Summary of capabilities

Plainville, MA, US

Viral vector development and manufacturing facility

Overview

Our state-of-the-art Plainville facility is designed to provide comprehensive viral vector services, from process development to commercial manufacturing. With unparalleled capacity and capabilities, we are fully equipped to meet evolving market demands.

Spanning 290,000 square feet, our site excels in the manufacturing of viral vectors for both clinical and commercial applications. Under one roof, this facility provides process and analytical development, characterization, validation, clinical and commercial manufacturing, as well as fill-finish services. This consolidation eliminates the need for costly and time-consuming facility-to-facility technology transfers.

In our ongoing mission to meet our clients' ever-evolving needs, our facility has been strategically designed to foster expansion and effortlessly adapt to future growth, with a capacity extending up to 400,000 square feet. Learn more about our site below.

Facility facts	
Capacity:	290,000 sq. ft. development and manufacturing capacity
Workforce:	260+ onsite employees
Contact info:	5 Commerce Blvd Plainville, MA, 02762
Facility highlights:	• Flexible design supports both suspension (up to 2,000 L stirred-tank bioreactors) and adherent (including iCELLis 500) processes. • Bioprocess sciences lab equipped for development, characterization, and scale-up to 500 L. • Digital innovation in facility design and operation including automation, augmented/virtual reality tools, and technology supporting environmental sustainability. • 11 cGMP suites dedicated to viral vector production and purification. • Two cGMP fill-finish suites capable of producing up to 5,000 vials of final drug product. • Dedicated manufacturing support areas for solution and component preparation. • Quality control labs to meet onsite bioanalytical testing needs. • Onsite warehouse to streamline storage and logistics.

Viral vector services capabilities overview

Facility offering	Specifications
Process development and pilot lab	• Dedicated support for each product throughout its manufacturing lifecycle from the onsite bioprocess services team. • Bioreactor capabilities ranging from ambr15, ambr250, and 2L for DOE studies, to 50 L, 250 L, and 500 L for scale-up and preclinical production. • Clarification filters sized and optimized for maximum efficiency. • Tangential Flow Filtration (TFF) used for concentration and buffer exchange processes. • Chromatography studies focused on optimizing Affinity and Ion Exchange Chromatography (IEX). • Centrifugal separations employed for efficient processing across various applications. • Automated liquid handling systems used for small-scale downstream screening studies.
Analytical services	• Continuous support and expertise in analytical methods provided by the onsite analytical development team. • Focus on establishing and refining assays that accurately measure product strength, purity, safety, and quality. • Strong partnerships with a wide range of externally qualified vendors, ensuring reliable and precise outsourced assays for specialized testing needs.
Aseptic fill-finish services	• Precision filling ensured by automated filling within a Grade A isolator for a sterile environment. • Certified capacity to handle batch sizes up to 5,000 vials ranging from 0.25 to 10 ml, with flexibility for custom configurations. • Comprehensive services for primary labeling and packaging available for all stages of production. • A cost-effective manual filling option available for budget-conscious preclinical supply needs.
Quality control labs	• Dedicated in-house quality control measures ensure consistent onsite QC. • Standardized compendial testing adheres to official guidelines. • Precise tests verify product identity through identity testing. • Trusted relationships with established outsourcing partners provide reliable testing services.
Process characterization	• Evaluation of raw materials and preliminary risk analysis ensure thorough initial assessments. • Validation of scale-down models for smaller-scale production testing. • Characterization studies utilize One-Factor-At-A-Time (OFAT) or Design of Experiments (DOE) methodologies. • Comprehensive documentation of findings and risk evaluations provided in summary and final risk assessment reports.
Clinical and commercial manufacturing	• Bioreactors ranging from 50L to 2,000L support scalable production, enabling batch scaling up to 4,000L. • Comprehensive regulatory support provided by our specialized viral vector services team.

Flexible equipment options to scale manufacturing processes

Platform	PD / Pre-clinical	Phase I-III / PPQ / commercial
Adherent	Flexible facility design	Flexible facility design
Suspension HEK293	15mL-500L	50L-2,000L
Suspension Sf9/Baculovirus	15mL-500L	50L-2,000L
Suspension other	15mL-500L	50L-2,000L
Perfusion	2L-500L	50L-2,000L
Drug product		
Fill-finish	Up to 5,000*	

*Larger batches available with qualification

Production platforms and processes

Vector type	Manufacturing modality*	
AAV	■ Adherent + suspension	■ Suspension + HSV
	■ Producer cell line + adherent	■ Suspension + baculovirus
Adenoviral	■ Adherent + suspension	
Herpesviral	■ Adherent + suspension	
Lentiviral	■ Packaging/producer cell line	
Retroviral	■ Packaging/producer cell line	■ Adherent + suspension
Key	■ Mammalian cells ■ Mammalian cells transient transfection ■ Mammalian cells infection ■ Insect cells	

*Additional manufacturing modalities also available; inquire for more information

For more detailed capabilities and capacity information please contact us.

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