Dr. PARK Web Site

Dr.PARK

Company Profile

World Largest Virus Vector CDMO Factory

Strength of Dr Park Co Ltd

- 1. Reasonable cost by one owner ,no investor
- 2. More than enough production capacity to meet global demand
- 3.One top decision making process by the one owner
- 4.

Current capacity 200,000 liter

But Dr park can increase capacity up to

400,000 liter in a few months

- 5. 100% QC control by ourself
- 6. 2-3 days downstream process even with
- 5000 liter

As regulators approved viral vector-based Covid vaccines in 2020, viral vector market is expected to grow strongly in the coming years

Factors that contributed to market growth

Improved Vector Design: Better understanding of virus biology allowed for the development of safer vectors, such as AAV, which has a lower risk of triggering immune responses and integrating into undesirable locations in the genome.

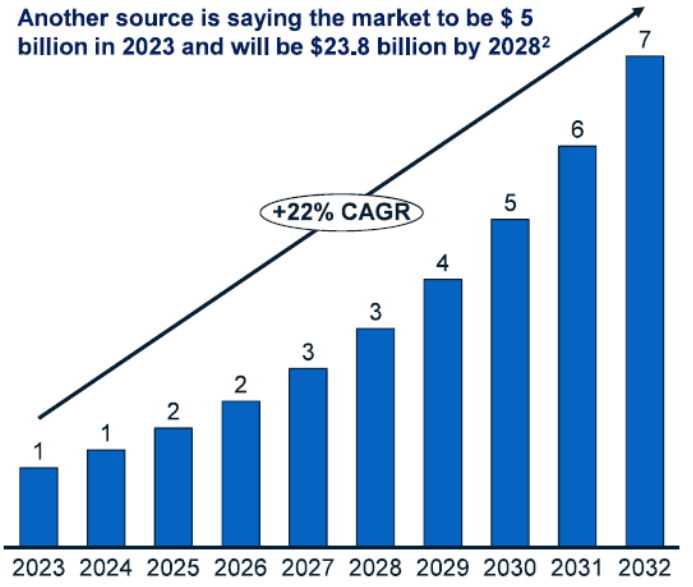
Better Production Methods: Advances in biomanufacturing enabled the large-scale, high-quality production of viral vectors.

Rigorous Preclinical Testing: Advances in animal models and safety testing protocols helped build a stronger case for the safety and potential of viral vectors in clinical applications.

Emergency use approval of viral-vector based covid vaccines by FDA led many to believe that regulators are becoming more comfortable with approving viral vector technology and thus will approve more viral vector products for other medical treatments in the future.

Viral Vector Market Size, $ billions[1]

Another source is saying the market to be $ 5 billion in 2023 and will be $23.8 billion by 2028[2]

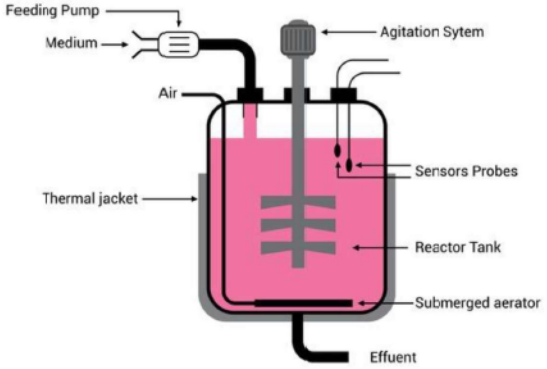


Source: IMARC

Viral Vector Production and Yield

Viral Vector production output is dependent on **the size of the bioreactor used** and its cycle time:

- **Small-scale Bioreactors (10 - 200 L)**:
  - Typically used for preclinical R&D or early-stage clinical trials.
  - Batches are smaller in size but are quicker to produce due to the smaller volume.
  - These systems have become popular due to their flexibility and lower contamination risk.
- **Large-scale Bioreactors (500 - 2,000+ L)**:
  - Used for late-stage clinical trials and commercial production by biopharma and CMOs.
  - A 2,000 L bioreactor is common in commercial production for gene therapy applications.
  - The actual output in terms of viral vector yield can vary depending on factors like the cell culture system, process optimization, and vector type, but large-scale batches can produce 10^16 to 10^17 viral particles (vg/mL or viral genomes per mL).
- **Cycle time and batches per year**
  - For viral vectors like AAV or lentivirus, each production cycle typically takes **2 to 4 weeks** that include 1-2 weeks of upstream processes and 1-2 weeks of downstream processes.
  - 2-4 weeks cycle time per batch is equivalent to **27 to 13 batches** per year (a 1000L bioreactor produces 27x1000 L per year)



