

# GMP VIRAL VECTOR, GENE THERAPY AND VACCINE MANUFACTURING

**Put our GMP expertise to work for you.**

ABL has a long history of development and manufacturing of preclinical and clinical virus-based biologics. From 30 years of groundbreaking work with HIV to supporting the latest gene therapy technologies, ABL offers a comprehensive portfolio of services for the effective design, development, manufacturing and analytical testing of vaccine and virus vector products.

**Viral vectors, gene therapy, viral vaccines, oncolytics, and other immunotherapies**



ABL has produced breakthroughs in viral technologies since its inception including the isolation and characterization of the first human retroviruses (HTLV-I and HTLV-II), early research on human immunodeficiency virus (HIV-I) and its characterization as the etiology of AIDS, and the development of one of the first diagnostic HIV-1 blood tests. This expertise in virology has made ABL an industry leader in supporting the development and GMP manufacture of gene therapies, viral vaccines and other virus-based technologies for clients around the world.

ABL provides manufacturing and development services to support viral based products including; Master and Working Cell Banks (MCB/WCB), Master and Working Virus Seed Stocks (MVSS/WVSS), GMP drug substance manufacturing for viral vectors and vaccines, GMP aseptic filling of live virus in vials, and GMP QC testing.

We routinely work with our clients to advance their production process from the bench to a scalable, GMP-compliant process that will support IND studies.

Early activities can include adaptation of cell lines from adherent to suspension growth, plaque purification of virus seed, development and optimization of large-scale transient transfection manufacturing, optimization of upstream and downstream processes, and development of quality control methods for release and stability testing.

## Services

- Cell line development
- GMP master/working cell banks (MCB/WCB)
- GMP master/working virus seed stock (MVSS/WVSS)
- Transient transfection scale-up
- Upstream process development
- Downstream purification development
- Manufacture of toxicology material
- GMP manufacture of drug substance (DS)
- Aseptic fill/finish of final drug product (DP) in vials
- Analytical method development and qualification
- Release and stability testing

## Manufacturing Platforms

- Sartorius BIOSTAT® STR Single-Use Bioreactors
- Cell Factories, HYPERStacks and other similar cell stack technologies
- Roller Bottles
- Column Chromatography (AKTA Explorer, Pure and Process Systems)
- TFF – UF/DF
- Depth filtration
- Aseptic Fill/Finish
  - Up to 10,000 vials/batch

## Experience

- Adenovirus
- Adeno-associated virus (AAV)
- Influenza
- Poxviruses, i.e. Modified Vaccinia Ankara (MVA), Vaccinia
- Retroviruses, i.e. HIV, Lentivirus
- Rhabdovirus, i.e. Maraba virus (oncolytic virus), Vesicular stomatitis virus (VSV)
- Virus-like particles (VLPs)
- Lytic and non-lytic viruses
- Enveloped and non-enveloped viruses

## Quality Systems

ABL's U.S. location adheres to Good Manufacturing Practices (GMP) standards and is ISO 9001 accredited. ABL Europe's facility is regularly inspected by the French regulatory authorities (ANSM) and is a GMP licensed site for the manufacture of drug substance and aseptically prepared small volume liquid (drug product) viral products in accordance with EMA regulations.

ABL welcomes client audits and keeps a permanent audit record detailing each audit performed, results, corrective actions taken, and follow up verification of the final outcome.

Contact Us Today



## **GMP VACCINE & VIRAL VECTOR PRODUCTION**

Download ABL's brochure describing virus manufacturing services

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## **ABL EUROPE AND SILLAJEN EXPAND STRATEGIC MANUFACTURING COLLABORATION FOR ONCOLYTIC VIRUS THERAPIES**

SillaJen, Inc., a clinical-stage, biotherapeutics company focused on the development of oncolytic immunotherapy products for cancer, and ABL Europe, an ABL, Inc. company providing dedicated viral vector GMP services for gene therapy, oncolytic products and vaccines for all stages of clinical supply, have expanded their strategic manufacturing collaboration.

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## **ABL EUROPE'S GMP MANUFACTURING FACILITY FOR VIRAL VECTOR PRODUCTION: SARTORIUS STEDIM**

A new production facility for the GMP manufacture of viral vectors from non-adherent cell cultures is opening in Strasbourg, France.

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