

PROCESS DEVELOPMENT & GMP MANUFACTURING AT 5 CMOS



Fab-switch Drug Substance - EU

- E.coli expression
- Fermentation and Purification
- DS and DP Formulation development
- Non-GMP& GMP batches
- DS Specification and release
- Storage and delivery

Fill-&-Finish - US

- Tech transfer
- Scale up & Engineering
- DP Specification and release
- DS & DP Stability
- Storage and delivery

Plasmid production - US

- Lentivirus packaging systems
- Plasmid processing
- Specification and release
- Storage and delivery

Lentivirus production - US

- Cells for production of lentiviruses
- Transfection types
- Upstream and downstream production
- Expected yield and process considerations
- Release tests for Vector Substance

CAR-T cells production - US

- Leukapheresis
- Activation & transduction with **lentivirus**
- Expansion & extra control (healthy vs sick)
- Release & storage
- Infusion

CAR-T cell & Switch Kit