Approved and In-Pipeline Gene Therapy Products

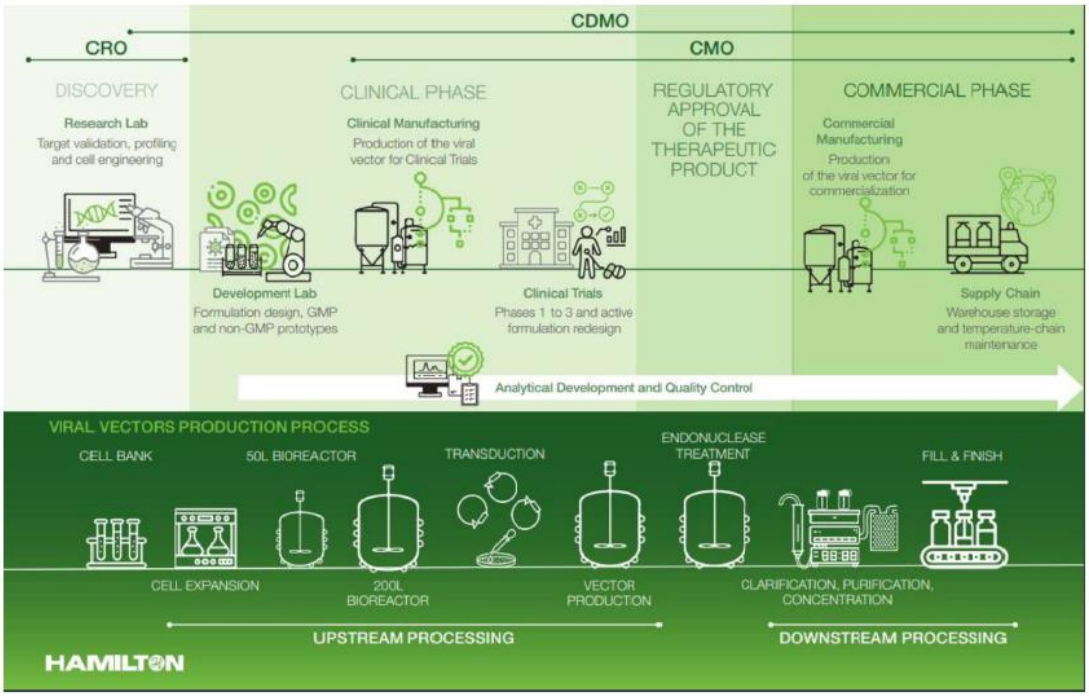
Product	Approved Year	Indication	Medical Practice Area	Cost of treatment (USD)	Patent Status
Gendicine	2003	Head and neck squamous cell carcinoma	Oncology		Off Patent
Oncorine	2005	Nasopharyngeal carcinoma	Oncology		Off Patent
Glybera	2012	Lipoprotein lipase deficiency	Metabolic Disorder		Off Patent
Imlygic	2015	Unresectable melanoma	Oncology		Off Patent
Strimvelis	2016	ADA-SCID	Immunology		Still in Patent
Kymriah	2017	ALL and DLBCL	Oncology	373,000	Still in Patent
Yescarta	2017	DLBCL	Oncology	373,000	Still in Patent
Luxturna	2017	RPE65 mutation-associated retinal dystrophy	Ophthalmology	850,000	Still in Patent
Zolgensma	2019	Spinal muscular atrophy	Neurology	2,100,000	Still in Patent
Zynteglo	2019	Beta-thalassemia	Hematology	2,800,000	Still in Patent
Libmeldy	2020	Metachromatic leukodystrophy	Neurology	4,250,000	Still in Patent
Abecma	2021	Multiple myeloma	Oncology		Still in Patent
Breyanzi	2021	Large B-cell lymphoma	Oncology		Still in Patent
Carvykti	2022	Multiple myeloma	Oncology		Still in Patent
Hemgenix	2022	Hemophilia B	Hematology	3,500,000	Still in Patent
Skysona	2022	Cerebral adrenoleukodystrophy	Neurology	3,000,000	Still in Patent
Elevidys	2023	Duchenne muscular dystrophy	Neurology	3,200,000	Still in Patent
Casgevy	2023	Sickle cell disease	Hematology	2,200,000	Still in Patent
Lyfgenia	2023	Sickle cell disease	Hematology	3,100,000	Still in Patent
Bizengri	2024	NRG1 gene fusion-positive cancers	Oncology	462,000	Still in Patent

As of today..

