CDMO Response 1 – Lonza AG (Large Global Gene Therapy CDMO)

Section 1 – Company Overview

Lonza is a leading global CDMO with >125 years of manufacturing heritage and over 25 years of gene therapy expertise. Our facilities in **Portsmouth, NH** and **Visp, Switzerland** are fully licensed for AAV commercial production under FDA and EMA oversight.
We currently support >10 commercial viral vector programs and offer full DS–DP integration.

Section 2 – Technical Approach

- **Tech Transfer:** We follow a structured 4-phase process (Assessment → Transfer → Verification → Validation) with full comparability data packages.
- **Scale & Process:** Up to 2,000 L iCELLis and stirred-tank platforms; tech transfer completed within 6 months.
- **Optimization:** Employ continuous perfusion and closed processing for yield improvement (~20–25%).

Section 3 – Project Plan

Milestone	Description	Timing
Kickoff & Data Review	Receive full process documentation	Q1 2026
Engineering Batch	Confirm process equivalence	Q2 2026
Validation Batches	Three PPQ batches under cGMP	Q4 2026
Commercial Supply	Launch and annual supply	Q2 2027 onward

Lonza assigns a dedicated **Program Manager** and **CMC Tech Lead**. Business continuity includes dual-site production (US + EU) and in-house QC analytics.

Section 4 – Regulatory & Quality

- Inspected by FDA (2023) and EMA (2024) with no major observations.
- ISO 9001:2015 certified; integrated QMS via Veeva Vault.
- Digital batch records and AI-based deviation trending implemented in 2024.

Section 5 – Cost Proposal (Indicative)

Activity	Cost per Batch	Notes
DS Manufacturing (1,000 L)	$510,000	Includes raw materials
DP Fill/Finish	$60,000	2 mL/5 mL vials
QC & Release	$30,000	Sterility, potency, AAV titer
Tech Transfer Fee	$275,000	One-time
Storage	$1.75/vial/month	-80°C storage

Assumptions: Client provides reference material; long-term stability managed externally.