

Life Sciences

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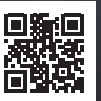
EDITION



SARTORIUS

**IMPROVING THE OVERALL EFFICIENCY
OF CELL LINE DEVELOPMENT**

\$15



SARTORIUS

By Jeremy Williams

Within the discovery-to-market development cycle for biopharmaceuticals, cell line development (CLD) plays a primary role in creating and selecting a cell line that becomes the Master Cell Bank (MCB) for clinical and commercial biomanufacturing. However, CLD, primarily driven by resource-intensive manual cell culture processes and analytics, is often associated with long development timelines and large, complex data volumes. For every project, a wealth of data is generated. Consequently, cell culture scientists often face multiple issues when balancing essential outcomes, including their target protein's quality, stability, safety, potency, and yield. The need of the hour is a modular design framework that can leverage this data, unify processes, and transform current workflows in ways that will enable demands for shorter timelines and increasing complexity of modalities.

"This is where we come in. With our wide portfolio, Sartorius offers the cell line, media, and testing solutions. We focus on developing expression platforms for proteins and viruses, together with the associated cell culture media and buffers, and product testing," remarks Jean-Marc Cappia, Head of Cell Line, Media, at Sartorius. The company provides innovative, high-throughput, and automated solutions for the early development of dedicated cell lines.

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service that we offer out of our acquisition of Ulm, Germany-based Cellca with the cell banking and testing services that we provide through the acquisition of UK-based BioOutsource, we are able to support the entire CLD workflow for our customers,” says Cappia. Today, Sartorius offers a full range of products, services, and consulting expertise that enables life science companies to streamline early-stage drug development and process development activities. “We help drug developers optimizing

their outcomes, resources, and project management by minimizing coordination efforts, project time, and financial investments.”

Delivering High-Yielding and Stable Cell Lines

Sartorius’ suite of innovative products and services are tailored to each phase in the drug development lifecycle allowing for speed and scalability simultaneously. At early development stage, their reliable CHO cell line development services minimize risk and timeline,

maximize cell line performance, and save resources. For later stages, Sartorius offers bioanalytical and lot release testing services. “Partnering with us not only helps accelerate the cell line development process but also ensures a smooth transition to commercial manufacturing,” mentions Cappia.

The CLD process with Sartorius begins with the team determining the customer’s gene of interest to produce the molecule. From there, they handle everything from the synthesis of the gene of interest to the final selection and characterization of the best clones “By combining the performance of both our media and cell line, we ensure a robust, predictable, and scalable bioprocess with high product yield and quality,” adds Cappia. Sartorius’ CHO cell banking platform allows the technology transfer of the cell culture parameters without the need for scale-up studies for an effortless pivot to cGMP manufacturing. A key aspect of Sartorius’ CLD is that from DNA to Research Cell Bank (RCB), the entire process takes 14 weeks. There is no need for time-consuming media and process optimization, or scalability studies. “From DNA to GMP cell bank, all of your drug development needs are met by a single vendor,” apprises Cappia.

Optimizing Cell Line Development

The ICH guidelines make it clear that developers need to fully understand their molecules through a series of bioanalytical analyses to characterize their new biologics structural and physicochemical properties, biological activity, and immunological properties. To that end, assays to characterize the potential drug must be developed to a high standard which adds time

to the development program. Many of these assays require specialized analytical equipment and expertise. In particular, cell-based bioassays are challenging to develop due to their inherent complexity. They are, however, a necessary component within the analytical package throughout the development program and, when utilized to assess potency, a critical assay within the lot release package requiring full validation and ongoing maintenance.

Sartorius has developed a suite of ready-to-use analytical and platform assays for complex cell-based testing. Their goal is to support a customer’s development at speed and reduce the risk with late-phase analytical assay development avoiding costly delays to programs. In addition, for new biologics, the team has developed ready-to-use, pre-qualified assay panels for key biosimilar targets. “For biosimilar developers keeping development costs down is critical. Our assay packages are ready-to-use with no development required, added to which they are extensively qualified with the reference medicinal product,” adds Cappia.

Partnering with Sartorius, life science companies can benefit from the unique predictable performance of their CHO media, protein expression, and testing platform. They help simplify the work and accelerate the timeline to clinical production. “Customers provide us the sequence for their gene of interest and, in less than four months, they receive a CHO Research Cell Bank producing five to eight grams per liter of their protein. Six months later, we provide a fully characterized Master Cell Bank (MCB) for their clinical production,” reveals Cappia. Customers also benefit from upstream process design that is directly scalable to a 2,000-liter Biostat® STR Bioreactor and facilitates their scale-up to clinical production.

Furthermore, companies can streamline early-stage process development activities via Sartorius’ biopharmaceutical manufacturing services by leveraging the expertise and experience Sartorius has acquired over many years while establishing biomanufacturing processes for clients. The company also expedites

the engineering of single-use and hybrid processes for scale-up during late-stage activities using process templates that reduce design costs and increase standardization.

Moreover, the company’s focus on drug discovery and cell biology is supported by innovative solutions for cell analysis, liquid handling, weighing applications, sample preparation, laboratory water, and related services.

A Trusted Partner

A testament to the expertise and efficacy provided by Sartorius is its success story with a customer who had difficulty expressing cytokines. With limited resources, the customer chose to rely on Sartorius’ capabilities and technical expertise for their cell line development project.



The Sartorius team was able to achieve very high productivity. Additionally, once the Master Cell Bank was characterized and manufactured, the Sartorius team developed an optimized upstream process that was quickly and easily transferred to the customer’s CDMO of choice. Through the entire engagement, a dedicated Sartorius client manager handled the coordination and

communication necessary to ensure no delays in the schedule or project timeline, which further simplified the customer’s experience.

Today, aided by valuable partnerships and many such success stories, Sartorius has established a strong presence in the biotechnology landscape. Their stellar performance and competency in accelerating cell line development is supported by its committed team with over 15 years of experience and expertise in assay development and has conducted over 150 CLD projects. “Multiple biosimilars development have been approved by EMA and/or FDA. We also have highly skilled and qualified technical support,” adds Cappia.

More recently, Sartorius opened a cell culture technology center and testing facility in Ulm, Germany, and has continued plans to expand globally to support biomanufacturing by simplifying and accelerating its customer’s path to clinical production. [LS](#)