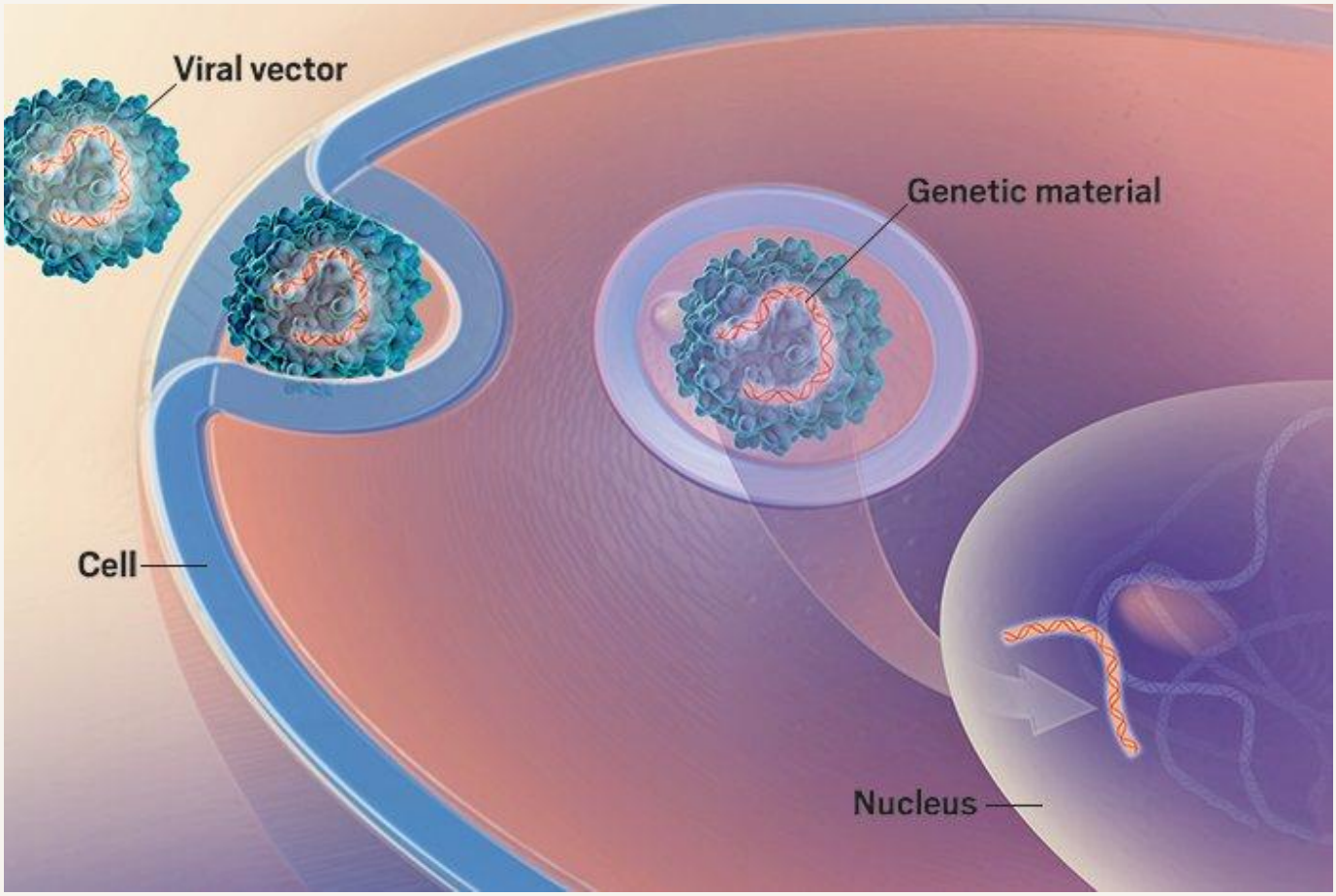
Pre-clinical phase	Clinical phase	Approved in 2023	Yearly approvals[1]
1,400 GT products	2,000 GT products	7 GT products	20 GT products

Source: FDA. 1. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics?utm_source=chatgpt.com

Viral Vector Development & Manufacturing for Gene Therapy



Source: Hamilton



	ADENOVIRUS	AAV	γ-RETROVIRUS	LENTIVIRUS
SIZE	~90-100 nm	~25 nm	~80-100 nm	~80-100 nm
GENOME	dsDNA	ssDNA	ssRNA	ssRNA
PACKAGING CAPACITY	~8 kb – 36 kb	~4.7 kb	10 kb	8 kb
TRANSDUCTION	Dividing and non-dividing cells	Dividing and non-dividing cells	Dividing cells	Dividing and non-dividing cells
TRANSDUCTION EFFICIENCY	High	Moderate	Moderate	Moderate
INTEGRATION	Non-integrating	Non-integrating	Integrating	Integrating
EXPRESSION	Transient	Transient or stable	Stable	Stable
BIOSAFETY LEVEL	BSL-2	BSL-1	BSL-2	BSL-2
IMMUNOGENICITY	High	Low	Moderate-High	Moderate-High
GENE THERAPY STRATEGY	*In vivo*	*In vivo*	*Ex vivo*	*Ex vivo*

Major steps of viral vector manufacturing

- Production and Manufacturing

1. Viral vectors are typically produced in packaging cell lines (e.g., HEK293T cells). The process involves Transfection of cells with vector components.

