

Andelyn Biosciences **Is Your Full-Spectrum** GENE THERAPY PARTNER

What We Do:



Plasmids



Vector
Manufacturing



Fill & Finish



Process
Development

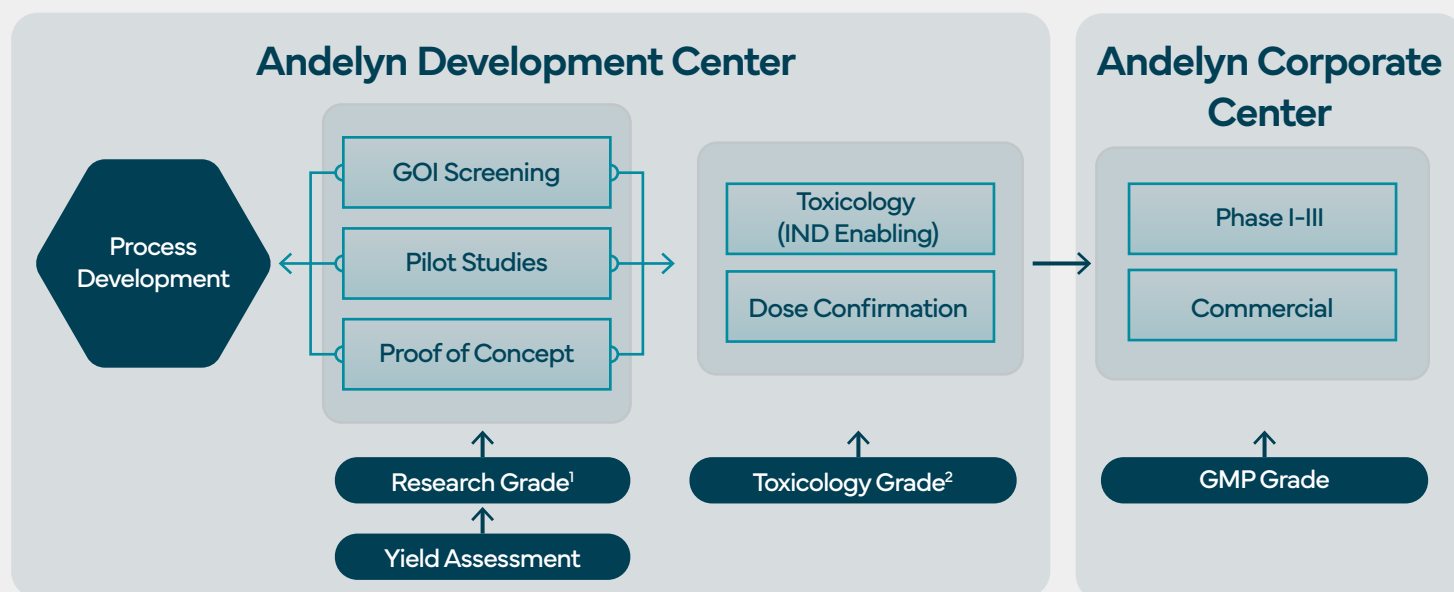


Analytics



Commercial
Readiness

Preclinical Pathway to the Clinic



Vectors for Preclinical Studies:

The preclinical vector manufacturing facility provides high quality research and toxicology grade AAV vector products. The adherent and suspension AAV production processes utilize single-use closed bioprocessing circuits when available.

Quality:

- **Consistency & Reproducibility** – Each batch delivers reliable and reproducible quality.
- **Rigorous QC Testing** – Strict quality control at every production step.

Analytics:

- **i. Standard Release**
 1. Genomic Titer by ddPCR
 2. SDS-PAGE
 3. RG Bioburden
- **ii. Upon Request**
 1. Empty:Full – by Mass Photometry
 2. Endotoxin
 3. Full suite of commercial grade testing available

CellSTACKS Production Scales:

SCALE	AVERAGE YIELD (RANGE)	TITER (VG/ML)	GOI PLASMID REQUIRED	TAT
S	1.00E+13 (2E+12 - 2E+13)	As requested up to 2E+13	0.25 mg	~4 WEEKS
M	2.00E+13 (5E+12 - 5E+13)	As requested up to 5E+13	0.45 mg	~4 WEEKS
L	4.00E+13 (1E+13 - 8E+13)	As requested up to 5E+13	0.85 mg	~4 WEEKS
XL	6.00E+13 (2E+13 - 1.2E+14)	As requested up to 5E+13	1.70 mg	~4 WEEKS
XXL	8.00E+13 (4E+13 - 2.5E+14)	As requested up to 5E+13	2.55 mg	~4 WEEKS
HYPERStacks® (5,10,20,30,60)	>2.5E+14	Request a quote		

Suspension productions also available via quote

Comparability:

The process used for preclinical manufacturing is the same as GMP and commercial grade, only modified for scale.

History:

Andelyn's preclinical manufacturing team has produced 2,500 preclinical vectors for 60+ programs that have transitioned into GMP manufacturing.

Andelyn
BIOSCIENCES

Advancing Discoveries.
Manufacturing Cures.™

Contact us



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