Emerson Experts Discuss the Benefits of Digitalization in the Life Sciences Industry

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Emerson's Michalle Adkins, Director of Life Sciences Strategy & Direction, and Karen Fung, Senior Engineering Manager, share insights on how digitalization can enhance drug development efficiency, patient care, clinical trial processes, and supply chain management, as well as improve collaboration and information sharing among different stakeholders.

Michalle Adkins, Director, Life Sciences Strategy & Direction

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BioPharma APAC
Access to Global Life Sciences and Health Businesses.

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Emerson's Michalle Adkins, Director of Life Sciences Strategy & Direction, and Karen Fung, Senior Engineering Manager

1. **How can digitalization help improve the efficiency and speed of drug development in the life sciences industry?**

Michalle Adkins: Technology transfer is traditionally a time-consuming, manual process. Because information is siloed across several systems, manually transferring the specific critical process parameters, quality attributes and other parameters has many opportunities for errors. While these errors are typically caught in the qualification and validation processes, it adds additional effort and time.

Managing process and procedural changes plus scaling production is often still paper based, requiring the process-specific step order and associated parameters to be manually transferred between many different people and systems.

A new digital technology, Process and Knowledge Management (PKM) software, is the next step in facilitating speed to market. PKM software shortens technology

transfer by standardizing information in a single fit-for-purpose knowledge management software application utilized throughout the entire development and commercialization process. End users and Emerson experts have demonstrated that this seamless collaboration and data democratization can help reduce time to market by 12-18 months or more.

2. **What are some ways that digital technologies can be used to enhance patient care and outcomes in the life sciences field?**

Michalle Adkins: Life-sciences manufacturers can best enhance patient care and outcomes by getting treatments to market quickly to alleviate suffering, and then by reliably maintaining supply of those treatments. Today's best digital technologies contribute to four life sciences pillars focused on achieving these outcomes:

Pipeline acceleration - Tools like PKM software are critical to standardizing process steps along with the associated critical parameters and attributes to shorten the technology transfer process and quickly bring new products to market. PKM's facility fit feature quickly compares existing facilities to see which equipment set has the necessary capabilities at the right scale to manufacture.

Flexible manufacturing - Many organizations are expanding their portfolio beyond single blockbuster drugs to deliver a wider range of more targeted treatments. Modern manufacturing execution systems and real-time scheduling software enable this flexibility, helping teams make changes to production without upsetting performance. Technologies such as automated import of configuration with solutions like Emerson's PK controller with DeltaV™ or the industry standard module type package enable near plug-and play connectivity among various process skids.

Operational integrity - Manufacturers must provide product orders in full and on time, so they cannot afford unexpected production outages. Predictive maintenance technologies, often supported by artificial intelligence and machine learning, are key to catching problems before they impact operations. Also, once a pending problem is detected, being able to schedule maintenance at the opportune time and understand implications of any production schedule changes is another capability that is helpful for this pillar.

Real-time release - Plants rely on digital technologies like electronic workflow, electronic batch records, and quality review manager software which can be used together to identify, review, and resolve exceptions as part of the process before batch completion, enabling release by exception. Organizations are starting to incorporate inline monitoring technologies to monitor, control, and optimize manufacturing processes as well as identify and prevent manufacturing problems before they cause delays to product release. Additionally, forward-thinking organizations are using Process Analytic Technology (PAT) and systems to take steps to minimize off-line testing, so that real-time release can one day be an achievable goal.

3. **How can digitalization help to streamline clinical trial processes and reduce costs in the life sciences industry?**

Michalle Adkins: In 2021 alone, life sciences manufacturers initiated over 31,000 new clinical trials. Teams producing treatments for those clinical trials need to produce batches quickly and make sure they can rapidly change out equipment and recipes to move to the next trial. Manual changes considerably increase the variables the teams need to consider, so they need digital tools to help eliminate mistakes and simplify the process of swapping equipment and changing out the associated recipes.