Three plasmids are needed

- Transfer plasmid
-Rep/Cap plasmid
-Helper plasmid

1. Viral particle assembly and release

2. Purification and concentration of viral particles

3. Quality control testing (titer, purity, potency)

- Applications

1. Gene Therapy: Delivering therapeutic genes to treat genetic disorders

2. Cancer Treatment: Oncolytic viruses and immunotherapy approaches

3. Vaccine Development: Viral vector-based vaccines (e.g., COVID-19 vaccines)

4. Research Tools: Studying gene function and cellular processes

5. Cellular Reprogramming: Generating induced pluripotent stem cells

6. CRISPR Gene Editing: Delivering CRISPR components to target cells

Contents

Company Mission Statement

At Dr. Park, our mission is to revolutionize the accessibility and efficiency of Cell and Gene Therapy (CGT) new drugs.
We are committed to maximizing the production efficiency and capacity of viral vectors, ensuring top-tier quality control to make these advanced therapies available to more people.

Our state-of-the-art Phase 1 plant, set to be completed in June 2025, will feature world-leading facilities with a production capacity of 5000L per batch. By the end of 2025, we aim to achieve the highest level of cGMP certification, underscoring our commitment to quality and excellence.

Founded solely by Dr. Park Yongho, without external investments, our vision is driven by the founder’s dedication to making CGT new drugs a mainstream treatment option. Through our cutting-edge production capabilities, stringent quality controls, and agile organizational structure, we strive to lead the next generation CGT new drug market as a premier CDMO company.

1 Company Information Brief

Overview

At Dr. Park, we are emerging leaders in the viral vector CDMO (Contract Development and Manufacturing Organization) industry, known for our unparalleled production capacity and commitment to quality.
Specializing in AAV (Adeno-Associated Virus) related products, we boast the world's largest production capacity for viral vectors, with an impressive 5,000 liters per batch and the ability to complete 40 batches per year.
We can increase our production capability up to 10,000 liters per batch if there is a client's request immediately, showcasing our flexibility and commitment to meeting client demands.

Services

We provide:

- Small to large-scale production and refining services for viruses at competitive prices.
- State-of-the-art quality control and examination facilities to ensure the highest standards of safety and efficacy.

Technology and Facilities

Dr. Park's latest process technology has been continuously improved and is provided to customers in collaboration with various companies involved in viral vector production and development.

1 Company Information Brief

Our facility is on track to complete all construction and pre-operational tests by June 2025, with the goal of obtaining cGMP certification by the end of 2025. With a production lead time of just two weeks,
Dr. Park is committed to delivering timely and efficient solutions to meet your needs.

Our advanced equipment includes:

GMP Plasmid Production :

• 700 Liter Fermentor x 2EA
500 Liter Fermentor 1EA

Upstream Equipment :

• 1000 Liter SUB x 4EA (Thermofisher Hyperforma)
• 500 Liter SUB x 1EA
• 250 Liter SUB x 1EA (Thermofisher Hyperforma)
• 50 Liter SUB x 1EA (Thermofisher Dynadrive)
• ACFM (Automated Cell Factory Machine) x 1EA
• ACFM Incubator
• 50 Liter Rocker Incubator (Thermofisher)
• QUANTUM Bioreactor (3 liters)
• Single Use Mixer

1 Company Information Brief

Midstream Equipment :

• Dynaspin (Thermofisher)

Downstream Equipment :

Our customized 800 LPM TFF equipment is the largest and most advanced globally, setting new standards in the industry.

• FPLC 10 LPM x 1EA
• TFF 800 LPM (40 ㎡) x 1EA
• TFF 200 LPM x 1EA
• TFF 20 LPM x 1EA
• AKTA PILOT 600 x 2EA
• AKTA FLUX x 1EA

Buffer & Media Preparation :

• 1000 Liter Mixer
• 200 Liter Mixer

1 Company Information Brief

Production Platforms

We are building a platform for large-scale GMP manufacturing and production technology for various viruses. Our virus production utilizes the Cell Factory system for both adherent and suspension
HEK 293 cells or single-use bioreactors in serum-free conditions for suspension HEK293.

GMP Plasmid Manufacturing

Plasmids are small circular DNA structures containing DNA fragments, widely used in genetic engineering and gene delivery (e.g., gene therapy, vaccine production). As experts in plasmid amplification, we adhere to GMP (Good Manufacturing Practice) standards, ensuring the effective minimization of risks during production that cannot be eliminated even after final product testing.

