



The Importance Of Automation And Data Management Across Biomanufacturing Workflows

An interview with:

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Created in cooperation with Life Science Connect, November 2019

Growing competition across the biomanufacturing industry is resulting in a greater need for efficiency and speed at all stages of development and manufacturing. However, traditional methods that rely on pharmaceutical scientists and researchers for manual data entry and transfer across the workflow increase the likelihood of errors, potentially delaying the delivery of your final product to the market.

In this space, technology and automation can serve as key tools for understanding your molecule by interconnecting and managing the data collected throughout process development. Implementing these tools requires the capability to link individual operations and their data, facilitating a smooth transition through the various stages of manufacturing to commercialization.

By using technology and automation to drive quality and efficiency in R&D, process controls can be automated and managed, allowing improved productivity while maintaining high quality standards during process optimization and scale-up.

The Trouble With Manual Data Entry And Management

Technology transfers are critical steps during which teams must ensure that minimal changes are made to a biopharmaceutical manufacturing process as it moves from small-scale to large-scale production. Any errors or delays during this transition can result in costly production delays or deviations, or worse, may require full redevelopment of the process itself. Transfer operations, which rely on systems that can not readily communicate or are incompatible, are prone to data integrity issues related to the manual entry and aggregation of vital data.

In addition, development or manufacturing investigations and troubleshooting operations require the involvement of multiple departments, all of which may generate data in different areas of the business. When an issue arises in the manufacturing suite, it is critical that process data collected from the batch in question is compared to the historical development data on which that process was built.

Comparisons like these can elucidate obscure process differences and make it easier to identify and address the root cause. Without end-to-end data management, the data must be manually transcribed to make that comparison. This inefficient analysis of data ultimately slows down the investigation and increases time-to-resolution, resulting in higher manufacturing costs, wasted resources, and an elevated risk of having to discard a batch (or more than one). Additionally, disparate systems from numerous vendors require R&D to maintain operational knowledge of multiple systems that do not share a common lexicon. Systems that do not speak the same language complicate data visualization, preventing clear and quick communication during technology transfers. If the data stored in an archive do not have meaningful identification, they cannot be retrieved.

Addressing these issues and others related to manual data entry and management is essential, as the accuracy and preservation of analytical data from the earliest stages of development directly contribute to the success of clinical trials and the regulatory approval process. When you mitigate the inherent risks of drug development through automation and technology, you make more informed decisions, need fewer development runs, speed up process development and manufacturing, and enjoy a shorter time-to-market for faster patient impacts.

Visualizing An Automated Solution For Data Management

Data automation software packages currently on the market already provide solutions for localized problems related to manual intervention. In most cases, it is trivial to identify a data automation solution for any given laboratory instrument. However, it is important that you take a step back and consider not just the software itself but the architecture in which it operates. Even software that is described as end-to-end may be deployed in such a way that it extends only throughout a limited area of a business rather than linking programs across entire development and manufacturing networks. When software solutions are deployed with a unified data management strategy and platform in mind, the resulting standardization of workflows extends beyond improving the consistency of operations across manufacturing scales; when implemented in a broad scope, integrated data management systems can result in quicker adoption of lessons learned and speed up the growth of process knowledge. This leads to more efficient operations throughout the business.

The ultimate solution would be a platform and software interface that can integrate and streamline process control and data management across the entire process development workflow. A standardized lexicon and user-friendly data visualization interface provide a deeper level of process knowledge, which allows faster and better decision-making. The software should also be able to communicate on standard profiles that are known in the industry, rather than customized ones unique to the software, and it should be developed with data integrity and security in mind.

As the industry continues to grow and evolve, it is also critical to have an integrated system that can adapt to the rapidly changing biopharmaceutical landscape. Cloud technology has allowed many industries to become more connected and should be utilized in biopharma in the same way. Similar to Apple's iPhone™ software updates or Tesla's auto-drive feature upgrades, data management software should be developed in a way that can be continuously updated and improved with new and better features. What we consider to be "end-to-end" today may not be the case just a few years from now.

Companies continue to become increasingly integrated and rely more and more heavily on real-time data feedback to make manufacturing decisions. Integrated companies can do more with less, and therefore divert resources toward more critical tasks and scientific development, if obstacles related to data management have been removed. And with ambitious industrial paradigm shifts like continuous processing, which relies on a constant generation of data that must be stored, managed, and shared, we expect the demand for robust data management systems to continue growing in the foreseeable future. This summary highlights just one of the changes we are seeing in the biopharmaceutical world, where the digitization of manufacturing using interconnectivity and real-time data is driving the industry toward new and exciting opportunities in drug development and manufacturing. Suppliers that focus on delivering the tools we need to reach our full potential serve as pioneers in this journey, as we all work together toward a better future of patient care.