Advanced control technologies, contextualization and standardization of data, and automated set-up and production workflows are essential to making these fast changes happen without introducing mistakes, and they are best handled with digital technologies. Parameterizing modular electronic workflow—and then using knowledge management applications like PKM to automatically populate the parameters combined with real-time scheduling software—delivers on fast changes with optimized facility throughput.

4. **What role do artificial intelligence and machine learning play in the acceleration of digitalization in the life sciences sector?**

Michalle Adkins: Tools like real-time modeling software allow organizations to visualize facility constraints, accommodate variability, maximize production, and understand the implications of any potential changes in the manufacturing process. Those capabilities are enabled by artificial intelligence (AI) and machine learning (ML) engines that can use multivariate data to dynamically model operations with appropriate constraints, leading to optimized operations and enhanced speed.

AI and ML also play a critical role in the predictive technologies that lead to improved operational integrity. Using pattern recognition and advanced algorithms, today's predictive technologies can detect problems before equipment fails or before batches are affected, giving a team time to intervene to save significant time, money, and effort.

5. **How can digitalization be used to improve supply chain management and logistics in the life sciences industry?**

Karen Fung: Operational excellence and scheduling are the two key components of supply chain management and logistics, and they both can be improved with targeted digitalization solutions. Real-time scheduling software can easily integrate with planning systems such as ERP solutions to automatically compensate and adjust schedules to fit needs such as equipment outage planning or supply shortage assessments to keep production (and resulting supply) as steady as possible regardless of operating conditions.

6. **How can digitalization help to increase collaboration and information sharing among different stakeholders in the life sciences field?**

Michalle Adkins: Digital tools promote collaboration and information sharing by standardizing recipes and data and then facilitating quick and easy scale up or out as a treatment moves through each stage. PKM software creates an electronic repository to capture recipe related decisions made across product development. This automatic capture of all data not only speeds the whole pipeline from research to commercial production, but also reduces errors, significantly reducing the technology transfer timeline.

With PKM software's standardization via templates, built-in workflows, and internal calculation engines to manage process parameters, teams can more easily collaborate across the entire development chain. All information from every step is easily discoverable and usable at any stage of the process. Teams can more easily conform to standards and more easily locate, share, and comprehend critical data.

7. **What are some challenges and obstacles to fully realizing the potential of digitalization in the life sciences industry and how can these be overcome?**

Karen Fung: It takes years to train a skilled operator, but technologies can narrow the gap between the most and least experienced people. Simulation tools such as Mimic simulation software can be used with the DeltaV distributed control system to create a comprehensive, immersive, and practical training program for new operators, for training any operator on significant process changes, or for updates when bringing in a new product to an existing facility.

Comprehensive human machine interface (HMI) tools like Emerson's DeltaV Live integrate displays from a wide variety of tools across the plant to help users better monitor operations. And when tools like DeltaV Mobile expand critical dashboards to users' mobile devices, operators gain access to critical information from anywhere in the world.

Forward-thinking automation suppliers are also building complementary partnerships to provide holistic solutions so life sciences companies can find everything they need from one source. For example, Emerson's recent partnership with Atos and Zaether helps life sciences providers find both a comprehensive software portfolio and extensive expertise in system integration and digital transformation implementation all in one place. Emerson's majority stake in AspenTech also provides access to expanded data management, analytical and review solutions.

Single-point access to a wide variety of subject-area experts makes it easier for life sciences organizations to quickly solve bigger, more complex issues such as flexible and modular manufacturing. Leveraging the expertise built into these partnerships helps teams improve their ability to accelerate the time-to-market of life saving treatments.

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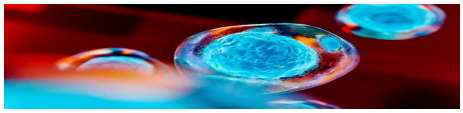

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