At Dr. Park, we apply these principles to plasmid production, guaranteeing the provision of safe and effective plasmid products. Our cutting-edge GMP facilities, developed through continuous research and development, position us at the forefront of industry trends. Our
exceptional performance spans applications in research laboratories, pharmaceutical development, and plant genetic engineering. We deliver reliable and effective results swiftly, ensuring our services are recognized internationally. Our annual plasmid production capability, adhering to GMP standards, is 3.9 kg per year.

1 Company Information Brief

Protein Bioproduction

Dr. Park has successfully produced many proteins based on more than 10 years of diverse experience in customized protein production and is a leader in recombinant protein production that is difficult for expression. We provide large amounts of protein expression and purification services from low doses using Dr. Park's own system at a low price. Dr. Park provides the most advanced high-throughput protein production platform based on the knowledge and know-how of the best protein production experts. Therefore, Dr. Park builds all systems to meet or surpass the customer's requirements through a high-level production platform.

Partnership with Dr. Park

Leverage our expertise in products, advanced facilities, and dedicated service to accelerate your path to market with confidence.

Contact Information

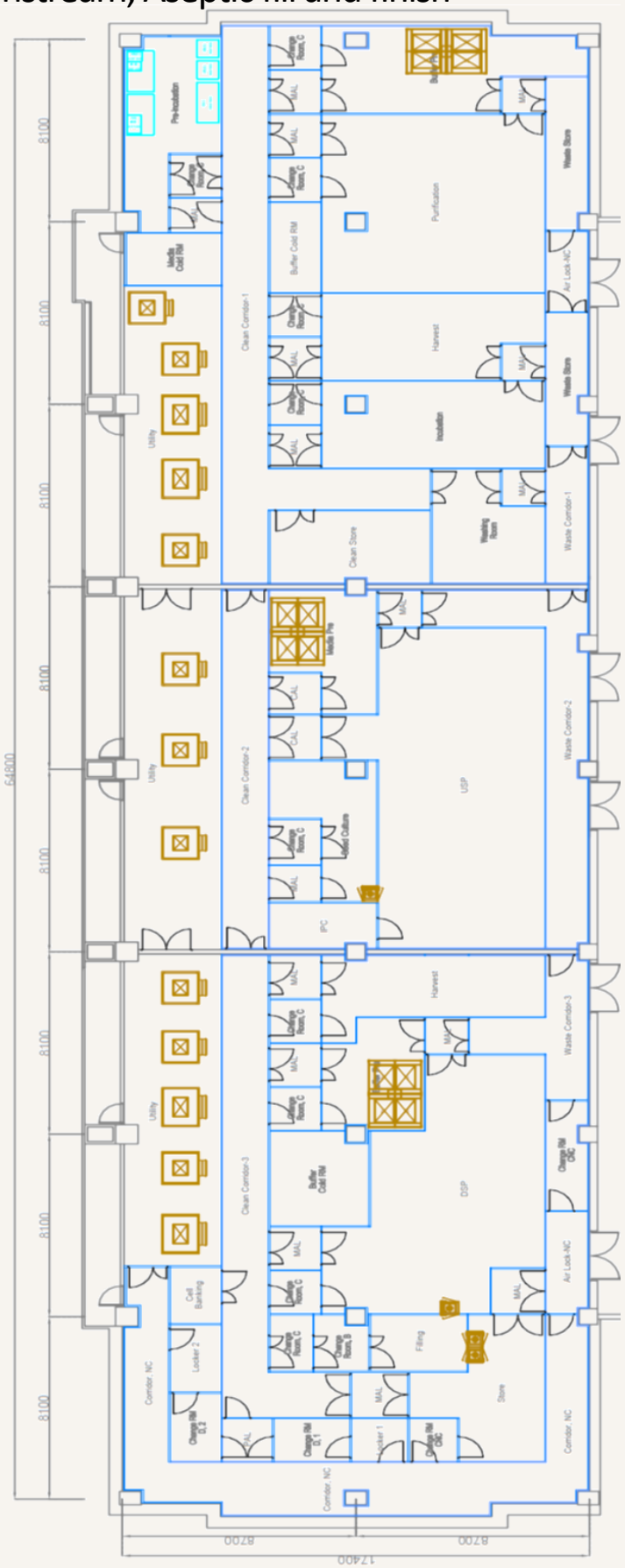
- Address: 555, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, South Korea
- Tel: +82-31-734-0077
- Fax: +82-2-6455-7512
- C.P: +82-10-8864-7512
- E-mail: president@drpark-cdmo.com

