GenScript PROBIO

GMP Viral Vector Manufacturing

GenScript ProBio Provides High-quality Viral Vector

Your programs are important, and your time is valuable. GenScript ProBio is a responsive and reliable CDMO partner of viral vector for pre-clinical, clinical and commercial use. We are ready to support you to deliver life changing therapies.

Viral vector

GenScript ProBio has proven experience with an extensive range of viral vector projects

- Lentiviral vector for cell therapy and gene therapy
- Retroviral vector for cell therapy
- AAV for gene therapy

Capability

Regardless of the virous of viral vector, you can count on reliable viral vector for pre-clinical, clinical and commercial uses with either adherent or suspension process

Capacity

Our viral vector facility has the capacity and state-of-the-art technologies to accelerate your gene or cell therapy development and manufacturing.

- 2,000 m^2 GMP cleanroom suites at Grade A and C, BSL-2
- Adherent viral vector production: Up to 96L
- Suspension single use bioreactor: Up to 200L
- F&F Speed up to 2,400 vials per hour (2R/6R/15R)
- GMP suites specifically designed for maximum productivity and efficient production

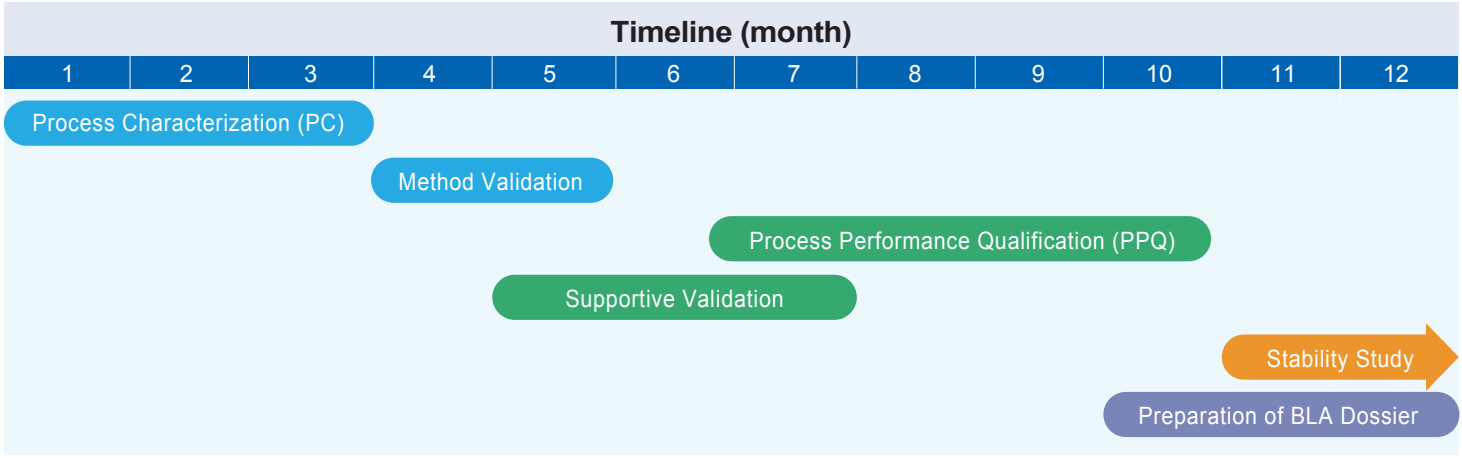
Integrated One-stop CDMO Solution: Preclinical to GMP Manufacturing

5-month IND ready | **Crude titer up to 1E+8TU/ml** | **< $5,000/patient**

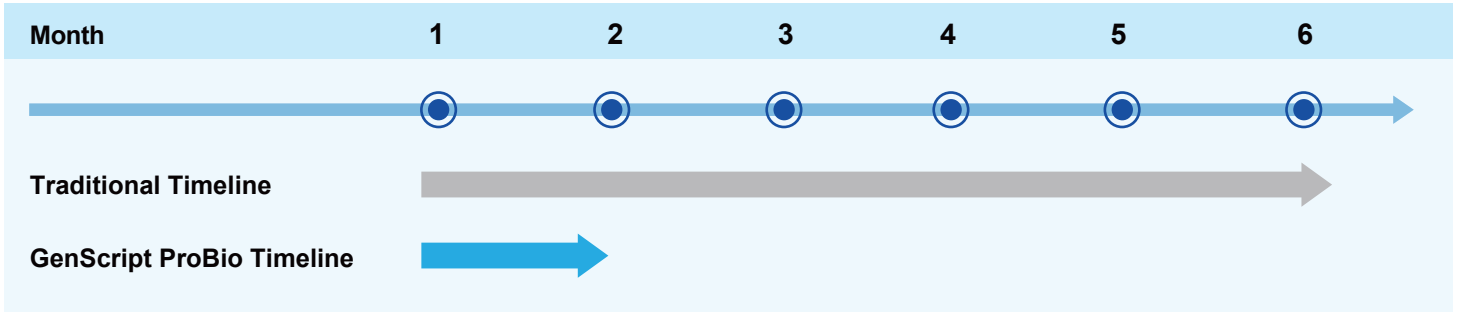
Pre-Clinical		Clinical		BLA/Commercial	
Pre-IND	IND-Enabling	Early Clinical	Late Clinical	BLA	GMP
• LVV packaging: LentiHelper™ plasmid and PowerS™-293T cell line with FDA DMF • AAV packaging: AAssistV™ plasmid and PowerS™-293 cell line with FDA DMF • RVV packaging system • PCB/MCB/WCB • Process development • Analytical method development • Stability study • Demo run/engineering run/GMP run		• Starting material manufacturing • Drug substance manufacturing • Drug product manufacturing • QC release • Stability study		• Process characterization • Analytic method validation • Process validation including PPQ • Starting material GMP manufacturing • Drug substance GMP manufacturing • Drug product GMP manufacturing • QC release • Stability study	

PreCMC Plasmid	GMPro™ Plasmid	GMP Plasmid
Pro Viral Vector	Clinical GMP Viral Vector	GMP Viral Vector

BLA PC/PV Study: 10~12 Months



GMP Viral Vector Manufacturing: 6~8 Weeks



Quality Management System: 90+ Audits with 100% Satisfaction

Follow ICH/FDA/EMA/NMPA/WHO Guidelines
Comply with the GMP Regulations of FDA/EU/NMPA

Customer Quality Verification (CQV)

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