GC Cell

Cell & Gene Therapy CDMO

Fully Integrated Capability for Cell and Gene Therapy from Research to Commercialization.

www.gccell.com

Cell & Gene Therapy CDMO Essence in a Snapshot

With more than 12 years of Cell & Gene Therapy research and commercialization, GC Cell fully understands the unique challenges around Cell & Gene Therapy development and manufacturing. We provide end-to-end, customer-centric CDMO services to bring more breakthrough treatments to patients.

GC Cell

Established in

2011. 06

CEO

Sungyong Won

Headquarter

Yong-in, South Korea

Headcount

+800 employees

Affiliates

artiva
Artiva Biotherapeutics, Inc.

MADE SCIENTIFIC
MADE Scientific, inc.

GC LTEC
GC LYMPHOTEC, Inc.

GC CL
GCCL Ltd.

	Site Overview	Capacity	Capability
Cell Center	· 20,806m² · 4 stories high with 2 basement levels	· 14 Clean rooms, 18,000 pack/year (based on Immuncell-LC)	· Process and Analytical Development clinical and commercial manufacturing
US Production Site	· BioCentriq GMP suite: Life Science Engineering center (3,200ft²) · BioCentriq PD Suite: 7 Deerpark Dr.(5,800ft²)	· 4 Clean rooms	· Clinical manufacturing Process and Analytical Development

Business at a Glance

From Discovery to Deliver For Patients in Need

Cell-based Therapies

Novel cell therapies with proprietary technology

Immuncell-LC approved for Hepatocellular Carcinoma (HCC)

R&D Pipeline

- Potential first-in-class or best-in-class addressing unmet needs
- CAR-NK Cell Therapy
- CAR-T Cell Therapy

Commercial Product

- Autologous CIK cells
- 10,000 accumulated patients treated
- No > grade3 adverse event
- With dual mechanisms killing cancer cells

Cell Banking

Global-level rigorous quality assurance of cell banking

- Conducting essential tests to ensure efficacy and availability for cell banking
- Dedicated storage space for cord blood

Bio Logistics Cold Chain Supply

Nation-wide coverage of High quality cold chain

- Specialized Bio logistics (Cold Chain -150℃ ~25℃)
- Delivers to over 5,000 hospitals daily
- Global quality standard of diagnostic test services

Accelerating Tomorrow's Cure, Enhancing People's lives

**Just like every cell, we started small with a big purpose:
to incubate ideas and nurture them into potential cure, into hope.
Connecting science to hope, and connecting life to a better future.**

Cell and Gene Therapy Licensing and Co-Development

Revolutionizing Cell Therapy:
R&D to Manufacturing to Commercial

L/O of immuncell-LC Globally and CAR-NK pipelines in APAC

Co-development or Combination Studies with Sound MoA

Cell and Gene Therapy CDMO with Excellecne

State-of-the-Art Facilities with GMP compliance

Scalability and Robustness
for Large-Scale Process & Production

Stringent Quality Control and Assurance

Technology Transfer when Needed

Clinical & Regulatory Track Records

Accelerating Clinical Development
and Fast-Tracking Approvals

Navigating Complex Regulatory Landscape

Ensuring Compliance and Safety

Successful Commercialization

Market Access Expertise of Cell and Gene Therapy

Distribution Networks and Cold Chain Supply Chain Management in Korea

360-Degree Approach of Launch and Market Access

Patient-Centric Approach

Fully Integrated Capability for Cell Therapies from Research to Commercialization

Fully-integrated CDMO Service Offering

Process Development

Low Cost of Goods
High Scalability enabling
Accessibility & Affordability

Manufacturing

2 Global Manufacturing Sites of
· US NJ (BioCentriq)
· Korea (GC Cell)

BioLogistics

Research & Discovery

6 Active Pipelines of NK Cell Tx under Development + Expanding Modalities & Indications

Discovery Hybrid Platform business

Clinical & Regulatory Development

3 Global clinical trials completed or ongoing

2 Additional trials to be initiated by Q1, 2024

Commercialization & Supply

1 Launched Auto-CIK Tx "Immuncell-LC"

10,000+

Patients Treated in Solid Cancer

Key Highlights

Research & Discovery NK cell therapy

6 Active Pipelines of NK Cell Therapy under Development + Expanding Modalities & Indications

Equipping a fully integrated value chain from drug development and manufacturing up to commercialization offers significant benefits in terms of insight and intelligence, which in turn optimize strategy and drug life cycle management.
This allows GC Cell to strategize the development up to approval with streamlined, data-driven decision making.