2 Factory Overview

▪Main Factory

GMP Plasmid / AAV Upstream, Downstream, Aseptic fill and finish

Factory Layout



▪QC Room

▪Storage Room

▪Utility Room

3 GMP Quality Control – Plasmid DNA

Test Name	Analysis Method	Evaluation
Purity	HPLC	Absorption rate ratio
	Spectrophotometry	OD260/OD280
Contamination	Bioburden	Acceptable bioburden level
	Endotoxin	Endotoxin acceptance criteria
Mycoplasma	qPCR	P/N control comparison
Host DNA detection	qPCR	P/N control comparison
Identity (sequence)	DNA sequencing	Sequence comparison to reference
Plasmid Concentration	Qubit	Fluorescence intensity
Plasmid Purity and Conformation	Electrophoresis (Enzyme cut)	Comparison of band profiles
RNase Impurity Identification	ELISA	OD450
pH	Potentiometry	-
Osmometry	Osmometry	-
Conductivity	Conductivity	-

3 GMP Quality Control – Virus Vector

Test Name	Analysis Method	Evaluation
Virus titer	qPCR	P/N control comparison
	qPCR (Limiting dilution)	P/N control comparison
Contamination	Endotoxin	Endotoxin acceptance criteria
	Bioburden	Acceptable bioburden level
Host cell impurity (DNA)	qPCR	P/N control comparison
Host cell impurity (Protein)	ELISA	OD450
DNase impurity	ELISA	OD450
Capsid identify	ELISA	OD450
Protein expression	WB	-
Plasmid impurity	qPCR	P/N control comparison
Mycoplasma	qPCR	P/N control comparison
Virus purity	HPLC	Absorption rate ratio
	AUC	Full / Empty ratio
Particle size	DLS	-
pH	Potentiometry	-
Osmometry	Osmometry	-
Conductivity	Conductivity	-

Equipments List

▪Fermentor

Fermentor 700 Liter x 2EA

Fermentor 500 Liter

▪Signle Use Mixer

Single use mixer 1,000 Liter

Single use mixer 300 Liter

Max Capacity : 3.9 kg / year (for GMP grade)

4 Equipments(Plasmid Manufacturing - Upstream)

Fermentor

▪700 Liter Fermentor

▪500 Liter Fermentor

Single use mixer

▪1,000 Liter Mixer

▪300 Liter Mixer

Equipments List

▪FPLC

AKTA Pilot 600 (Cytiva)

▪TFF

TFF 20 LPM

TFF 200 LPM (20 m^2)

AKTA Flux (Cytiva)

FPLC

▪**AKTA Pilot 600**

(Cytiva)

4 Equipments(Plasmid Manufacturing - Downstream)

TFF

▪AKTA Flux

(Cytiva)

▪TFF 20 LPM

▪TFF 200 LPM (20㎡)

Equipments List

▪Bioreactor

50 Liter Rocker Incubator (Thermofisher)

50 Liter SUB (Thermofisher)

250 Liter SUB (Thermofisher)

1,000 Liter SUB x 4EA (Thermofisher)

500 Liter SUB

3 Liter Bioreactor

▪ACFM

ACFM (Thermofisher)

ACFM Incubator (Thermofisher)

▪Centrifuge

Dynaspin (Thermofisher)

▪Mixer

200 Liter Single Use Mixer (Thermofisher)

Current Capacity : 5,000 Liter / batch

Additional 5,000 Liter 40 Batch/year (200,000 Liter/year)

Available immediately as needed.

Bioreactor

▪50 Liter Rocker Incubator

(Thermofisher)

▪50 Liter SUB

(Thermofisher)

Bioreactor

▪250 Liter SUB

(Thermofisher)

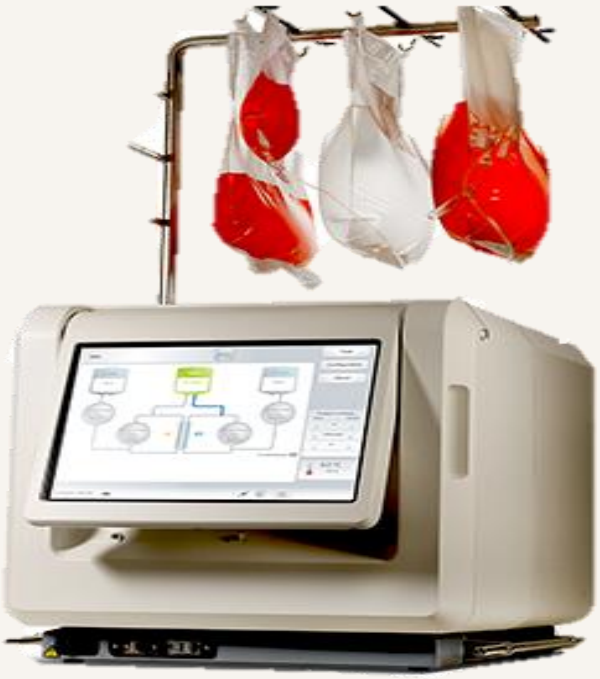
▪1,000 Liter SUB

(Thermofisher)

