

Category	Plasmid DNA Manufacturing Attributes	Research Use Only (RUO)	GMP (GMP Clinical)
Operations	Personnel	Process Development Scientists	Manufacturing Technicians
	Manufacturing Scale	5 L, 30 L	22 L, 50 L, 200 L
	GMP Raw Materials	cGMP grade material when available, may not be QA released	cGMP grade sourced from qualified suppliers. ID test only
	Environment / Facility	PD lab / Not Classified	GMP Suite / ISO 7
	Equipment Qualification	PD equipment	Qualified Equipment
	Single-Use/Glass	Single-Use / Glass	Single-Use
	Cell Bank (RCB/MCB/WCB)	RCB	MCB/WCB
	Critical Process Parameters	Monitored	Defined, and optimized
	Material Control		Fully Traceability of Materials
	Full room changeover prior to each production		✓
	Production in segregated & dedicated space		✓
	Aseptic fill and finish		✓
	Master Batch Records		✓
	Environmental Monitoring		✓
	Raw Material Testing Requirement	Use of Vendor COAs	✓
	Manufacturing Summary Report		✓
QC	Certificate of Testing (COT)	✓	
	Certificate of Analysis (COA)		✓
	Specifications		✓
QA	TSE-BSE Free Certificate		✓
	Focused QA oversight		
	Full QA Oversight for production		✓
	Full QA oversight for release		✓
	Customized Quality Agreement		✓
	Standard Quality Agreement	✓	
	Change Control		✓
	Deviation, OOS control		✓
	Batch Record QA review		✓
	GMP Statement issued by QA		✓
REG	Document support for IND and IMPD filing		✓