

# Plasmid Production Service



MicroBiopharm Japan

## MicroBiopharm Japan (MBJ) Outline

- 80 years of **experience in fermentation** business
- Manufacturing APIs **under cGMP** in global market
- Audited by **FDA, TGA and PMDA**
- **Reliable, stable, and affordable plasmid** from lab to commercial



Kiyosu site



Yatsushiro site



Headquarter



Iwata site

## Why MBJ's Plasmid?

- Grade : from Research Grade to GMP
- Capacity : from 3L to 2000L
- High Productivity : >1g/30L tank, >10g/300L tank
- High Purity : 90-95% as SC (supercoiled)
- Lead Time : Non-GMP 2 months, GMP 6 months

## Customer's Feedback

- ✓Low Price & High Productivity
- ✓High quality/stability
- ✓Experience of large scale production
- ✓Reliable company based on long track record etc.



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## Plasmid Grade

Production Conditions	Research Grade	GMP (From Apr 2024)
GMP Requirement	Non-GMP	GMP
Manufacturing Site	MBJ labs	SUS:30L, 90L SUF:300L
Production Environment	Non-GMP lab	GMP Clean room suite
Batch Size	~ 1 g (up to 30L)	~ 1g (30L) ~ 10 g (300L)
Lead Time	2 months	6 months
GMP Cell Bank	-	○
Product Analysis	Result of Analysis	Certificate of Analysis
Release Tests	-	○
Quality Assurance	-	○
Document Support	-	○

## Quality Control

Assay	Method
DNA Concentration	UV spectrophotometric method
Endotoxin	Kinetic Chromogenic LAL
DNA Purity	UV spectrophotometric method
Restriction Digest	EtBr stained agarose gel electrophoresis
Residual Host Genomic DNA	Q-PCR method
Residual Host Protein	BCA method
Residual Host RNA	Fluorescence Spectroscopy
Bioburden	Membrane Filtration Method
DNA Homogeneity (SC ratio)	Capillary Electrophoresis
Plasmid Identity	Sanger method
Identity by T5 Digestion and Densitometry	Agarose Gel Electrophoresis
Appearance	Visual inspection