions. Examples include asset performance optimization, digital tech transfer, improved workforce productivity, continued process verification, manufacturing line digital twins and virtual commissioning, emulation of automation, soft sensors, yield optimization, and reducing time to commercialization.

When embarking on, or going through, the digital transformation journey, what are the critical components for success and what are the main challenges to overcome?

SACHIN MISRA: According to the recent Digital Investment Index (DII) report by Ernst & Young and Oxford Economics, 55% of life sciences companies lack clearly defined digital strategies and goals. Furthermore, only 2% of leaders are realizing the full benefits of their digital transformation initiatives across the core processes of their organizations. To ensure resilient operations, protect value chains and improve production efficiency, life sciences leaders must advocate for widespread digital adoption within their organizations. Certain perspectives support that mission.

First, think beyond the technology. Leaders advocating digital transformation should organize around the practical applications of digital tools and exemplify how they solve business challenges. For example, rather than demonstrating augmented or extended reality technology without business context, demonstrate the ability to monitor a production line remotely or conduct operations training virtually.

Second, critically define capabilities. True at-scale digitalization requires time, resources and the proper technologies if it is to deliver maximum business impact. Every organization will need specific capabilities—a unique combination of people, processes, data and technologies—to support a digital transformation that is sustainable, scalable and embraced by all who use it. It is therefore important to select a partner who can aid and accelerate determination of the unique capabilities required for success.

Finally, create a digital culture. A holistic approach is essential, especially in embracing rather than simply using new tools. Important here is cross-functional collaboration between members of the organization on how best to train their people on the use and application of digital tools. Prioritizing programs focused on cultural change around new tools and processes helps build support with both leadership and staff.

The bottom line is that traditionally risk-averse life sciences organizations must embrace rather than fear digital transformation in order to grow, and it must be planned to reverberate across the entire organization.

Can you identify the most important areas for change in production processes and the trends that you see for addressing these challenges?

SACHIN MISRA: Digitalization of documents to become structured, and enabling reusable data is a fundamental requirement and is achievable using natural language processing (NLP). NLP enables conversion and contextualization of unstructured pdf or Word data into a standard International Society of Automation (ISA 88) format for easy ingestion by downstream systems. This eliminates manual transcription of data into multiple systems and reduces tech transfer time, removes human-induced data errors and ensures data integrity, resulting in faster time to market while adhering to quality requirements.

Several technologies have already made automation more accessible for pharma companies. The next step is 'plug and play' automation where systems and modules have common standards and communications protocols that make line configuration and reconfiguration easy.

In addition, robotic automation is becoming more attainable. Autonomous mobile robots (AMRs) promise to change how materials are delivered to work cells and how finished goods reach the warehouse, enabling full dock-to-dock solutions. The rise of robotics and automation in many manufacturing industries has long raised alarms about the disenfranchisement of skilled labor. In reality, robots and humans working collaboratively get more work done in a safer environment while ensuring the highest levels of quality. Cobots, or collaborative robots, are now emerging as tools for the human workforce to help improve overall efficiency on the shop floor. They can be programmed to perform non-value-added work while humans focus on skills-intensive operations.

With companies now having access to more data than ever before, tools that enable full utilization of that data, such as AI and ML, are having a major impact on manufacturing. ML algorithms analyze historical data, recognize trends and infer logical conclusions for data-driven decision-making in real time. AI and ML help improve areas such as batch process parameter optimization, inventory management, supply chain visibility and risk management, asset performance optimization and closed loop capacity improvements, yield and schedule optimization, line side next best action, and model predictive control for continuous manufacturing process control optimization.

Finally, predictive maintenance, made possible by the internet of things (IoT), AI and ML, helps avoid downtime, potentially reducing maintenance costs by about 20% and halving unplanned machine outage.

Technology transfer and scale-up are recurring challenges throughout the pharmaceutical development and production process. How important is digital transformation in overcoming these challenges and accelerating drugs to market?

