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EMBRACING NECESSARY DIGITAL TRANSFORMATION IN BIOMANUFACTURING

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It is surprising that, given the abundant scientific and commercial innovation present, our industry has been relatively slow to implement modern digital solutions in the manufacturing space. This is especially true in the realm of data analytics, where we continue to trail other industries.

For instance, many biopharmaceutical manufacturing processes still involve manual record-keeping, which presents a potential challenge to data integrity and limits the opportunity to derive valuable insights. Unfortunately, the "way it's always been done" ideology can present manufacturers with real and sometimes serious consequences.

In December 2018, the FDA posted its final guidance on Data Integrity and Compliance with a Drug cGMP Question & Answer. It specified that all contract development and manufacturing organization (CDMO) partners should be able to demonstrate compliance with up-to-date regulations relevant to the project at hand. In the eyes of regulators, rigorous process management and data integrity are taken very seriously. Disruption, slowdowns, and even total shutdowns – such as the FDA's publication of Form 483 against generics firm Able Laboratories, which later closed[1] – provide several compelling reasons to disrupt tradition, strive for progress, and make the leap toward digital transformation.

From a more proactive (and optimistic) point of view, embracing innovation in biopharmaceutical digital integration and data analytics affords us a very real opportunity to improve our manufacturing processes and quality of our decision-making, especially as we navigate a radically and rapidly changing landscape.

BRIDGING DISPARATE DATA

Our industry's delayed adaptation is not for a lack of want. Biopharmaceutical manufacturing firms have historically shaped production processes to GMP parameters defined by regulatory authorities and industry trends around the world. For example, because the FDA requires visual inspection of formulations, the manufacturer may opt to assign an associate to manually inspect the drug product vials instead of a more streamlined and effective process: automated high-definition cameras to inspect for defects and particles. These devices are far more effective at facilitating reliable and consistent particle detection than the human eye alone. Though digitalized particle detection has advanced over recent years, these technologies have not been readily adopted, sometimes due to difficulties in validation.

Additionally, our industry is producing a trove of valuable but highly fragmented data. When leveraged correctly, this data helps us improve product and process quality and enables business intelligence for more data-driven decisions. Many systems and equipment used to record production data operate on proprietary file management systems or systems that don't interface well with other systems. The goal is to centralize and standardize data management for quality and business processes, so that data across all areas, including operations and business, can be accessed for past, current, and predictive analytics.

By digitalizing manufacturing and quality control processes, we can begin to aggregate and understand "big data" over time and transmute it into a structured, usable format. From there, we can perform advanced predictive analytics to detect potential manufacturing errors and outcomes or discover automated root causes for identified deviations.

Contemporary cloud-based data architecture solutions – such as those offered by Google, Amazon, and Microsoft – will play a pivotal role in structuring our data. These services allow manufacturing organizations to automate and streamline data analytics. Once data-driven analytics reaches a proven level of operational and quality maturity, further process automation based on analytical outcomes may be possible in a GMP setting.

KEY ADVANTAGES OF DATA TRANSFORMATION

The most immediate advantage of large-scale, actionable analytics is improved business visibility. Soon, we can expect to see far greater control over data integrity and long-term viability in a radically new landscape and increasingly competitive market. By integrating data capture, supply chain, and facility management systems, organizations will gain a better understanding of true per-unit production costs, shifting from traditional to activity-based cost analysis. A fully integrated system is capable of factoring human labor, material and equipment usage, facility power, and more, providing excellent clarity over the course of production.

Digitalization will facilitate automated notifications and allow for audit trails for events where adverse deviations (unintentional or malicious) would otherwise go undetected. Inline monitoring and automation of quality control processes prior to the generation of results (e.g., automatically calculating results and transferring them to LIMS to produce colony counts and reports) would significantly reduce or eliminate the opportunity for data integrity problems.

It is entirely conceivable that new algorithms – working from finely-tuned sensors measuring various process parameters and quality attributes – will enable us to detect process deviations in real time and potentially even predict errors based on historical data. Predictive analytics is a lofty but entirely realistic goal. From there, we could run data simulations that show us an expected impact of potential process changes, adding appreciable value during process development. While that's likely several years down the road, it has been successful in other industries and can be achieved in life sciences as well.

Eventually when a manufacturer's data modeling and strategy become mature, we could use that data to make important GMP decisions. For instance, we could rely on predictive analytics to provide a root cause analysis for GMP processes, identifying potential process or business challenges in advance. That being said, working with many regulatory authorities to validate these methods will take a considerable amount of time.

