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Germfree launches biopharmaceutical isolator for cell and gene therapy workflows

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The new Grade A aseptic isolator combines fully welded stainless-steel construction with configurable process features for small-scale CGT manufacturing, quality control and filling operations.

Germfree, a full-lifecycle engineering and manufacturing partner for mission-critical environments across life sciences, healthcare and biocontainment, has launched a new aseptic biopharmaceutical isolator designed to provide a flexible, modular Grade A processing environment for cell and gene therapy applications.

The new technology, made and serviced in the U.S., will enable CGT developers to bolster their contamination control strategy around open steps in manufacturing workflows.

Germfree is bringing the new aseptic isolator to market in response to rising customer demand, especially for their critical role in the manufacture of CGTs.

The introduction of the new platform aligns with Germfree's mission to create environments that serve the CGT industry.

Until now, the company has been building bespoke aseptic isolators on request as a service for customers seeking an alternative to off-the-shelf options.

The aseptic isolator's fully welded, complete 316 stainless-steel construction is designed to support frequent cleaning and decontamination.

Configurable shelving, racks and penetration locations allow the system to be adapted to individual workflows while preserving the cost efficiency and lead times of a standardised platform.

Additionally, it is manufactured in the U.S. and serviced with a U.S.-based team, helping to secure supply chains that underpin rapid CGT scalability.

“This product line reflects Germfree’s growth as a total solutions company, building not just your cleanroom but every critical environment you need for your process,” said Forrest Brown, Chief Strategy and Services Officer at Germfree.

“We’re closing the gap between a premium-finish custom system and an off-the-shelf product, giving customers a robust, configurable isolator without the cost and complexity typically associated with highly customized equipment. Adding an expert team of US-based CQV and Service Technicians on top of this makes the Germfree aseptic isolator a great option for biopharma companies to consider.”

Though the aseptic isolator is appropriate for multiple sectors, it is particularly well suited for small-scale processes, QC workflows and semi-automated benchtop or manual filling operations.

“Patient-derived cell therapy manufacturing is the definition of a ‘critical process,’ given that each individual batch represents a single patient dose – and sometimes, the last one they can get,” said Brandon Serle, Value Stream Manager at Germfree.

“Our aseptic isolator is small enough for straightforward installation in a variety of cleanroom spaces, even with tight doorways and low ceiling clearances. It is configurable to the needs of different processes, and easily scalable as developers move into clinical trials and advance towards commercial manufacturing.”

Germfree anticipates commercial availability as soon as Q1 2027.