SACHIN MISRA: Adopting digital technologies

to create a stream of reusable knowledge data enables data integrity and reduces manual efforts in interpreting and extracting data relevant for downstream functions, for internal operations and for external partners. Ideally, each knowledge application and solution would create native digital data reusable by other downstream functions. While this is true for most modern applications, work is needed to identify the key reusable data elements and how they will be consumed by boundary systems. Pharma companies who have done this are now leveraging datalakes, data warehouses, graph databases and service-orientated architecture (SOA) integration mechanisms to weave multiple digital threads into an enterprise digital fabric and are realizing efficiency and effectiveness benefits across the entire value chain.

How should companies be approaching their tech transfer challenges?

SACHIN MISRA: Tech transfer involves many types of data and sources, from process and materials information to quality and testing requirements, all generated by a range of functional stakeholders and systems. It does not lend itself well to a single source of truth repository.

Start by assessing which functions, organizations and parties experience delays or latencies, either because they must recreate data or due to knowledge gaps that could be addressed by making upstream knowledge available consistently in a ready-to-use format. Having identified these downstream recipients, define what data they need, and the level of aggregation and structuring required to deliver it. Aggregating disparate knowledge can be cumbersome, and most pharma companies have created compendia of documents for knowledge sharing. Leveraging NLP, AI and ML technologies and tools transforms curated unstructured and structured knowledge data into a consistent, well-defined format conforming to standards such as ISA88. This digital data can then be orchestrated securely across a network of internal and external partners, enabling them to reuse and ingest some or all of it and streamline functional and system needs.

Can you comment on where the relevant digital technology and solutions are heading, and can you identify any emerging trends? What is likely to make the biggest impact in the immediate future?

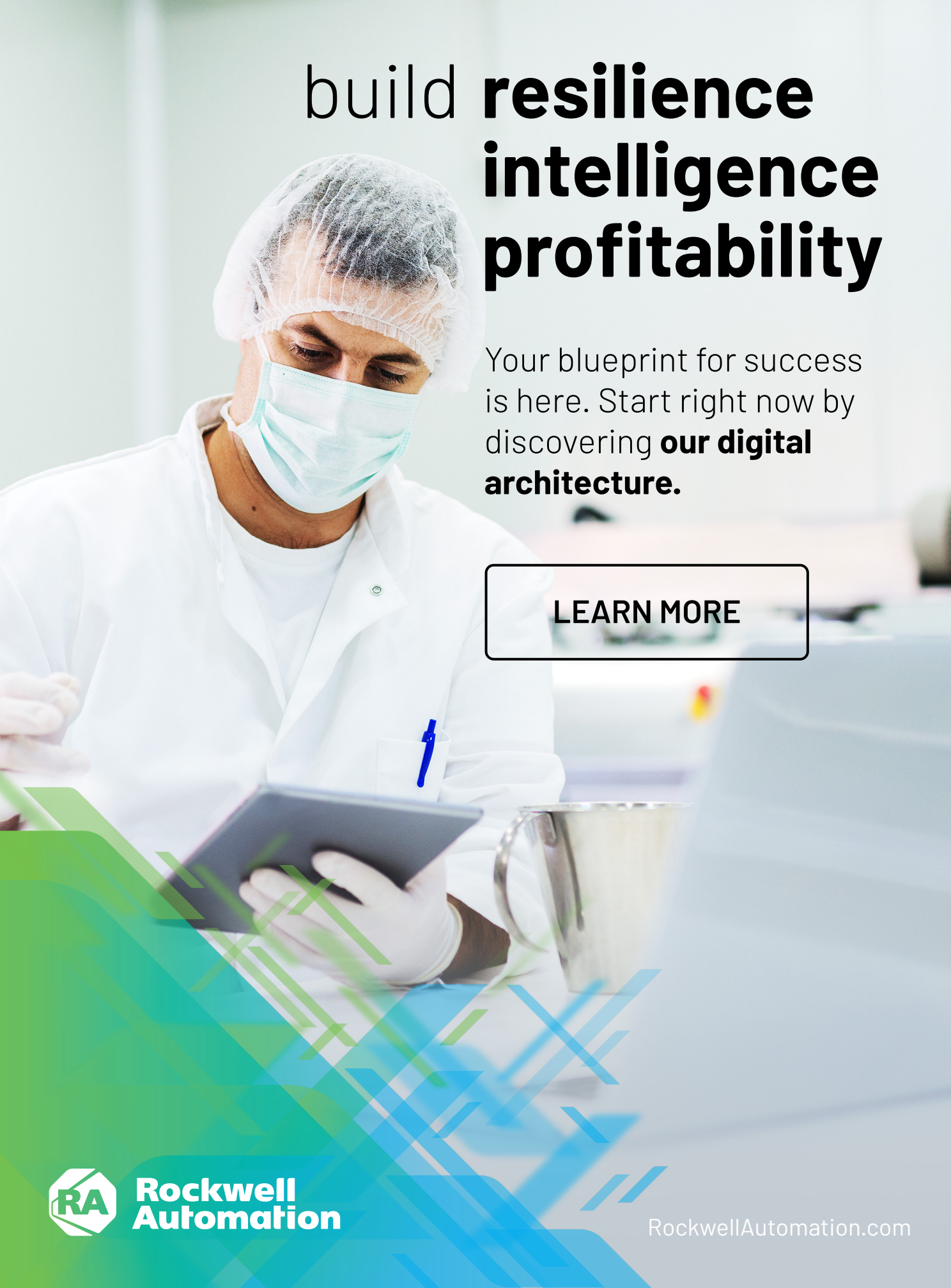
SACHIN MISRA: As manufacturers mature the connected enterprise into the autonomous enterprise, they must focus on optimizing process control, using new ML techniques to reduce manufacturing cycle time and quality incidents. Those who are data rich and savvy are capitalizing on AI initiatives to improve autonomy in manufacturing operations. Companies are augmenting legacy control strategies with prescriptive ML and Model Predictive Control (MPC) capabilities that achieve greater production throughput, yields, and achievement of critical quality attributes.

