How Automation Helps to Accelerate Product Development

Sumeet Dalvi from Emerson explains how advanced automation solutions, paired with unified data strategies, are enabling life sciences organisations to expedite technology transfer and bring new treatments to market faster.

It is widely recognised within the healthcare industry that patient expectations are rapidly evolving, with an increasing demand for higher service standards and prompt access to safe and effective therapies. This puts life sciences manufacturers under growing pressure to bring innovative new drugs, devices and treatments to market as quickly as possible, without compromising safety or efficacy. This in turn creates significant challenges throughout the entire development chain as organisations strive to achieve more efficient production processes, faster clinical trials and streamlined regulatory approvals.

Today, there are more emerging therapies in development that are patient centric than traditional blockbuster therapies. This challenges manufacturers to become increasingly flexible and agile, ensuring they can quickly switch production between different therapies. The ability to rapidly pivot their manufacturing can give organisations a competitive edge, making them better positioned to capture emerging market opportunities.

The need to streamline changeover efficiency is driving manufacturers to introduce variable, rather than fixed, product recipe parameters as part of a more integrated control strategy. This means that vital parameters such as ingredient proportions, processing conditions and timing can be adjusted to accommodate variations in product formulations, production scales, or regulatory requirements without having to redesign the entire process. This flexible approach reduces downtime and costs by enabling manufacturers to quickly switch between different products or therapies, while maintaining high product quality.

Along with offering greater flexibility, production facilities must of course continue to operate smoothly and efficiently. Operational integrity and timely product delivery requires the ability to adjust to unforeseen disruptions, with the prediction and prevention of equipment failures and process deviations that could impact production schedules and create manufacturing losses. Organisations are also striving for real-time release and sustainable operations. With the integration of in-line quality monitoring, this enables real-time process adjustments and automatic exception handling helping to eliminate or reduce time-consuming manual checks, batch reviews and testing. Continuous real-time monitoring and analytics enables manufacturers to quickly identify any process deviations, make informed decisions and adjust operations proactively. This then enables them to maintain high product quality, reduce downtime and production costs, and ensure regulatory compliance. Greater operational insights and improved process control can also help to drive the changes necessary to reduce waste and optimise energy usage, helping companies to achieve sustainability goals.

Optimised Data Management

For manufacturers looking to optimise their operations, increase speed-to-market and secure an advantage over their competitors, effective data management must be a core foundational element. To optimise data management, manufacturers need to bring together diverse data from disparate systems, ranging from process control to quality assurance. This integration prevents critical production data from becoming trapped in silos, instead ensuring that it is readily and coherently available at a single, unified point. Today's life sciences organisations are embracing automation as a core element of data management. The goal is not just gaining access to more data but unlocking 'data as a product'. This requires a boundless automation approach, with seamless and traceable movement of contextualised information across the entire development and manufacturing chain, from research through to commercial-scale production. This will help to make technology transfer faster and easier and enhance operational sustainability. Ultimately, achieving these objectives helps to ensure that treatments are delivered to patients around the world in the shortest time possible.

Process Knowledge and Workflow Management

During the process development and clinical manufacturing stages, the focus is on identifying the most effective and reliable means of manufacturing a new product consistently. Whilst undertaking the many experiments during these stages, the teams involved need to know which version of the process is the current one at any point in time, the order of unit operations and the specific parameters for each experiment. With greater experience of the manufacturing process and more results from experiments, the teams will refine the process and quality parameters, update risk assessments and devise control strategies to mitigate any potential issues.

Achieving these objectives demands integration and analysis of a lot of data from multiple sources. Storing and organising this data across various systems, formats and recording tools can lead to significant delays and potential errors if performed manually.

Advanced automation tools designed to provide seamless data mobility can help to maintain data integrity and context, reduce manual work and streamline the management and transfer of information across development, clinical manufacturing and commercial scaling. Tools such as process knowledge management (PKM) systems and digital workflow management solutions help to standardise processes and improve flexibility.