R&D Pipeline Under Development

Type	Project (Product)	Indication	Pre-clinical / Phase 1 / Phase 2/3	Remark
ALLOGENIC Cord Blood NK	GCC4001 + Rituximab AB-101 (AlloNK)	r/r Lymphoma Lupus Nephritis (Autoimmune)		- Phase 1/2a clinical trial - Initial data readout at ASCO ('23.06) - First patient dosed in Phase 1 trial in patients with Lupus Nephritis ('24.04)
	GCC4001 + AFM13 AB-101 (AlloNK)	r/r Hodgkin Lymphoma / CD30+		- Innate cell engager AFM13 + GCC4001
CAR-CBNK	GCC2003 AB-201 HER2 CAR-NK	HER2+ Solid Cancer		- US FDA IND cleared ('22.09) - Australia HREC + Korea MFDS IND cleared ('23.12)
	GCC2004 AB-202 CD19 CAR-NK	B Cell Lymphoma		- Process development, non-clinical stage
	GCC2005 AB-205 CD5 CAR-NK	T Cell Lymphoma		- Pre-clinical data readout at AACR ('24.04) - IND preparation underway for Korea
AUTOLOGOUS Peripheral Blood CIK	Immuncell-LC	Pancreatic Cancer		- Reapproved for HCC as Advanced Therapy ('21.08) - Indication expansion : ongoing Phase 3 clinical trials in pancreatic cancer

Prioritized

*There are currently 4 pipeline projects and 4 platform development projects in the discovery stage.

Cell Therapy CDMO

CDMO Projects

Classification	Project	Approval Status
Cord Blood-based	F	In progress
iPSC-based	G	
Umbilical Cord-derived	H	
Cell-based vaccine	A / B / C	IND Approved
CAR-T	D / E	

Regulatory Approvals

14 IND Approvals

Ministry of Food and Drug Safety

FDA U.S. FOOD & DRUG ADMINISTRATION

TGA

BLA Approval

1 BLA Approval

Ministry of Food and Drug Safety

GMP Manufactured Products

5 Inspections by Ministry of Food and Drug Safety

7 Client Products

3 Audits by

5 In-house Products

Partners & EU QP

Cell & Gene Therapy CDMO

94,000+
Commercial Batches

14,000+
Personalized Cell Therapy

We're pioneers

with our own commercialized cell therapy product

360° Approach to Cell Therapy

With more than 17 years of cell therapy research and commercialization, we have fully integrated capability and capacity to support our clients throughout the entire journey.

Tech Transfer Harmonized Cross border

Flexibility for seamless intercontinental tech transfer between Asia and USA. Flesibly switch manufaturing to where the product is needed the most.

Bio Logistics Cold Chain Supply

From vein to vein, GC Cell is the only All-in-One provider that can collect sample, manufacture and deliver final product back to the patient.

Commercial Expertise with Forward Thinking

The concept of 'end in mind' is particularly crucial for cell therapy modality. GC Cell is not just focused on the development and manufacturing aspects of cell therapy but is also acutely aware of the market dynamics and regulatory requirements that will come into play once the product reaches the market.

Cell Therapy CDMO

Scope of CDMO Service

- iPSC, MSC, NK, T, CAR-NK, CAR-T
- Up to 200L scale-up

- CAR-T

CDO Product Service

Process Development Service	**a. Establishing large-scale culture methods according to GMP standard** **b. Specification of the cell culture and manufacturing methods**
Quality Test Development Servicet	**a. Establishing test standards for incoming raw materials** **b. Setting up donor tissue suitability test and IPC criteria standardization** **c. Quality control criteria establishment** **d. Procure stable packaging and long-term storage system**
RA Consulting	**a. CTD Module 3 documentation filing** **b. Consultations on IND approval**

CMO Advanced Biological Product CMO (Cell Therapy/Gene Therapy)

Cell Bank(MCB/WCB) Manufacturing

Commercial Product Manufacturing

Investigational Product Manufacturing

Aseptic Process Validation

CAS Service Scope of CDMO Service

Sterility Test (KP, USP)

Endotoxin Test (Chromogenic)

Mycoplasma Test (KP, USP)

Adventitious Virus Test (In vitro)

Mycoplasma Test (qPCR) Validation

Procedure

Product CDMO

STEP 01
Client Contact

STEP 02
Sign Non-dislosure Contract

STEP 03
Technical Exchange
Project Scope Discussion

STEP 04
Proposal
(Quotation)

STEP 05
Contract Negotiation & Execution

STEP 06
Tech Transfer & Scale-up

STEP 07
GMP Engineering Run
GMP Product Manufacturing

Product CAS

STEP 01
Client Contact

STEP 02
Estimated Quotation for Testing

STEP 03
Discuss Test Availability and Schedule

STEP 04
Neotiation of CAS Contract

STEP 05
Sign CAS Contract

STEP 06
Pre-test

STEP 07
Main Test

Connecting science to hope,
Connecting life to a better future.

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