Process control has evolved greatly. Recent developments in edge computing and

advanced analytics are enabling the next evolution: machine learning control (MLC). With MLC, companies can automatically derive new optimization algorithms from previously unknown correlations in large datasets. This enables faster production scale-up and increased return on investment (ROI). In an autonomous enterprise, real-time sensory information is combined with advanced ML algorithms, helping predict equipment failures, reduce downtime and improve worker safety.


Image courtesy of Rockwell Automation

Reflecting on where we are today, there are certainly lessons from other industries already reaping the benefits from emerging and disruptive technologies. As the pharmaceutical industry forges ahead with digital transformation, it must work alongside the regulatory agencies to align with good manufacturing practice (GMP) requirements in order to fully realize the same benefits.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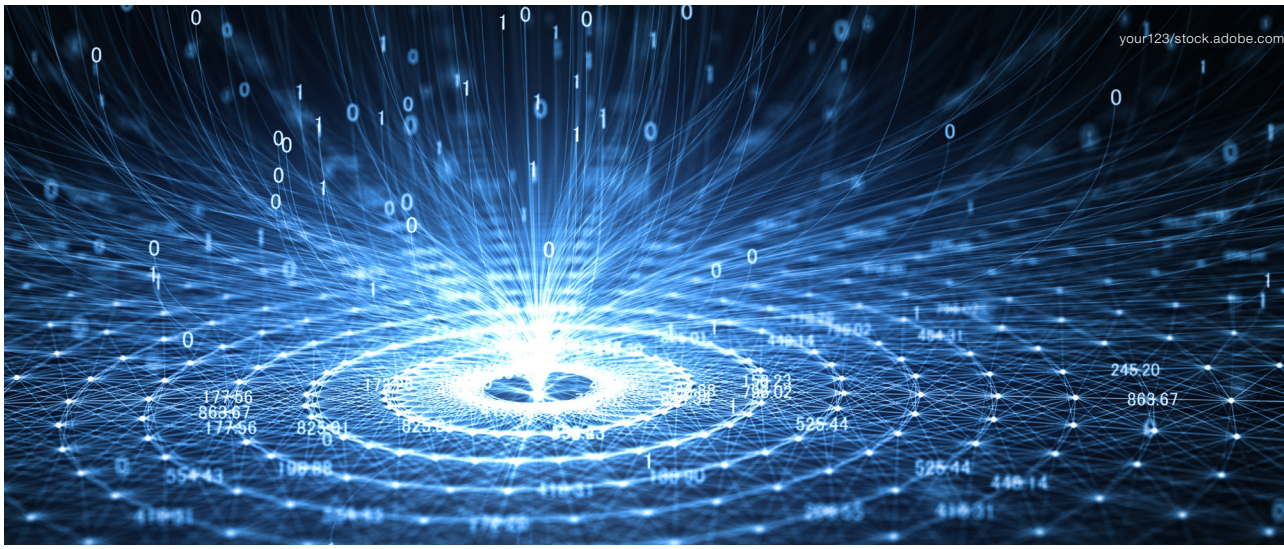