PKM software facilitates the seamless management of product and process specifications throughout the drug development lifecycle, while digital workflow management solutions provide intuitive interfaces to enforce workflows and support quick, efficient task execution no matter the skill level of authors. PKM software provides a development team with centralised recipe management – a single source of truth for the product definition, specification structures, and process terminology needed throughout the product lifecycle. Data within PKM software can be accessed securely from

anywhere via a web-based interface, making it easier for users to collaborate and access essential documents and data for real-time decision-making.

Organisations also need a means of storing all their process and manufacturing data in a federated data fabric, accessible by any authorised user and application. Many therefore plan to extend enterprise service buses and centralised data lakes to an integrated industrial and business data fabric. The fabric seamlessly connects diverse systems to collect and store large volumes of data, which is then made accessible for analysis and reporting locally and across the enterprise. Together, PKM software and an industrial data fabric reduce the amount of time spent on low-value tasks and dramatically shorten the technology transfer process.

Simulation Solutions

As companies prepare to transition to commercial-scale manufacturing, selecting the right production site is crucial. Whether constructing a new manufacturing facility, identifying an existing location with the necessary capacity, or outsourcing manufacturing to contract manufacturers, robust data management remains vital. For greenfield sites, companies often perform design simulation to ensure the plant meets the required specifications. Simulation tools help to identify potential bottlenecks before construction begins and can also be used to train operators in advance of start-up, helping ensure optimal performance from day one. Simulation tools also benefit existing facilities. For example, by using automated model creation software, organisations can assess a site's capacity for specific products and uncover and eliminate potential inefficiencies before they impact production.

Efficient and accurate simulation requires vast amounts of data, and to supply this, teams are increasingly connecting simulation software to their integrated data fabric solutions. By leveraging contextualised information in a data fabric, teams can quickly and easily build the various models necessary to take full advantage of what the simulation software can deliver. The more data and context the team has, the more accurate the results will be.

For existing or outsourced manufacturing sites, companies often perform facility fit assessments to determine the best site for manufacturing a certain product at a given scale. Advanced PKM solutions include facility fit tools that use data to identify whether a site has the necessary equipment and capacity to meet production goals. These tools can provide highly specific recommendations and alert users when manufacturing configurations do not meet their needs.

Commercial Manufacturing at Scale

When moving into large-scale production, the need for fast, flexible data access increases. Manufacturing teams must be able to view data from a variety of sources, such as the process control system, manufacturing execution system, quality management tools and edge sensors. They also need to contextualise the data and present it to multiple personnel, enabling them to make critical decisions quickly.

To ensure batches are consistently produced according to requirements, production and quality teams rely on precise data that confirms product quality. Every manufacturing and release step must always be right first time, which requires continuous monitoring of the entire process, including the calibration and health of all the devices involved. To support this, device management systems are essential. These systems run alongside the distributed control system (DCS) to help teams calibrate assets and document the status and health of devices such as measurement instrumentation. They track device status and calibration details, and provide an automatic audit trail of device changes, for validation and auditing purposes. They also issue alerts when a change happens, helping to ensure smooth, uninterrupted production.

Alongside device management, teams need high-quality data on the health of balance-of-plant assets that are integral to the process, such as cooling towers, HVAC systems and pumps. Monitoring these systems ensures potential failures are identified and addressed before they impact manufacturing. Modern plants use wireless vibration sensors and edge analytics to feed critical health data from rotating machinery into their DCS and data fabric. This helps teams stay on top of the overall health of the plant and identify issues before they deteriorate and lead to failures that can impact operations. Moreover, having all connected data within a unified data fabric, teams can leverage more complex, AI-based analytics systems to provide the instantaneous feedback and decision support necessary to support more autonomous operation.

Conclusion

As life sciences companies strive to enhance their speed to market, manufacturing flexibility, operational efficiency and sustainability, their reliance on data continues to grow. Fortunately, modern automation systems are designed with seamless data flow in mind, ensuring data reaches the right place at the right time, with full contextual accuracy to support real-time decisions. Building a foundation of data mobility now will provide long-term advantages, helping organisations to stay flexible and agile in an increasingly complex global marketplace. Not only will this foster a competitive edge, but it will also enable the faster delivery of life-saving therapies to patients worldwide.

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