

**FUJIFILM**  
Value from Innovation



# CELL & GENE THERAPIES

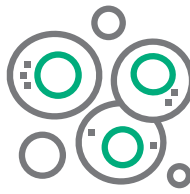
**Contract Development, Manufacturing,  
and Technology Solutions**

# Comprehensive Cell & Gene Therapy Solutions

Spanning across development and manufacturing services, integrated testing capabilities, and technology platforms to support and de-risk your therapy from early discovery through commercial production



Cell Therapy



iPSC-based Therapies & Technologies



Gene Therapy



## Partners for *Life*<sup>™</sup>

As Partners for Life, we are committed to building enduring, trust-based relationships that span the entire drug development cycle.



# Cell Therapy Solutions

CDMO experience and know-how to de-risk your path to patients

## Established Partner. Proven Expertise.

1

commercial  
cell therapy

4

successful regulatory  
inspections

EMA (2022, 2024, 2026),  
FDA (2024)

10+

years experience  
with cell therapies

50+

allogeneic GMP  
batches produced

30+

leukapheresis  
shipments received

2,500+

clinical shipments to  
10 countries

### Development

- On-site development and analytical laboratories
- Automation and process closure solutions
- Process optimization and characterization services
- Platform analytical methods and bridging solutions
- Regulatory support for IND & BLA submissions

### Manufacturing

- Five flexible Grade B GMP suites
- Commercial readiness support - process and method validation
- Quality control labs for compendial, analytical, and cell-based assays
- Stability testing and sample management
- Apheresis processing
- Clinical pack out and distribution services
- Long term storage

### Adherent & Suspension for Allogeneic & Autologous CT

#### Immune Cells

CTL •  $\gamma\delta$  T • CAR • NK  
Cell banking

#### iPSC Stem Cells

Mesenchymal  
Hematopoietic

#### Whole Cell Cancer Vaccine

#### Exosomes

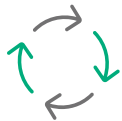
### Patient Supply

- Vein-to-vein support with donor & patient lot track & trace
- Multiple intermediate & drug product storage conditions
- Assembly through distribution of patient shipments

# iPSC-based Therapies

World-leading iPSC-derived cell therapy CDMO with broad cell differentiation and protocol development

## Advanced cell technology & manufacturing



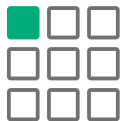
### Proprietary Reprogramming

- Non-integrating episomal vectors
- QC ensures vector clearance and pluripotency
- 14 GMP and 1000+ RUO iPSC lines available
- On demand reprogramming services



### Genetic Engineering

- Fully licensed methods (CRISPR, etc.)
- Enable partner possession and use
- Gene modifications and reporters



### Proprietary Differentiation

- Proprietary differentiation protocols
- Catalog and custom cell types
- RUO- and GMP-grade differentiated cells



### Industrial Manufacturing

- GMP cell bank production
- Scale-up to meet screening needs
- Scale-out to assess population responses
- Preserve cell viability post-freezing at large scale
- World class QA and QC ensures reproducibility



## Capabilities & Solutions

- **Established Cell Therapy Facility Manufacturing** with core expertise in iPSC differentiation for clinical use
- **5** iPSC-based therapeutic products developed
- **>20** clinical batches manufactured
- **20+** GMP iPSC banks manufactured
- Custom cell line development with **full suite of gene editing technologies**
- Extracellular Vesicle (EV, exosome) manufacturing

## GMP iPSC Lines

- **14** fully consented cGMP iPSC lines with master files
- Lines have successfully cleared IND-filings and are actively being **used in clinical trials**
- Multiple off-the-shelf GMP iPSC lines available
- Research banks of all iPSC lines available for testing
- Oncogene panel and tri-lineage differentiation tested
- **Largest inventory** of HLA typed donors for industry use; male and female donors with O+/- blood types

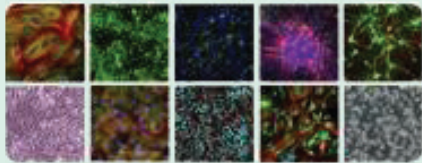
# iPSC Technology & Services

Leveraging our human iPSC technology to revolutionize scientific research

## Extensive Product Portfolio

Over 250 products covering apparently healthy and disease cell lines and use

Innovative culture protocols that enable native modeling in multi-cellular 2D and 3D cell culture