Digitalization Moves Forward in Pharma Equipment and Processes

By Jennifer Markarian

Bio/pharmaceutical manufacturing harnesses the benefits of digital transformation

The benefits of digital maturity in pharmaceutical manufacturing were made evident by the COVID-19 pandemic during 2020 and 2021, as the sudden need to develop, manufacture, and distribute treatments and vaccines intersected with travel restrictions, social distancing and supply chain interruptions. Digital technologies that could meet these new challenges and aid manufacturing scale-up and speed to market, such as automated digital data collection and augmented and virtual reality (AR/VR) remote collaboration tools, were already available and had been adopted by some, but the new demand spurred greater adoption. The need to solve manufacturing challenges gave more companies the incentive to initiate or make further progress on their digital transformation journeys.

"These events directly showed the payoff of information technology (IT)/operational technology (OT) integration achieved over the last several years, but also revealed that we have an opportunity to do much more," says Dan UpDyke, strategic marketing manager at Rockwell

DIGITALIZATION MOVES FORWARD IN PHARMA EQUIPMENT AND PROCESSES

Automation. "The ability for the industry to pivot and quickly bring new therapies to market highlighted the need for flexible, scalable and connected manufacturing systems. We have already seen an increase in integrating data and recipe management through a manufacturing execution system (MES) and flexible distributed control systems (DCS)," says UpDyke. "These are technologies that enable faster time to market by reducing the efforts to shift to new products."

"As an industry, we've seen we need to be more efficient, and we need to be able to monitor and manage processes remotely from a centralized location. People are focused on process intensification and how to better digitize and automate their processes," says Merrilee Whitney, head of the BioContinuum Platform at MilliporeSigma, the US and Canada life science business of Merck KGaA.

The pandemic created a higher awareness of the need for digitalization, adds Dirk Wollaert, Vertical Market Pharma at Siemens headquarters in Belgium. Digital technologies were key to the success of the rapid development and rollout of the COVID-19 vaccines, facilitating cross-company collaborations even across national borders. "Globalization and industry standardization to facilitate smoother transition from one production plant to another became more important," he explains.

Another change that accelerated in the past two years was a transition to the cloud for software solutions and data storage, adds Pamela Docherty, Life Sciences Industry manager at Siemens USA. "The ability to push data from the manufacturing floor to the cloud creates a backbone for digitalization," she says.

In bio/pharmaceutical manufacturing, the application of "Industry 4.0" techologies, such as digitalization, must be aligned with regulatory requirements, including good manufacturing practices (GMPs). The International Society for Pharmaceutical Engineering (ISPE) has trademarked their initiative as Pharma 4.0, also dubbed the "Smart Factory," and has developed an operating model, which the Pharma 4.0 special interest group notes goes beyond IT to organizational, process, and resource aspects (1).

"There is a cultural aspect to digitalization because it's a significant investment that results in changes to the operational structure of a facility; it is beneficial when the digitalization comes from the top," explains Yvonne Duckworth, automation engineer and Industry 4.0 subject matterexpert at the CRB Group, a life sciences engineering and construction company. "We are seeing more often that management is driving the adoption of digitalization in new facilities. It is becoming a standard and expected part of facility design."

