



Quality Control and Stability

Nearly 20 years after their first use, no gene therapy product has received commercial approval in the United States. Few scientists have the late-stage regulatory compliance experience that the Vivante team offers. We have successfully produced and released over 60 batches for worldwide clinical trials, including product for two Phase III clinical trials and a consistency series for regulatory approval filings and in preparation for commercial launch, and we understand the complexities and the high level of scrutiny associated with viral-based products. Our clients value our extensive industry experience in product characterization and release and regulatory submission support.

QC and Stability Testing Capabilities

- Assay development
- Assay transfers
- Analytical and cell-based methods
- Cell and virus bank characterization
- 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



Regulatory Support Services

- IND submissions
- CMC-related filings
- BLA submissions
- Cross-references to Vivante's Type V DMF in your submissions

Experience. Rapid Results.

Vivante GMP Solutions
8066 El Rio | Houston, TX. 77054
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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