

Spain's 53Biologics announces over €2m expansion to tackle high-demand stabilisation of next-gen therapeutics

New freeze-drying (lyophilisation) capability at Boecillo site, strengthens 53Biologics' position as a key player in global biomanufacturing.

Boecillo, 1 de octubre de 2026

European contract development and manufacturing organisation (CDMO), 53Biologics, is announcing an over €2 million infrastructure expansion at its Boecillo site in Spain, installing cutting-edge freeze-drying infrastructure (lyophilisation) to support secure handling of next generation therapeutics. The investment marks a significant step forward for the company, which continues to scale to fulfil a growing international pipeline, as advancements in biologics mean that there is high demand for fill & finish technologies with the capability to safely and efficiently handle highly sensitive molecules.

The new 1.8 m² lyophilisation system at 53Biologics' Boecillo cGMP facility, directly addresses an urgent sector need for stabilisation technologies that preserve shelf-life, without degrading the active compounds found in today's therapeutics. In practice, this means an expansion in Boecillo's fill & finish capacity of up to around 10,000 2R vials per batch; bringing the new manufacturing step in house for biologic medicines that are difficult to keep stable in liquid form.

An end-to-end solutions provider for pharmaceutical and biotech companies, 53Biologics seamlessly supports international biopharma partners from early-stage discovery to global commercial launch. The equipment has already been used to produce preclinical batches, for development work before human trials, and the company expects the new service to be fully operational for cGMP manufacturing by early 2027.

Pablo Gutiérrez, CEO of 53Biologics, said: "Adding lyophilisation to our in-house fill & finish capabilities is an important step in the evolution of 53Biologics' service offering. "We are investing in the areas that matter most to our customers, ensuring that we can confidently meet the industry's changing clinical and regulatory demands when it comes to the next generation of drug manufacturing. Scaling our operations in this way, allows our customers to access a broader range of manufacturing solutions through a single partner, reducing complexity and facilitating the transition from development to clinical manufacturing."

The new freeze-drying capacity is part of a process of gradual expansion of 53Biologics' filling capacities over recent years, during which the company has

introduced equipment and technologies such as a Grade A isolator (ISO 5), closed-system filling of bottles and bags (Grade C, ISO 8), semi-automatic filling and crimping, labelling and secondary packaging, as well as the analytical laboratories that support these operations.

A one-stop-shop approach

The expansion is part of 53Biologics' broader commitment to providing customers with a one-stop-shop solution for their pharmaceutical development and manufacturing needs.

In addition to its in-house capabilities, 53Biologics works with a network of specialised partners to provide fill & finish support for specific requirements or technologies that may not be available within its own facility. This approach allows the company to extend its service offering while ensuring that projects with technical, process or presentation requirements can still be managed through a single point of contact.

"Being a one-stop-shop does not mean that every technology has to be physically in-house. It means being able to provide the right solution for each project," added Mr Gutiérrez. "Where a specific fill & finish requirement falls outside our internal capabilities, we can leverage specialised partners, allowing us to maintain a flexible and customer-focused approach."

New lyophilisation capability

Freeze-drying, or lyophilisation, removes water from a frozen formulation under vacuum. With a suitable formulation and process, it can protect sensitive biologics and extend shelf life. For clinical programmes supplying several sites, improved stability can make storage, transport and handling easier to manage.

Because modern drug pipelines are heavily weighted toward these complex, temperature-labile molecules, it is estimated that over 60% of biologics on the market would not be viable without lyophilisation. The addition of lyophilisation significantly broadens the range of drug products that 53Biologics can support. The company has a Telstar Lyomonic 2 ST lyophiliser, with 1.8 m² of shelf capacity, enabling the processing of both liquid and lyophilised presentations.

The fill & finish platform also supports closed systems up hundreds of litres and vial formats ranging from 2R to 30R, with batch sizes tailored to the requirements of orphan drugs and Phase I–III clinical programmes.

53Biologics' integrated offering also includes release and GMP storage from -80°C to room temperature, as well as labelling and secondary packaging. With the addition of lyophilisation, 53Biologics continues to expand its capabilities to support plasmid DNA and recombinant proteins, across clinical development stages and beyond.

About 53Biologics

53Biologics is an end-to-end biologics CDMO built to keep progress moving. By combining scientific expertise, integrated in-house capabilities and a collaborative way of working, they enable confident decision-making as biologics programs evolve. They support clients' biologics from early development to commercialisation. With USP and DSP development, GMP manufacturing, quality control and fill & finish connected under one roof, they reduce handoffs, protect continuity and help clients grow without disruption.

Media contact

Patricia De La Madrid, Business Development and Marketing Manager

pdelamadrid@53Biologics.com