4 Equipments(AAV Manufacturing - Upstream)

Bioreactor

▪3 Liter SUB



▪500 Liter SUB

Automated Cell Factory

▪**ACFM**

(Thermofisher)

▪**ACFM Incubator**

(Thermofisher)

Centrifuge

▪**Dynaspin**

(Thermofisher)

Equipments List

▪FPLC

AKTA Pilot 600 (Cytiva)

FPLC 10 LPM

▪TFF

TFF 800 LPM (40 ㎡)

TFF 20 LPM

4 Equipments(AAV Manufacturing - Downstream)

FPLC

▪**FPLC 10 LPM**

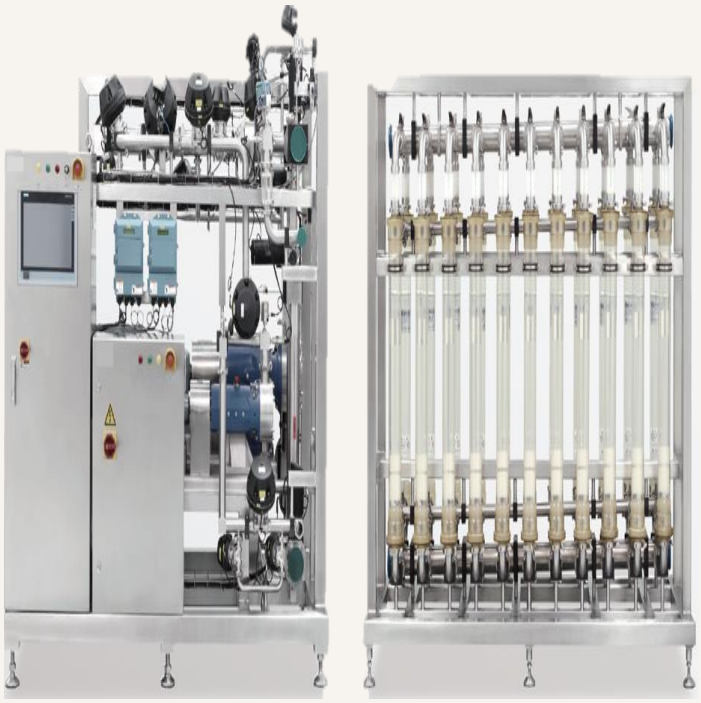
▪**AKTA Pilot 600**

(Cytiva)

4 Equipments(AAV Manufacturing - Downstream)

TFF

▪TFF 800 LPM (40 ㎡)



▪TFF 20 LPM

Equipments List

▪Beckman

Optima AUC

CytoFLEX SRT

Vi-Cell MetaFLEX(Bioanalyzers)

Vi-Cell Blu(Cell Viabilty Analyzer)

BioMEK i5 (Liquid Handler)

▪Thermofisher

EVOS M5000 (Inverted Microscope)

QuantStudio 5 (qPCR)

SeqStudio (Sanger sequencer)

Multiskan Go (Microplate reader)

▪Shimadzu

GC-2030 (GC-MS)

PPSQ-51A (Peptide Sequencer)

▪NOSQUEST

MicroIDSys (MALDI-TOF)

▪Youngin

Chrozen HPLC

YL9100 (LC-MS)

NMReady 60PRO (NMR)

▪ILLUMINA

iSeq 100 (NGS)

▪NANOSCOPE

F1-CIS (Confocal laser)

▪HORIBA

LA-350 (Particle size analuzer)

▪SERON

AIS2300 (SEM)

▪HIMAC

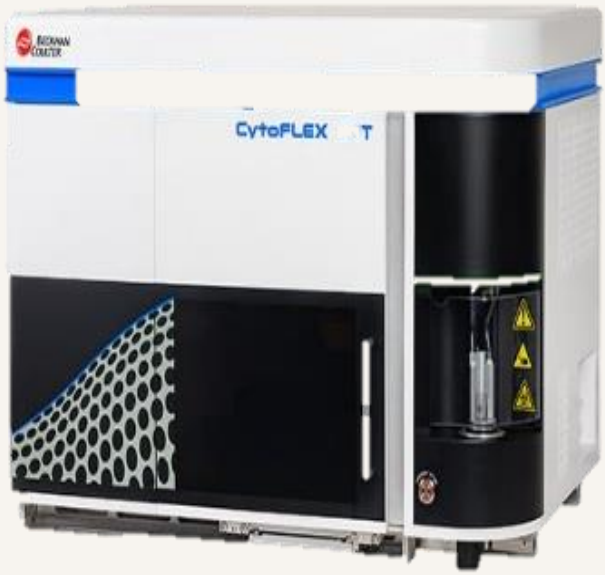
CS150NX (Centrifuge)