DIGITALIZATION MOVES FORWARD IN PHARMA EQUIPMENT AND PROCESSES

In the past five years, pharma manufacturers have been moving toward digital maturity. Assessed using the BioPhorum Group's Digital Plant Maturity Model (2), some manufacturers are at level 1 (predigital); some are at level 2 (digital silos and islands of automation); many are at level 3 (connected plants) on their way to level 4 (predictive plant with real-time predictive analysis); and others want to adopt some aspects of level 5 (autonomous, adaptive plant), says Duckworth.

Although in past years digitalization primarily meant moving away from paper-based systems to digital reports that were then printed to electronic or physical paper, a new paradigm enables a jump from Pharma 2.0 paper-based systems to the Pharma 4.0 operator-centric connected plant, said Gilad Langer, industry practice lead at Tulip, which supplies a cloud-based frontline operations platform (3). "This paradigm shift changes the culture and the processes, but doesn't significantly change the operator's workflow. Instead, digital apps are built to bring the physical world to the digital world with sensors and cameras, with digital output as the evidence. Data from equipment and human activities are collected via the industrial Internet of things (IIoT)," explains Langer.

From data to digital twins

Digital tools depend on good data collection. Having equipment set up for data collection and data analytics is increasingly important, says Duckworth. Machine sensors and process analytical technology (PAT) instruments can communicate directly with data collection systems using the IIoT. These large quantities of data are needed for machine learning, including artificial intelligence systems and digital twins, which are representations of the physical world in the digital world.

Visualizing data in ways that scientists and engineers can use to improve understanding and to optimize processes is also important. Technologies can enable an "end-to-end digital thread of information," says UpDyke. "Multi-site manufacturing in different markets is pushing the industry towards more connectivity, improved visibility across sites and organizations, and increased knowledge and information sharing that will enable expedited recipe development."

New England Controls, Inc. (NECI), which partners with Emerson, has developed and deployed new digital tools in the past year that enable access to data sources and aggregation into analytical tools to link the "physical plant" to the "digital plant," says Michael Cody, director of digital and clinical manufacturing at NECI. Access to data with operational context is crucial for pharma manufacturing facilities, says Cody. "The need to aggregate and analyze data from a variety of data sources is pushing equipment and technology providers to be able to interface and communicate with those digital tools in a meaningful way," he explains.

Digital twins are a tool being increasingly used in a wide range of scenarios, from engineering optimization of individual pieces of equipment to analysis of full manufacturing systems. Examples from the past year, says

Docherty, include digital twins for process development with an innovative mixing application, a representation of a new skid to enable faster fabrication, an offline training system for a continuous direct compression line, and an alerting system to ensure that people were keeping proper distance on the manufacturing floor.

Siemens also collaborated with GlaxoSmithKline on a digital twin project that modeled and controlled the adjuvant particle manufacturing process. The project proved the concept that digital twins could be used in vaccine process development and transferred to manufacturing (4).

As biopharmaceutical facilities shift to modular, multi-product facilities, digitalization enables efficient automation. A DCS can be used to connect the components, even as the process flow changes depending on how the different production modules are combined, says Docherty. Siemens and Sartorius, for example, demonstrated a modular production system using the Siemens DCS with Sartorius' Biostat bioreactor system. The companies set up an agreement to build standard interfaces between the Sartorius unit operations and the Siemens control system for closer integration (5). This system would allow the option of a fully paperless manufacturing facility.

Augmented reality tools

AR digital tools are finding a wide range of uses in pharma manufacturing. Prior to 2020, AR was being developed for training and as an aid for technicians following standard operating procedures, for example, and it was being used for remote equipment maintenance and troubleshooting. When the pandemic suddenly made being on site impossible, AR/VR suppliers, such as Apprentice IO, stepped up with kits that included smart glasses and the technology to connect remotely (6), and pharma manufacturers and their suppliers began using them for tasks such as remote factory acceptance testing (FAT) and installations. The efficiency of these tools is expected to drive continued use. For example, reports Duckworth, using AR for FAT has now become an accepted practice.

Manufacturers also began using AR/VR tools for remote inspections, audits and facility tours. Suppliers such as Avatour offer cloud-based communication platforms with 360-degree video capabilities so that viewers can control what they are seeing. "By combining [this communication] with sensor data and geo-location stamps, these platforms provide independent third-party validation of what exactly transpired during each site visit," asserts Devon Copley, cofounder and CEO of Avatour.

