Case study

Sorvall™ BIOS 16 Bioprocessing Centrifuge doubles biotech lab efficiency overnight

Company

A leading biotechnology company.

Background

The prevalence of devastating neurological diseases and the societal burden are growing as a result of an aging population across the globe. Today neurological diseases are the leading cause of disability and second leading cause of death worldwide.

One of the most persistent challenges for the biotech industry is a lengthy development time, where companies invest heavily in R&D in search of potential products to help patients. Any streamlined processes or improved efficiency has a significant impact on the financial investment of drug development — as well as the length of time until new drug therapies are available to patients suffering from these diseases.

One of the longest established independent biotechnology companies in the world is bringing new scientific understanding to diseases for which there are no adequate treatments. The company has pioneered the discovery, development and delivery of innovative neuroscience therapies for people living with serious neurological and neurodegenerative diseases, as well as related therapeutic adjacencies.



Thermo Scientific™ Sorvall™ BIOS 16 Centrifuge

Investing in new laboratory technology to minimize development time and material demands enables the company to advance more drug candidates into clinical trials faster to address unmet medical needs. It has recently adopted the Thermo Scientific™ Sorvall™ BIOS 16 Centrifuge for cell culture clarification in its Technical Development department. The Sorvall BIOS 16 Centrifuge offered the department immediate throughput increases — doubling their efficiency overnight, allowing better use of staff time, and improving functionality and reporting.



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Industry challenges

The company has built research platforms to support key drug modalities, including small molecules, biologics, antisense oligonucleotides and gene therapy. Therapeutic proteins — also referred to as biologics — differ dramatically from traditional small molecule drugs. Biologics (which include monoclonal antibodies, growth factors, cytokines, enzymes and many other types of proteins) are often as much as a thousand times the size of small molecule drugs and are manufactured in living cells rather than through chemical synthesis.

Although this type of drug is much more complicated to make and characterize, using biologics allows biotech scientists to attack serious disease in ways that might not be possible with other technologies. Antibodies and antibody-like proteins have become the most common type of biologic because of the exquisite specificity and long duration of action of this type of molecule.

The company's Technical Development department includes more than 100 protein development and another 10 or more chromatography development scientists and engineers who are responsible for the development of biotechnological processes for various therapeutic proteins to support its clinical and commercial manufacturing.

A scientist in the Technical Development department explains: "Usually, we receive experimental samples from the cell culture group or our various manufacturing facilities, which we further purify and submit for analysis to our Analytical Development group. Much of this work is part of the general development roadmap where we identify studies or activities required for early development and late-stage characterization. We rely on platform unit operations, which we have modeled in a small-scale lab environment. Our small-scale models are verified and represent manufacturing processes very closely. We also support manufacturing deviations when necessary due to resource allocation or capability requirements."

The workflows of the Technical Development department play a critical role in the development of multiple aspects of protein purification — including column chromatography, filtration, membrane separations, validation of viral and contaminant clearance, scale-up, technology transfer



Thermo Scientific™ 2000 mL BIOS swinging bucket rotor

and process validation. Data and reports generated by this process also support activities such as process characterization, process scale-up, technology transfer, process validation and regulatory filings.

As such, any streamlined processes or improved efficiencies in the Technical Development department affect multiple areas of the company's drug development processes.

Among their numerous responsibilities, the biotech scientist identifies opportunities for making process improvements, evaluates new technologies, and surveys the literature for potential ideas that may benefit process development.

He explains the impact of process development efficiency: "A platform process is possible to the high degree of sequence homology across many of the humanized mAbs, which greatly enhances process development efficiency. However, in most instances there is still need for molecule-specific optimization to maximize productivity and yield or to achieve a specific product quality attribute. We can't get rid of process development — there will likely always be some process development activities — but if the development time, material demands and other resources can be minimized, more drug candidates can be advanced into clinical trials faster to address unmet medical needs."

With the goal of improving throughput in its laboratories, the biotech company's Technical Development department adopted the Thermo Scientific Sorvall BIOS 16 Centrifuge in May 2019 for cell culture clarification in R&D activity.

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The solution

The Sorvall BIOS 16 Centrifuge is designed for high-quality harvesting, separation and purification in the bioprocessing methods that require run-to-run reproducibility and traceability. With an enhanced capacity of up to 16 L of sample volume, the Sorvall BIOS 16 Centrifuge is designed for high-throughput bioprocessing — helping biotech companies maximize productivity and efficiency.

The Sorvall BIOS 16 model is available with a choice of four Thermo Scientific rotors, which in this instance provided flexibility for a 1 L or 2 L bottle capacity to improve existing workflows. The Sorvall BIOS 16 Centrifuge's ability to accommodate 2 L bottles was a major advantage for the company. For example, the company's cell samples are grown in 2 L Finesse bioreactors, and prior to adopting the Sorvall BIOS 16 Centrifuge, scientists were having to use 1 L bottles.