4 Equipments(Quality Control)

Beckman

▪Optima AUC

▪FACS (with Sorter)



4 Equipments(Quality Control)

Beckman

▪Bioanalyzers

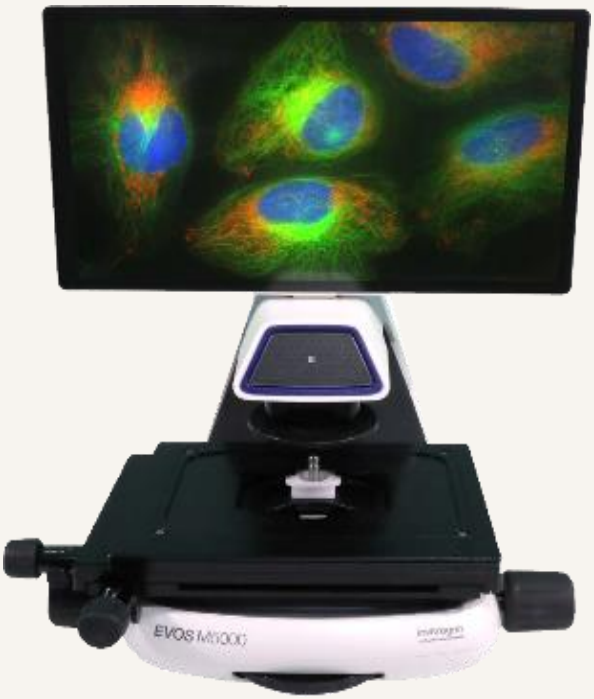
▪Cell Viabilty Analyzer

▪Liquid Handler

4 Equipments(Quality Control)

Thermofisher

▪Inverted Microscope



▪qPCR

Thermofisher

▪Sanger Sequencer

▪Microplate Reader

4 Equipments(Quality Control)

Shimadzu

▪GC-MS

▪Peptide Sequencer

4 Equipments(Quality Control)

Youngin

▪HPLC

▪LC-MS

▪NMR

4 Equipments(Quality Control)

NANOSCOPE

▪Confocal laser

SERON

▪ Scanning Electron Microscpoe

4 Equipments(Quality Control)

NOSQUEST

▪MALDI-TOF

ILLUMINA

▪NGS

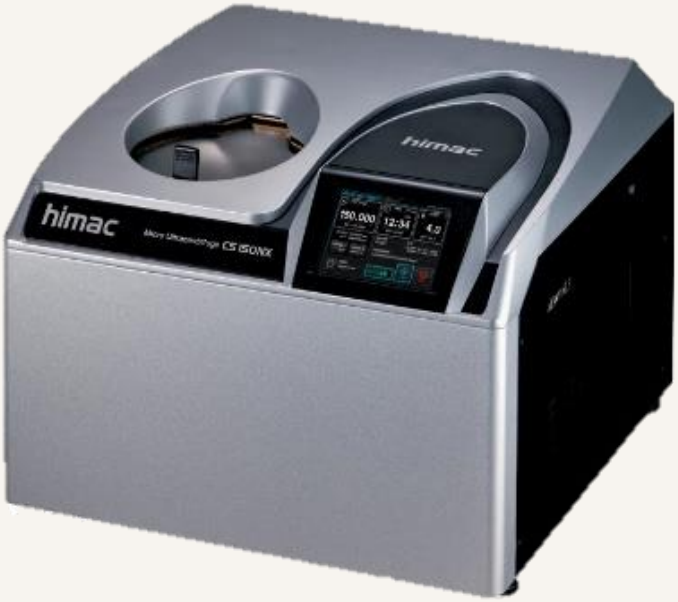
4 Equipments(Quality Control)

HORIBA

▪**Particle size analyzer**

HIMAC

▪**Centrifuge**



5 The Road Ahead

01

Completion of GMP Facility

Our state-of-the-art GMP facility is scheduled for completion
* in June 2025, Seongnam, South Korea.

02

GMP Certification

GMP Certification Planned for 2025
* Certified by the Ministry of Food and Safety(MFDS), South Korea

03

Ongoing Maintenance

We will continuously collaborate with companies in need of gene therapy solutions, investing in ongoing research and quality improvements to ensure we meet the highest standards.

"Innovating for health"

Dr.PARK

Thank You

Headquarters. (13215) Sunil technopia 12F, 555,
Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, SouthKorea
Tel. 82-31-734-0077
Fax. 82-31-0242
E-mail. president@drpark-cdmo.com
Whatsapp. +82-10-8864-7512
Web. https://drpark-cdmo.com/