Summary of capabilities

Plainville, Massachusetts

Facility facts:

Contact Info: 5 Commerce Blvd
Plainville, MA 02762
Tel: 781-325-1212

Unique offering:

- Our site location in Plainville, MA is a 290,000 sq. ft. facility with room for expansion
- Purpose-built for large-scale manufacturing
- Pilot lab (up to 2,000 L) accelerates transfer of approved products with continuous process improvement capabilities
- Digital innovation in facility design and operation including automation, augmented/virtual reality tools, and technology supporting environmental sustainability

Specialized capabilities:

- Viral vector-based manufacturing suite design: suite adjacencies to facilitate process segregation and inter-suite transfers
- 11 cGMP DS suites, 2 cGMP DP suites
- Full-service QC labs
- Pilot lab supports platform process development, process transfer, and scale up
- Centralized support services
- State-of-art digital manufacturing technology
- Infrastructure in place to support further expansions

Viral vector services capabilities overview:

Facility offering	Specifications	
Cell Culture Platforms	• Single-use/non-product contact equipment • Adherent and suspension culture • Depth and TFF for harvest and concentration • Common vector types	• HEK293, HEK293T, and Sf9 platform seed train and vector production processes • Customized transfection and infection parameters as necessary
Purification Platforms	• Single-use/non-product contact equipment • Depth and other filtration methods • TFF concentration and buffer exchange	• Chromatography: Affinity, SEC, IEX, HIC, etc. • Viral inactivation/clearance • Centrifugal separations (not recommended)
Analytical Assay and QC Capabilities	• Assay transfer (from FL or client) and establishment • Process establishment and engineering material testing • Process characterization testing support • Compendial assay verification, qualification, and validation	• QC DS and DP in-process and batch-release testing • cGMP stability studies • Reference standard qualification • Assay bridging and product comparability studies
Aseptic Fill and Finish Services	• Pre-fill formulation/compounding services • Optima Isolator and Filler – Grade A in Grade C suite • Fully automated, robotic-assisted filling and capping – up to 5000 vials • Standard pre-qualified vial configurations available	• 0.25-10 mL in 0.5-10 mL vials (Crystal Zenith®/glass) – option for 50R glass vials. • 100% IPC weight check • 100% visual inspection • Primary labelling and packaging • Validated shipper/shipping

* For detailed capabilities and capacity information please contact your Thermo Fisher Scientific representative.

Summary of capabilities

Production platforms and processes

ADENOVIRAL

Adherent + Suspension
Mammalian cells infection

AAV

Producer cell line + Ad	Adherent + Suspension	Suspension + HSV	Suspension + Baculovirus
Mammalian cells + infection	Mammalian cells transient transfection	Mammalian cells	Insect cells – infection

LENTIVIRAL

Packaging/ Producer cell line	Adherent + Suspension
Mammalian cells	Mammalian cells transient transfection

RETROVIRAL

Packaging/ Producer cell line	Adherent + Suspension
Mammalian cells	Mammalian cells transient transfection

HERPESVIRAL

Adherent + Suspension
Mammalian cells infection

For more detailed capabilities and capacity information please contact your Thermo Fisher Scientific representative.

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