



GENEMEDICINE

Integrated CDMO Services

‘One Stop Solution from R&D ideas to clinical trial-ready product’

CDMO Service Process



***From GeneMedicine, clients can expect
Instantaneous and Integrated services;***

Instantaneous	Prompt service by proven experience and expertise in virus vectors
Integrated	Orchestrated service fulfilling time and cost-efficient project
Quality	committed to global quality standards and confidentiality for clients
Competent	in proactive mitigation of risk factors in virus vector CMO/CDMO project

2014

Operating since 2014

>20

Experts with over 20 years of experience

3680+

Multipurpose GMP facility with 3,680m²

7+

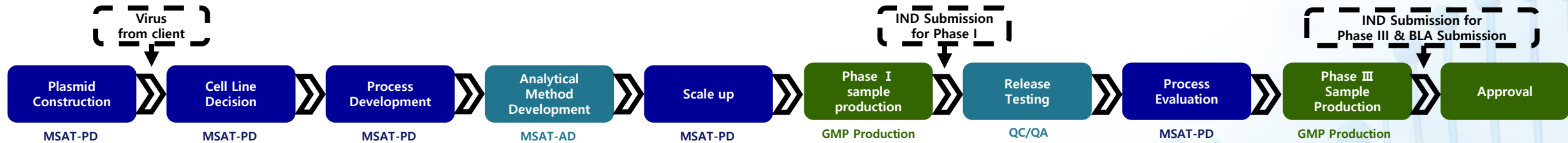
Various Viruses
(Ad, AAV, LV, HSV, Vaccinia, etc.)

6+

BLA filing experienced persons



Surpassing Limitations
Exceeding Expectations



Fast and Integrated Service for FDA, EMA, PMDA IND

MSAT-PD

I. Process Development

- Upstream Process Development
 - Plasmid Construction
 - Determination of Cell Line & Type
 - : HEK293, A549, Vero, Sf9/Baculovirus, etc. // Adherent, Suspension
 - Research Cell/Virus Banking
 - Optimization of Cell Culture : Fed-Batch, Perfusion
- Downstream Process Development
 - Optimization of Chromatography : Affinity, AEX, CEX, HIC, MMX, etc.

II. Scale Up

- Technical Transfer
- Non-Clinical Sample Production

III. Process Evaluation

- Quality by Design (QbD)
- Design of Experiment (DoE)

GMP Production

I. Banking System

- Cell Banking : Master Cell Bank, Working Cell Bank
- Virus Banking : Master Virus Bank, Working Virus Bank

II. Manufacturing

- Ad, AAV, LV, HSV etc.

MSAT-AD, Quality Control, and Quality Assurance

I. Method Development

- Analytical Method Transfer and Validation

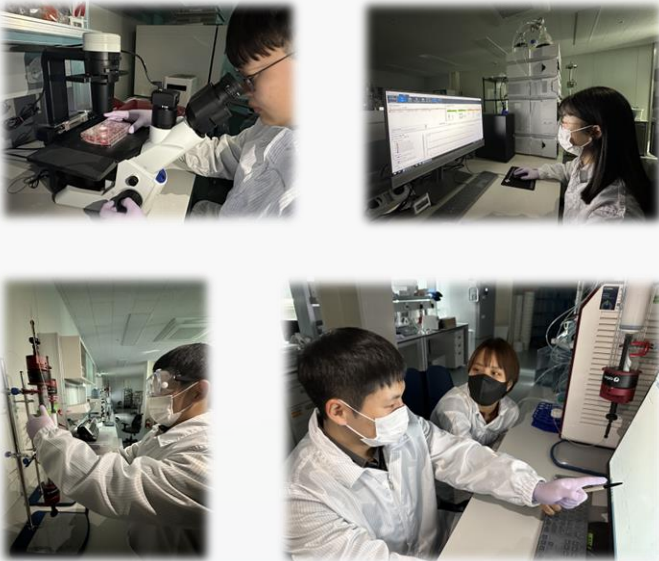
II. Release Testing

- Batch Release Test, In-Process Control (IPC) Test
- Stability test

III. Documentation

- Master Batch Records, SOPs, CTD Related Documents etc.

Process Development



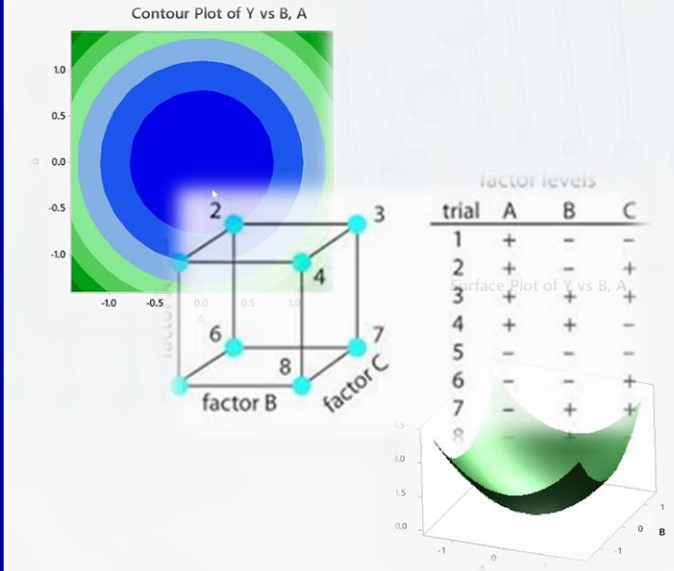
- **Upstream Process Development**
 - Research Cell/Virus Banking
 - Optimization of Cell Culture
- **Downstream Process Development**
 - Optimization of Chromatography