A key goal for data integration is the development of automated inline monitoring and inline testing protocols, facilitating real-time batch releases. If all required data (such as manufacturing data, quality data, etc.) is aggregated and available, it can facilitate a nuanced evaluation of these parameters and automatically clear a product batch for release, with appropriate redundancies and bounds built into the program. The more we utilize our data, the more we understand our processes and the better we can encourage process improvements and continued innovations through digital transformation.

WORLD EVENTS DRIVING THE ADOPTION OF DIGITAL

Following the initial COVID-19 outbreak, global travel – and entire business sectors – came to a sudden halt. This event underscores an emergent benefit of high digital integration: the ability to access key operational data remotely and rapidly.

In other large business sectors, it is often expected that project and operational data is made available for remote access, whether that is in the form of web portals, phone apps, or other means of communication. Data transparency is top of mind for many businesses and clients, and in biopharmaceutical manufacturing, this will inevitably become the expected standard.

For industries that lack this level of collaborative integration, events like COVID-19 have a disruptive effect. In our industry, the inability to travel makes on-site plant inspections– a fundamental part of manufacturing oversight– difficult or impossible. With integrated, automated data collection, key metrics can be acquired, structured, and digitally shared with stakeholders at any time. By making remote virtual auditing much more accessible, this approach could also potentially reduce the number of physical audits required. It is safe to assume that biopharmaceutical developers who adapt and lead in the digital sphere stand to seize a competitive advantage in a somewhat amorphous but rapidly stabilizing market.

IMPROVE VISIBILITY AND DRIVE RESULTS WITH AN OUTSOURCING PARTNER

Accordingly, an effective contract development and manufacturing organization is committed to meeting its time-to-delivery targets in any business environment. As your CDMO partner responsible for helping your formulation reach market, Samsung Biologics is excited to lead the way in data integration and utilization for biopharmaceutical manufacturing.

For instance, our newly rolled out Live Virtual Tour (LVT) helps clients remotely assess our production facility as if they were physically there. With this solution, potential and existing clients (as well as regulatory auditors) can evaluate our cGMP compliance and quality documentation system from any location around the world. We have adopted the latest in cloud architecture and 5G technology to create an innovative platform that saves time and streamlines logistics in a post-COVID environment.

As we continue to integrate data collection and create new information streams to promote data transparency, we look forward to providing our partners exceptional strategic clarity and peace of mind.

Experience the future of biopharmaceutical manufacturing with Samsung Biologics.

Contact us for further inquiry at *sbio.bd@samsung.com*

Our state-of-the-art facilities in Incheon, South Korea offer our life science partners:

Cost Competitiveness
We provide clinical and commercial supply of biologics at globally competitive rates.

Regulatory Compliance
We are routinely inspected and compliant with the FDA, EMA, PDMA, and MFDS.

Segregated Inoculation Suites
We reduce risk of cross contamination and ensure minimal changeover time.

Cutting-Edge Equipment
Our bioreactors and chromatography skids utilize the latest technologies and automation, and our analytical capabilities for both in-process monitoring and product release are among the most sophisticated in the world.

Product Safety & Robust Supply
We have extensive experience undertaking critical process steps at large scale associated with viral reduction, inactivation, and filtration, delivering peace of mind.

ABOUT SAMSUNG BIOLOGICS

Samsung Biologics (KRX: 207940.KS) is a fully integrated contract service provider offering development, manufacturing, and testing services, all from a single location. We provide highly tailored solutions to clients, while meeting the evolving needs of the global healthcare industry.

With proven regulatory approvals and the largest single site capacity, Samsung Biologics is a trusted CDMO partner of choice, and is uniquely able to provide seamless offerings from cell line development to final fill/finish as well as laboratory testing services at every stage for biopharmaceutical products.

Our facilities are all cGMP compliant holding 364KL total capacity with scales ranging from 1KL and 5KL to 15KL. We continue to invest and upgrade our capabilities through two 1KL single-use bioreactors that provide further flexibility and efficiency in accommodating a wide range of client demands. Samsung Biologics plans to expand its aseptic filling services through the addition of two lyophilizers and a flexible fill line. We believe and are committed to an on-time, in-full delivery of the products we manufacture with our flexible manufacturing solutions, operational excellence, and proven expertise.

REFERENCES

1. *https://www.fda.gov/media/70711/download*

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