CDMO Response 3 – Thermo Fisher Scientific (Viral Vector Services, Lexington, MA)

Section 1 – Company Overview

Thermo Fisher offers integrated **Gene Therapy CDMO** services combining viral vector manufacturing, fill/finish, and analytical testing.
The **Lexington, MA** site provides commercial AAV manufacturing under FDA/EMA licensure, while the **Alachua, FL** site supports early-phase work and redundancy.

Section 2 – Technical Approach

- **Tech Transfer:** Thermo Fisher's "FastPath" platform enables streamlined transfer in 4–6 months.
- **Manufacturing System:** Closed single-use bioreactor trains (1,000–2,000 L).
- **Yield Maximization:** Proprietary AAV recovery process provides up to 30% higher vg/mL recovery compared to traditional column chromatography.

Section 3 – Project Plan

Step	Target Completion
Process & Method Transfer	Q2 2026
Engineering Run	Q3 2026
PPQ Batches	Q4 2026–Q1 2027
Launch Readiness	Q2 2027

Dedicated **Client Success Team** assigned with integrated planning and logistics support.

Section 4 – Regulatory & Quality

- FDA-inspected in 2024 (no Form 483).
- EMA, MHRA, and PMDA recognized site.
- Track record supporting over 20 approved biologics and 5 gene therapy launches.
- Supports serialization, global distribution, and import/export compliance.

Section 5 – Cost Proposal (Indicative)

Activity	Cost per Batch	Notes
DS Manufacturing	$490,000	1,000 L single-use
DP Fill/Finish	$80,000	Fully integrated
QC & Stability	$45,000	Includes release & 12-month stability
Tech Transfer Fee	$300,000	Fixed
Storage	$1.40/vial/month	Includes monitoring

Assumptions: Analytical reference standards provided by client; DP label & pack excluded.