

# The success of your novel product starts with ABL



Utilizing custom design and development to achieve regulatory approval

ABL's 30+ years of viral-vector development and GMP production accelerates your novel gene therapies, vaccines, oncolytics and immunotherapies.

With facilities in the U.S. and Europe, we offer a comprehensive portfolio of effective process design, development, GMP production and QC Analytical testing services.

#### SCIENTIFIC DEPTH

Experts positioned across the organization to ensure an efficient technology transfer process and analytical method development.

### **OPERATIONAL EXCELLENCE**

Viral vector specialists optimize, scale and manufacture regulatory compliant supply of your innovative product to clinic and market.

#### **SPEED**

Streamlined approach to support product design and execution from bench to market.

#### **FLEXIBILITY**

Nimble organization with the right resources in place on your team to meet time, scale and technical challenges.

Multiple global facilities, suites and production platforms, leverage your existing processes and accelerate your path to market.

**Experience producing numerous viral vectors for** 

GENE THERAPIES | VACCINES | ONCOLYTICS | IMMUNOTHERAPIES



















# Global Viral Vector Development, Production and Aseptic Fill/Finish

Specialists ready to execute

LET'S START THE DISCUSSION TODAY

## **Global GMP Production for Clinical and Pivotal Trials**

- U.S. and European compliant GMP facilities
- Single-use bioreactor systems (SUBs) up to 500L
- Fully integrated project management
- HYPERStack<sup>®</sup>, roller bottles, cell factories
- iCELLis® 500+ and iCELLis® Nano systems

# **Large Volume Commercial Capacity**



- Commercial scale 3 x 2,000L
- Phase III to commercial
- Viral vector focused facility
- On-site QC
- Three (3) suites with bioreactor seed trains: 50L, 200L, 500L, 2,000L

# **Live Virus Aseptic Fill/Finish**

- Fill volumes < 0.5 mL to 100 mL
- Small lots fills (> 200 vials) with low hold up volumes (25mL to 50mL)
- Qualified in Type 1 borosilicate glass and Crystal Zenith<sup>®</sup> vials
- 100% visual inspection and ADQ procedures.

# Comprehensive GMP Manufacturing Support



Process design



**Process feasibility** 



Upstream and/or downstream process development



Assay development and qualification



Master and working cell and virus banks



Scale-up and engineering run(s)



**GMP** bulk drug substance



**GMP** aseptic fill/finish



Analytical lot release testing



**ICH stability testing** 



Chemistry, manufacturing and controls support

# ABL, catalyst for your life changing innovations.

An Institut Mérieux Company

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