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BIOPROCESSING INSIGHTS

Introducing New Bioprocessing Technologies in the Era of COVID-19

**By K. John Morrow Jr., PhD**

Bioprocessing is undergoing dramatic changes as companies develop new manufacturing strategies; according to Artur Miguel Arsenio, PhD, head of product management at Sartorius Stedim Biotech. “The digitalization of several elements of our value chain is transforming the way we operate and meet our customers’ needs,” he

told GEN. “With the end-to-end integration of systems and data, we are introducing bundling and cross-selling of multiple systems, including digital companions.”

A critical feature of the Bioprocessing 4.0 concept is the reduction of human error. “The increase of automation, remote diagnostics, real-time process monitoring and control can significantly reduce the need for manual

tasks,” he stated, “thus decreasing the risks for an important source of contamination. Furthermore, automation and smart connected systems empower the performance of human workers on manual tasks, helping them to avoid errors and reducing risks.”

The company predicts that flexible automation integration will reduce the project effort for installing an upstream /downstream bioprocessing

facility by 50–75% because activities are substantially reduced during the integration. The modular packages allow rapid and flexible deployment or change of various consumable configurations to allow process adaptation and quick system upgrades.

“Tailored configurations can be easily updated with a simple software change, even in a cGMP environment,” Arsenio continued. “These smart modular package units allow us to override manual set-up and running issues, significantly reducing human error during set-up and process runs.”

A better process understanding also helps to limit the number of actions dependent on humans (and options offered), further reducing opportunities for errors. Data analytics tools enable process optimization, further reduc-

ing the need for human intervention, and the quality by design strategy reduces the risk of failed batches due to increased process understanding and therefore reduces costs.

For Arsenio, Bioprocessing 4.0 is a new concept, focusing on system and data connectivity in the biotech industries. “We believe it to be an enabler of transformative innovation within the industry (the way we work, our processes, our products and platforms). It brings the potential to react flexibly and in a scalable way to changing market demands and it aligns with the industry’s drive to significantly reduce CAPEX and OPEX associated with the manufacturing of lifesaving biopharmaceuticals to an expanding global market.”

Today the overriding challenge to the bioprocessing industry is the

Coronavirus COVID-19 threat and the need to ramp up production rapidly.

“Sartorius’ Ambr systems are helping the industry to speed up process development to reach clinical trials. PAT (Process Analytical Technology) also plays an important role,” maintains Arsenio. “Furthermore, the market demands of the COVID-19 pandemic call for significant improvements, such as time-to-clinic and time-to-facility. A proper layout of automation can improve time-to-facility, by bringing options for faster integration. Biobrain, a new automation platform for our biomanufacturing systems, is a smart modular package unit, engineered to ensure seamless integration of SU instruments into different supervisory control and data acquisition (SCADA) or Digital Control System (DCS).” **GEN**