

BioTechnique Expands Aseptic Filling & Lyophilization with Flexible Formats and Advanced Cycle Development

BioTechnique broadens capabilities with end-to-end fill-finish, advanced lyophilization development, and integrated multi-temperature 3PL support.

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BioTechnique®, a full-service CRDMO, announced expanded aseptic fill-finish and [lyophilization](#) capabilities supporting pharmaceutical programs from development through commercial supply. These services are integrated with BioTechnique's third-party logistics and storage platform, offering controlled warehousing across ambient (15–25°C), refrigerated (2–8°C), frozen (–20°C), ultra-low (–80°C), and cryogenic (–190°C) conditions.



Automated Optima fill-finish line at BioTechnique, designed for high-precision vial filling with direct transfer into lyophilization.

The platform now supports vials (2R–100H), prefilled syringes, cartridges, and bags, with end-to-end processes including formulation, compounding, sterile filtration, filling, stoppering, optional lyophilization, capping, QC testing, 100% visual inspection, labeling, and packaging—powered by the ACE® cloud eQMS for real time documentation.

Integrated Lyophilization Expertise

BioTechnique's lyophilization cycle development services cover formulation support, cycle design/optimization, scale up, validation/QA, and final product testing, enabling robust, inspection ready processes that protect product integrity over shelf life. The company's lyo leadership includes collaboration with Dr. Serguei Tchessalov, a globally recognized SME in freeze drying science and tech transfer, strengthening client outcomes from early development through commercialization.

Highlights

- Filling formats: Vials (2R–100H), syringes, cartridges, and bags; aseptic line design for precision and reliability.

- End-to-end process: Formulation □ compounding □ sterile filtration □ filling □ stoppering □ optional lyo □ capping □ visual inspection □ quality control testing □ labeling/packaging.

- Lyophilization product cycle development: Formulation, optimization, scaleup/transfer, validation & QA, final product testing.

- Integrated quality: ACE® eQMS for controlled documentation, real time tracking, and audit ready reporting.

- CRDMO model: In house development, filling, lyo, QC, storage, and logistics—fewer handoffs, faster timelines.

3PL Services Supporting the fill/lyo lifecycle:

- Inventory Monitoring: Fully electronic, real-time digital inventory and temperature monitoring with optional custom access.

- Multi-temperature storage: Ambient (15–25°C), refrigerated (2–8°C), frozen (–20°C), ultra-low (–80°C), cryogenic (–190°C) for DS/DP, excipients, samples, and consumables.



BioTechnique's Flexicon filling line enabling precise, sterile fill-finish production for clinical and commercial programs.



The BioTechnique facility encompasses 268,000 sq ft and sits on 39 acres, with opportunities for future expansion. The facility is equipped with 9 cleanroom suits and advanced manufacturing capabilities.

- Freight Options: GDP-aligned shipping with real-time tracking and documented chain of custody for temperature-sensitive freight.

About BioTechnique®

BioTechnique, a division of PSC Biotech Corporation, is a full-service Contract Research, Development, and Manufacturing Organization (CRDMO) specializing in cytotoxic and therapeutic sterile injectable fill-finish services. BioTechnique provides comprehensive support from investigation and clinical stages through commercialization, batch sizes both large and small.

BioTechnique operates a state-of-the-art facility designed to handle a diverse range of pharmaceutical products, including cytotoxic and highly potent compounds, therapeutics, antibody-drug conjugates (ADCs), monoclonal antibodies, suspensions, and vaccines. Supported by an environmentally controlled warehouse and adaptable manufacturing systems, BioTechnique is committed to delivering high-quality fill-finish solutions.

For more information on BioTechnique's capabilities, visit www.biotechnique.com.

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