Clean Cells doubles capacity with opening of new production suites

Clean Cells increases number of suites from five to nine, to meet growing demand for production and characterization of cell and virus banks. New facility opened in January 2023

Montaigu-Vendée, near Nantes, France, November 27, 2023 – Clean Cells, part of the Clean Biologics group, a provider of biopharmaceutical product quality control services and manufacturer of starting materials, today announces the launch of operations in its new production suites, located in the new facility opened in January 2023. These suites almost double Clean Cells' portfolio of Good Manufacturing Practice (GMP) facilities. The company now has nine GMP-grade BSL2[1] laboratories, in addition to its non GMP-grade and BSL3 laboratories. With a total production area of 638 m^2, the new facilities create a twofold increase in the company's total capacity for the production and characterization of cell and virus banks.

By increasing its production capacity for starting materials, Clean Cells aims to offer its customers greater flexibility and faster project turnaround times. Cell and virus banks are the first step in any bioproduction process. They play an essential role in the development of production processes, by ensuring the safety and stability of the biological products through robust testing procedures. They also have a significant impact on the success of biopharmaceutical production projects. Thanks to its comprehensive range of services, Clean Cells can provide its customers with fast access to the biological materials they need, which, in turn, allows them to fast track their production projects. All this ultimately ensures that novel treatments reach patients sooner.

"We are delighted to launch operations in our BSL2 production suites. These new facilities will enable us to respond better to the growing demand from our customers, while at the same time delivering the agility and flexibility that our partners have come to expect from us," said Lucy Thulot, head of production at Clean Cells. "Our new equipment allows us to offer our biopharmaceutical customers, biotechnology companies, CDMOs and CROs a service that is both reliable and customizable. Our full service offering means we can meet their requirements at every stage of a project, from the production of cell and virus banks through to full characterization. We offer a reliable and agile one-stop-shop; that gives us a real competitive advantage."

By offering a complete project package that extends from production through to storage, Clean Cells can support its partners at every stage in the development of their biopharmaceutical products. The Clean Cells teams can assist from research right through to the production of fully characterized GMP-grade cell and virus banks for use in the pharmaceutical production of vaccines, therapeutic antibodies and gene therapy, as well as for other bioprocesses and biopharmaceutical applications.

The company's new production suites are subject to continuous environmental and equipment monitoring to ensure compliance with both GMP and other regulatory requirements in force in Europe and the US, notably those stipulated by the EMA and FDA. Its facilities comprise:

- 365 m² GMP-grade zone (compared to 185 m² at the old premises) housing production units (20 m² per unit), dressing areas, access corridors and airlocks

[1] Laboratories with biosafety level 2, also known as P2 laboratories

- 73 m² non-GMP or feasibility laboratory space (compared to 20 m² at the old premises)
- 140 m² storage area (compared to 85 m² at the old premises), which can house over 40 cryo-containers with an autofill function
- The units are also fitted with equipment such as cell counters (ViCell/NucléoCounter), static and shaking incubators, and WAVE bioreactors

"With over two decades of experience in cell and virus production, Clean Cells leverages its new cutting-edge facilities, comprehensive characterization services and secure long-term storage solutions to position itself as a trusted partner in the production and characterization of integrated cell and virus banks," said François Pedelaborde, head of sales at Clean Cells. "Clean Cells also acts as an accelerator for CDMOs and supports these companies in expanding their activities. Through this work, it ensures that its GMP-grade suites are used exclusively for high added-value products."

Alongside production at its new GMP-grade suites, Clean Cells also plans to expand its business activity in new areas, such as clonal selection, so that it can support its customers even earlier in the pharmaceutical development process.

The company plans to recruit additional staff to support its growth in cell and virus bank activities.

About Clean Cells
Clean Cells is a subsidiary of Clean Biologics. It offers (i) quality control and biological safety tests for biopharmaceutical products to assist in regulatory compliance, (ii) production of cell banks and GMP-grade BSL2 virus seed stock, (iii) supply of secure storage for these products and (iv) development and validation of bespoke analysis tools. The company was created in 2000 when three biologists from the Aventis–Institut de France Foundation sought to offer innocuity testing for biopharmaceuticals. Clean Cells is now one of the largest European companies within this sector. Its strong customer focus and sizable product catalog (which expands annually) have made it a key player in the development of novel treatments and in personalized medicine. Clean Cells also stands out for its ability to react and adapt to its customers' needs and the transparency of its production and quality control processes.
Based near Nantes, in Western France, Clean Cells employs 133 staff.
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