Scale Up



- **Technical Transfer**
 - MSAT-PD → GMP Production
- **Non-Clinical Sample Production**
 - 10 L → 20~50 L Culture Supernatant

Process Evaluation



- **Quality by Design**
 - RA, QTPP, CQA, CPP, Design Space
- **Design of Experiment**
 - OFAT, FFD, RSM

Method Development

- Method Development/Verification
- Method Qualification/Validation
- Characterization
- Safety Testing
- GMP Release and Stability Testing
- Virus/Cell Banking Testing
- Comparability Studies
- Raw Material Performance Testing
- *etc.*

Potency & Quantitative Assays

- Target Gene Expression (Transgene)
- Genome & Capsid Titer (UV, qPCR, ELISA)
- Infectious Adenovirus Particle (TCID50)

Safety

- Bioburden/Sterility
- Mycoplasma
- Absence of Adventitious Virus
- RCV (AAV, LV, Ad, HSV, Vaccinia, *etc.*)
- Endotoxin

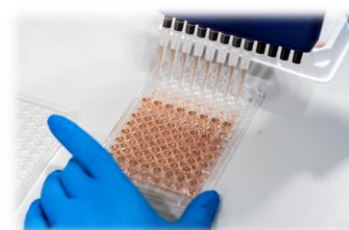
Impurities

- Residual Benzonase, BSA, HCD, HCP
- DNA Size distribution

Structure & identity

- Virus Morphology
- DNA Sequence
- Virus Size (DLS)
- Cancer Selectivity

QC Testing



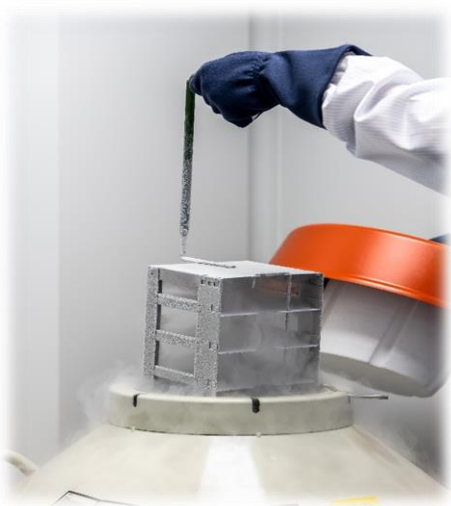
**Batch Release Test
In-process Control Test
Stability Test**

Documentation



**Master Batch Record
CTD Related Document
SOPs**

Banking System



- **Cell Banking**
 - Master Cell Bank
 - Working Cell Bank
- **Virus Banking**
 - Master Virus Bank
 - Working Virus Bank

Manufacturing



- **Ad, AAV, LV, HSV, Vaccinia Viral Vector**
- **Therapeutic Vaccines**

Manufacturing Information

Manufacturing Site

- 3 X Independent BSL2 Manufacturing Suites

Manufacturing Platform

- Ad, AAV, LV, HSV, *etc.*
- Therapeutic Vaccines
- Culture Type : Adherent, Suspension

Suspension Cell Line

- Wave Reactor System : 5 ~ 10 L Culture
- SUB (Single-Use Bioreactor) System : 20 ~ 200 L Culture (Batch, Fed-Batch, Perfusion)

Adherent Cell Line

- Cell Factory System : 2 ~ 70 L Harvest
- Bioreactor System : 10 ~ 100 L

GM CDMO GMP Facilities and Equipment

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Culture System



Purification System



24/7 Monitoring System



HVAC System



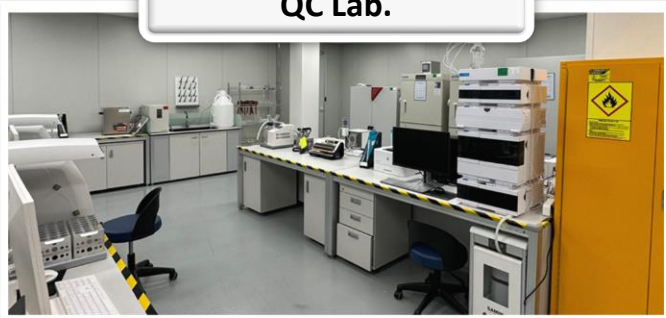
WFI System



PD Lab.



QC Lab.



QA Office



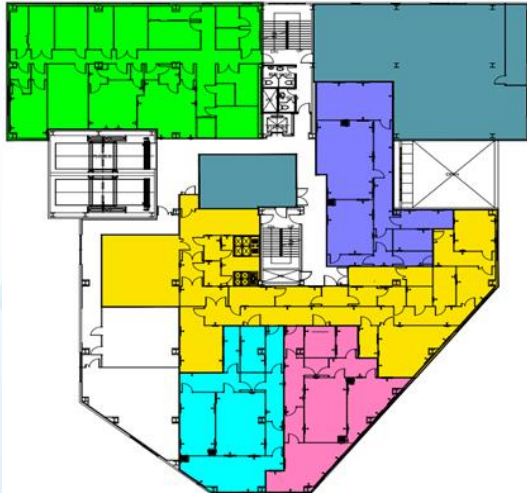
GM CDMO GMP Site Information

GENE MEDICINE

- 5F (266m²) : MSAT-AD, MSAT-PD
- 4F (1,604m²) : QA/QC Office, QC/MSAT-PD Lab, Utility



- 3F (1,604m²) : HVAC, Suite 1, 2, 3, Microbiology Lab



Surpassing Limitations ***Exceeding Expectations***



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