

BioTechnique Announces Successful DEA Licensing

New license expands BioTechnique's capabilities in controlled substance manufacturing and secure pharmaceutical development.

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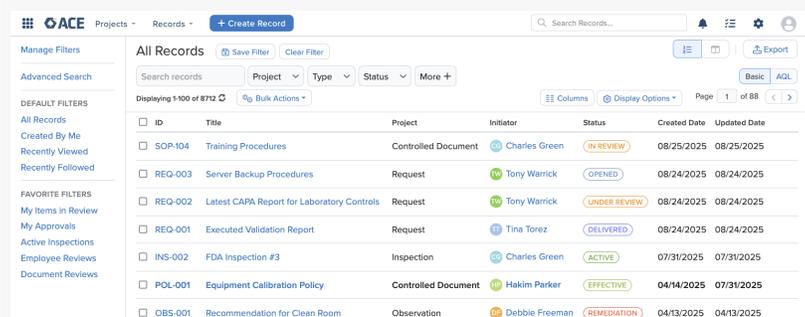
BioTechnique is pleased to announce the successful issuance of its Drug Enforcement Administration (DEA) manufacturing and handling license, marking a significant advancement in the organization's pharmaceutical development capabilities. This milestone reflects BioTechnique's rigorous scientific standards, operational excellence, and readiness to support clients working with controlled substances.

The licensing process required the development of DEA-compliant standard operating procedures (SOPs) and documentation, followed by extensive review and alignment with BioTechnique's internal quality systems. The team executed thorough transcription and verification of all regulatory citations, ensured precise tailoring of each SOP to controlled-substance workflows, and conducted detailed digital workflow planning for future-state documentation and mass balance tracking.

BioTechnique also completed major facility and security upgrades, including installation and



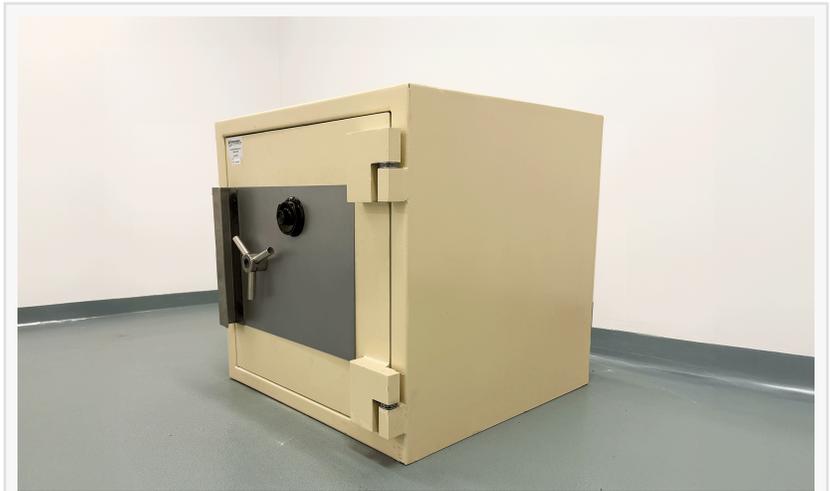
The BioTechnique facility encompasses 268,000 sq ft and sits on 39 acres, with opportunities for future expansion. The facility is equipped with 9 cleanroom suits and advanced manufacturing capabilities.



ID	Title	Project	Initiator	Status	Created Date	Updated Date
SOP-104	Training Procedures	Controlled Document	Charles Green	IN REVIEW	08/25/2025	08/25/2025
REQ-003	Server Backup Procedures	Request	Tony Warrick	OPENED	08/24/2025	08/24/2025
REQ-002	Latest CAPA Report for Laboratory Controls	Request	Tony Warrick	UNDER REVIEW	08/24/2025	08/24/2025
REQ-001	Executed Validation Report	Request	Tina Torez	DELIVERED	08/24/2025	08/24/2025
INS-002	FDA Inspection #3	Inspection	Charles Green	ACTIVE	07/31/2025	07/31/2025
POL-001	Equipment Calibration Policy	Controlled Document	Hakim Parker	EFFECTIVE	04/14/2025	07/31/2025
OBS-001	Recommendation for Clean Room	Observation	Debbie Freeman	REMEDIATION	04/13/2025	04/13/2025

Orders and inventory are tracked using ACE, PSC Software's AI-Powered quality management system (QMS) and workflow automation platform.

verification of surveillance, alarm, and physical security systems, along with completion of all required employee background checks. A pre-inspection readiness meeting with the DEA inspector confirmed expectations and inspection scope, followed by a successful preliminary documentation assessment. The comprehensive onsite inspection evaluated facility controls, documentation integrity, and controlled-substance handling processes.



Completion of major facility and security upgrades were a part of BioTechnique's process for DEA approval.

The licensing effort progressed from initial AI-assisted SOP generation in June 2025 to license issuance in December 2025. The use of advanced AI tools significantly accelerated documentation development, allowing the team to concentrate on validation, facility readiness, and compliance strategy.

With the DEA license now in place, BioTechnique expands its ability to support clients requiring controlled-substance handling, high-potency compound processing, and secure, compliant manufacturing environments. This achievement reinforces the organization's commitment to innovation, regulatory excellence, and the advancement of complex pharmaceutical therapies.

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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