



# Aseptic Fill and Finish

Drug product manufacturing is the most critical phase of drug development. The Vivante team has over 15 years of experience filling viral products for Phase I-III clinical trials. We offer fill and finish as part of our comprehensive manufacturing programs that include bulk product manufacturing and we also offer fill and finish as a stand-alone service. We fill a wide range of product types for gene therapy and vaccine applications.

## Product Types Filled

- AAV vectors
- Adenoviral vectors
- Attenuated viruses
- Lentiviral vectors
- Retroviral vectors
- Live viruses

## QC and Stability Testing Capabilities

- Assay development
- Assay transfers
- Analytical and cell-based methods
- Raw material release testing
- Product release testing
- Potency Assays

## ICH Compliant Stability Storage Conditions

- 70°C ± 10°C
- 40°C ± 10°C
- 20°C ± 5°C
- 5°C ± 3°C
- 25°C ± 2°C with 60% RH ± 5% RH
- 40°C ± 2°C with 75% RH ± 5% RH



## Batch Sizes

100 vials- 25,000 vials

*Experience. Rapid Results.*

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# Vivante GMP Solutions

## *Expertise*

Vivante has more late-stage viral vector manufacturing experience than any other CMO.

## *Compliance*

Our team will apply our extensive regulatory and compliance experience to your project. We have successfully filed a BLA and two MAAs for a viral vector product.

## *Service*

Having had our own product development pipeline, we know how critical having the right CMO partner is. Our team cares as much about your project as you do, and it shows in the outstanding customer service we provide.

## Process Development

- Fully characterized production cell lines
- Cell line and culture process optimization
- Purification development
- Pre-clinical manufacturing
- Potency assay development
- Technology transfer
- Formulation development

## QC and Stability Testing

- Client assay transfer and validation
- Analytical and cell based methods
- Raw material release testing
- Product release testing
- ICH compliant stability testing

## cGMP Manufacturing

- Bulk production of Phase I-III clinical trial products
- Multiple production platforms for suspension and adherent cells
- Large scale ultra/diafiltration
- Large scale chromatographic purification
- Virus bank production and characterization
- Cell bank production and characterization

## QA and Regulatory Support

- Fully compliant quality systems
- Dedicated quality assurance team
- QP inspected facility
- IND and CMC preparation
- DMF on file with FDA

## Aseptic Fill and Finish

- Component preparation
- Compounding/formulation suites
- Class 100 filling suite
- Liquid and lyophilized products
- Labeling

## cGMP Storage & Materials Mgmt

- Secure facility
- FDA and ICH compliant storage
- 24-hour temperature monitoring
- Backup generators
- Inventory control
- Clinical trial distribution with temperature monitoring