Regulatory agencies also used these tools, and although such tools will not replace physical inspections, their use is expected to continue (7).

mRNA vaccine manufacturing

The data analysis and clear communication allowed by digital tools has demonstrated its benefits for process development and technical

transfer, making time to market faster. Digital manufacturing technologies were successful in helping vaccine manufacturers, such as Moderna and Pfizer, accelerate their technology transfer and manufacturing process.

"The capability to perform technology transfer from Moderna to their contract manufacturing partner, Lonza, was enabled by the digital technologies deployed in their respective facilities," says Cody. "Both Moderna and Lonza utilize DeltaV as their process automation system and Syncade as their manufacturing execution system. NECI teams partnered with Moderna and Lonza teams to transfer equipment automation strategies and electronic batch records from company to company, accelerating the manufacturing capacity and establishing supply chain capability as the Moderna COVID-19 vaccine was completing clinical trials and FDA emergency use approval."

The availability of digital tools and the collaboration of implementing them in a refurbished facility was key to the speed of bringing BioNTech's mRNA vaccine to commercial production in Europe, adds Wollaert. The process was brought online in under six months, while under normal circumstances it would have taken at least one year, he observed.

Siemens, a long-time partner of BioNTech, assisted the company in converting a facility in Marburg, Germany to mRNA vaccine production using end-to-end digitalization of production. Siemens Opcenter Excecution Pharma was chosen as the new MES, and the digital system enabled conversion to paperless documentation of production with electronic batch records. Although the process has a number of manual work steps, operators are guided through these with the software's workflow management component. The Siemens Simatic PCS 7 distributed control system was used to automate processes (8).

Looking ahead

FDA recognizes the role of digitalization and is working with industry suppliers to better understand these technologies. "The pandemic created significant opportunities for education and experimentation of digitalization with FDA," says Jason Spiegler, senior director of Life Sciences Strategic Initiatives, Siemens Digital Industries. Although initial projects looking at digital twins took place within FDA's Center for Devices and Radiological Health (CDRH) (9), the understanding developed in device manufacturing can be applied to other FDA branches, suggests Spiegler. Spiegler also co-leads a joint FDA and industry computer software assurance (CSA) team that is focused on educating and promoting the adoption of risk-based CSA best practices for the life sciences industry. "CSA is foundational for unleashing the potential of digitalization on the shop floor," says Spiegler.

Although paper-based systems are still prevalent in the industry, the benefits of digital and automated systems were made more clear by the upheaval over the past two years, and the industry can expect more digitalization of manufacturing equipment and processes in the coming year.

"There is more of an acceptance that digital transformation is necessary and worth the investment in a regulated industry. This new awareness will help drive digital transformation and move the industry significantly forward," predicts UpDyke.

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Digital Transformation Project Reduces Downtime

Polpharma, a large drug manufacturer in Poland that makes APIs and generic prescription and over-the-counter drugs, conducted a digital transformation project, including manufacturing operations. The company implemented technologies that allowed it to digitize documents and activities, collect data from multiple points of the production processes, and automate data flows, says Magdalena Rzeszotalska, Corporate Communications and Corporate Social Responsibility Director. The aim was to eliminate manual activities, and to develop and employ a digital twin of operations.

"A key benefit we were able to realize is to connect data points into a comprehensive model of manufacturing and supply-chain activities that allows us to simulate, predict, and optimize underlying processes and activities to improve time to market, quality, and cost," says Rzeszotalska.

One of the projects used data collected from the supervisory control and data acquisition system combined with augmented reality/virtual reality (AR/VR) to visually replicate the factory floor location and improve remote connection between subject matter experts or external service providers located outside the facility with the technicians located inside. An AR scan virtually locates the external personnel with the technician, allowing the team to communicate and resolve factory-floor problems. This practice resulted in a 10–15% reduction in maintenance downtime and was adopted across the company to help maintain social distancing during the COVID-19 pandemic, reports the company.