

## **Virotherapy Platforms**

Virotherapy has developed into an increasingly promising therapeutic approach for managing various human diseases, including cancer. Emerging virotherapy manufacturing strategies have sparked integrative advancements that have made it possible for more effective and therapeutically applicable treatment techniques. Such clinical virus manufacturing alternatives offer significant promise for pronounced therapeutic benefit when used in conjunction with an immune-based therapeutic approach.

There are three main commercial pharma manufacturing services in the rapidly developing field of virotherapy: anti-cancer [oncolytic viruses](#), viral vectors for [gene therapy](#) and viral immunotherapy in [vaccines](#). Vibalogics have industry-leading viral expertise in each.

## **Virotherapy – Areas of Expertise**

### **Oncolytic Virus**

*Specialists in the manufacture of replication-competent engineered and wild-type oncolytic viruses, with a track-record you can trust.*

Oncolytic viruses (OVs) are at the forefront of cancer treatment and have the potential to improve patient health dramatically. OVs need the specialized infrastructure and knowledge that Vibalogics can provide for development and manufacture as leading experts in oncolytic virus development and manufacture.

[\\*Find out more\\*](#)

### **Gene Therapy**

*Expertise across gene therapy vectors produced by transient, helper-virus, and stable producer cell lines minimizes time-to-market.*

Viral vector gene therapies are an exciting novel approach to treating serious conditions. However, they pose unique development and manufacturing challenges. Vibalogics' viral vector gene therapy manufacturing service is founded on our team's decades of experience in the field, dedicated to delivering results with a transparent and consultative approach.

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### **Vaccines**

*Scalable capacity and effective cost of goods management for vaccine product development and manufacture.*

The production of live viral vector vaccines is a difficult, multistep process. Without professional process development and production support, there is a high risk that unforeseen difficulties and

problems may arise, causing expensive delays. Vibalogics specialists work both efficiently and comprehensively to deliver industry-leading results, fast and cost-effectively.

[\\*Find out more\\*](#)

## **Manufacturing**

Virotherapy production is a complex, multi-stage process. We utilize over 15 years of experience with live viruses, such as herpes virus (HSV), adeno-associated virus (AAV) and cytomegalovirus (CMV), for manufacturing. Our industry-leading expertise in viral vector manufacturing and clinical supply services is vital, while our world-class virotherapy manufacturing facility means we can meet the rising demand for complex viral-based products.

There are three main branches in the field of virus manufacturing: [cell and virus banking](#), [drug substance & drug product](#), and [fill-finish](#). Vibalogics viral vector manufacturing experts specialize in all three service offerings.

### **Manufacturing – Areas of Expertise**

#### **Cell & Virus Banking**

*High-quality master and working cell and virus seed banking services provide critical starting materials for clinical-and-commercial supply.*

Vibalogics specialize in the manufacture of high-quality GMP and non-GMP cell and virus banks in multiple expansion formats and sizes, starting materials that are critical to your production process and overall timeline management. We achieve successful clinical manufacturing and release time after time for our clients requiring reliable starting material generation.

[\\*Find out more\\*](#)

#### **Drug Substance & Drug Product**

*Single-use production technologies, adherent and suspension processes, and non-aseptic or aseptic conditions from 50-2000L scale.*

For usage in a variety of regulatory environments around the world, Vibalogics has decades of experience producing live viruses and viral vectors under non-GMP and GMP virus manufacturing conditions, including oncolytic viruses, gene treatments, and vaccinations. A CDMO that comprehends the complexity of viral generation is necessary for the complex, multistage process of manufacturing viral therapies. Our preclinical-through-commercial virotherapy manufacturing services are second-to-none.

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#### **Fill-Finish**

*Liquid and lyophilized fillings for up to 40,000k vial batches in high-throughput fill lines by Bosch and Bausch+Ströbel.*

Our dedicated aseptic fill finish operators are available to provide a thorough and fast solution via semi-automated and high-throughput capabilities, whether it be as a part of your manufacturing

project or as a stand-alone service. From drug product to final container, our fully-integrated and seamless clinical supply services reduce risk, while our team has unmatched experience with drug product manufacture and fill, reducing costs and mitigating risk.

[\\*Find out more\\*](#)

## **Development**

Specializing in live viruses and viral vectors, we enable our customers to create and produce transformative oncolytic viruses, gene therapy, and vaccine solutions to enhance human health through stellar Process and Analytical Development. Vibalogics maximize the success of your virotherapy with a comprehensive drug substance development plan, beginning with process development and technical transfer feasibility, through cGMP production and validation.

Offering industry-leading pharmaceutical development services since 2002, Vibalogics has supported global clientele across clinical and regulatory arenas with comprehensive CDMO and pharma contract development services in both [Process Development](#) and [Analytical Development](#).

### **Development – Areas of Expertise**

#### **Process Development**

*Full drug development services are offered to transfer and mature processes for optimized scale, productivity, product profile and cost of goods.*

We provide reliable, scalable drug product development processes built on targeted technical transfer and development principles, as well as a consulting partnership that meets needs from the clinic to the marketplace. By providing upstream and downstream drug substance development services based on a systematic, stepwise methodology, Vibalogics offers phase-appropriate tech transfer and development services efficiently and effectively.

[\\*Find out more\\*](#)

#### **Analytical Development**

*Method development and transfer services span characterization and quality control assays for identity, purity, potency, titer, and safety.*

To demonstrate a well-characterized product and process, complete analytical method transfer and development for a variety of quantitative and qualitative test methods are required. Vibalogics offer assays to direct your development and release accurately and consistently. Vibalogics frequently transfers, develops, qualifies, and validates compendial analytical methods (EP/USP) for products that are used by customers as in-process controls or batch release and stability assays for quality control.

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