Thermo Fisher Scientific's customer describes the use of the Sorvall BIOS 16 Centrifuge in the Technical Development department: "Our group is focused around chromatography and non-chromatographic mAb capture and purification technologies. We use the Sorvall BIOS 16 Centrifuge as an efficient way to support our development activities. We needed the increased capacity in the range that the Sorvall BIOS 16 Centrifuge provided, as we are constantly processing >10 L."

Why Thermo Scientific Sorvall BIOS 16 centrifuge?

The biotech company's positive prior experience with the Thermo Scientific™ Sorvall™ LYNX Centrifuge was a factor in the adoption of the Sorvall BIOS 16 system. In addition to increased capacity, the Technical Development department also benefits from the Sorvall BIOS 16 Centrifuge's reliability, efficiency and safety features, such as:

- Compact design, automatic front-to-back centrifuge door opening and closing capabilities with Auto-Door technology, and Auto-Lid rotor lid opening technology and storage to help optimize everyday centrifuge use
- A standard power supply that eliminates the need for expensive hardwiring
- Latest global safety standards
- Energy savings with Thermo Scientific[™] Eco-Spin[™] windshielded rotors

- The Centri-Touch interface with a bright, highly visible and glove-friendly display that simplifies run setup, and is further enhanced with access controls such as user login with password protection
- Real-time run monitoring and control with the Thermo Scientific[™] Centri-Vue[™] application
- Assistance with GMP/GLP compliance through data logging and easy-to-use Thermo Scientific[™] Centri-Log[™] Plus data collection software.

The rotor, buckets and bottles are provided as a set, and they have been engineered to simplify operation of the centrifuge while maximizing productivity. The laboratory chooses from four Thermo Scientific rotors and swinging bucket sets:

- 6 x 1000 mL swinging bucket rotor
- 8 x 1000 mL swinging bucket rotor
- 6 x 2000 mL swinging bucket rotor
- 8 x 2000 mL swinging bucket rotor.

The biotech scientist describes why the Sorvall BIOS 16 Centrifuge was particularly suitable to deal with the need for high-volume capacity: "Previously we were separating samples from 2 L bioreactors with 1 L centrifuge bottles. The multiple spin cycles were time consuming and prone to sample loss and increased human error in identifying samples correctly. The Sorvall BIOS 16 Centrifuge now enables us to do high-throughput processing of small-scale experimental arms to be processed/analyzed separately."



Thermo Scientific™ 2 L Bottles

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Working with Thermo Fisher

Thermo Fisher has a long-standing relationship with the biotech company and deploys an on-site laboratory support group dedicated to equipment lifecycle management and scientific services for the company's lab community, providing employees with support from more specialized resources. The company's laboratories have invested in a lot of Thermo Fisher general laboratory equipment such as bench-top centrifuges and incubators, among many.

The biotech scientist explains the relationship between Thermo Fisher's laboratory support group and the Technical Development laboratory personnel: "The support group will take care of all hardware and software tickets when equipment needs corrective maintenance by creating work orders keeping historical data and documentation. They were crucial coordinating the delivery and installation of the Sorvall BIOS 16 Centrifuge in our lab. They're a great technical team, and the centrifuge installation was blissful. Their very friendly staff maintains our other pieces of equipment too. They are always knowledgeable and eager to discuss technical topics."

Conclusion

Thermo Scientific Sorvall BIOS 16 Centrifuge enables streamlined completion of high-quality harvesting, separation and purification bioprocessing methods that require run-to-run reproducibility and traceability. As centrifuges are an essential part of any bioprocessing laboratory, the improved productivity and efficiency extend far beyond the Technical Development laboratories to other departments within the biotech company working on these drug development projects.

With the Sorvall BIOS 16 system implementation complete, the impact these changes have had in the Technical Development department, as well as on the entire organization, have become clear.

The customer sees the big-picture benefits of increased productivity and efficiency, and they plan to continue exploring opportunities for making improvements to benefit process development.

He concludes: "We're always looking for more streamlined lab processes with high-throughput capabilities and reliability. It affects the bigger picture — our dedication to delivering processes and products for our patients in a proactive manner through innovative science and a culture of collaboration."

Partnering with Thermo Fisher Scientific

Thermo Fisher Scientific is the leader in laboratory equipment, software and related services. We're proud to provide providing enterprise-wide, multi-laboratory solutions that have become the corporate standard at leading organizations. Our laboratory equipment is found at many of the world's leading biotechnology companies so to support our ever-growing global customers, we also provide implementation, training, maintenance and support from the industry's largest worldwide laboratory services network.

With our continued mission of enabling our customers to make the world healthier, cleaner and safer, the Thermo Scientific Sorvall BIOS 16 Centrifuge is just one of the many examples of our continual dedication in listening to our customers and designing products for a better performance and efficiency. So, with an enhanced capacity up to 16 L of sample volume, a compact footprint with innovative features and capabilities, the Sorvall BIOS 16 Centrifuge is designed for high quality harvesting, separation and purification within the bioprocessing methods that require run-to-run reproducibility and traceability. So, while the customer continues their steps in improving overall bioprocessing processes, Thermo Fisher Scientific too will continue improving its products to assist them, and customers like them, on their quest.