## Custom Platform for Expanding Disease and Screening Models

Expertise in homozygous and heterozygous gene modification (KO, KI, Reporters, SNP)

Licensed Engineering Methods

- CRISPR
- Zinc Finger
- TALENS



## Wide Population and Engineering-based Disease Portfolio with Isogenic Controls

Providing isogenic controls to engineered and patient-derived disease cell lines

iCell DopaNeurons	
01279	— AHN — SNCA A53T
11299 Patient Line	— LRRK2 G2019S — LRRK2 G2019S/G
11344 Patient Line	— GBA N370S — GBA N370S/N

## Access and Partnerships

Access to expansive healthy and disease donor & iPSC material



Extensive application portfolio and CRO partnerships that drive implementation and results

PhenoVista Biosciences  
*phenotypic assay services*



FUJIFILM Cellular Dynamics is the longest standing iPSC provider of apparently healthy normal (AHN) and disease models with a proven record of leadership across Industry, Regulatory, and Academic sectors.

**Our cells continue to lead the industry and drive successful drug discovery.**



# Gene Therapy Solutions

Comprehensive viral vector CDMO capabilities

## Development

- Optimized, scalable platform approaches
- Pilot scale capabilities to 500 L
- Tox & IND-enabling support studies
- Process characterization and validation
- Assay development and method optimization
- Comparability studies
- Regulatory support for IND & BLA submissions

## Manufacturing

- Multiple dedicated BSL-2 suspension production suites
- Flexible upstream and downstream processing
- Single-use technology
- Perfusion capabilities
- On-site fill/finish capabilities
- In-process, final product and stability testing
- Global regulatory track record

**Dedicated. Trusted. Proven.**

**250+** clinical batches produced

**50+** INDs supported

**7** pre-commercialization programs

**2,000 L** clinical to commercial supply

**25+** indications supported

## Therapeutic Focus

- Gene therapies
- Gene modified cell therapies
- Oncolytic viral therapies
- Viral vaccines

# Viral Vector Capabilities

Any stage. Any vector. Flexibility to support your goals.



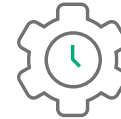
Optimized processes and proven AAV approach



Deep technical AAV experience and demonstrated tech transfer expertise



Seamless scalability up to 2,000 L



Templated documentation and ready to use materials



Validated analytical toolbox

## Preclinical to Commercial Experience

- Optimized, scalable platform approaches
- High yield suspension capabilities
- Advanced analytics: potency, purity, and characterization expertise
- Global regulatory network

## Manufacturing Capabilities



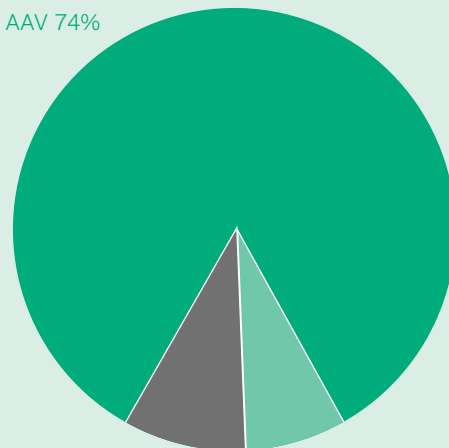
- 3 x 200 L
- 6 x 500 L
- 8 x 2,000 L



- Vials (2R to 10R)
- Batch sizes up to 3,000 units

## Technical Expertise

AAV 74%



Other viral vectors 12%

Adenovirus 11%



Viral Vectors Centers of Excellence:

- Development: UK and USA
- GMP Manufacturing: USA



Range of viral vectors: AdV, LVV, HSV, MVA / vaccinia, and more



Advanced therapies innovation center

12+

AAV serotypes: AAV1, 2, 5, 6, 8, 9, rh10 and novel capsids

# Let's discuss your science



## Cell Therapy CDMO

### ● Thousand Oaks, CA, USA

- Process & Analytical Development
- GMP Manufacturing



## iPSC Technology & Services

### ● Madison, WI, USA

- Process & Analytical Development
- GMP Manufacturing for iPSC-based Therapeutics
- Human cells derived from induced pluripotent stem cells



## Gene Therapy CDMO

### ● College Station, TX, USA

- Process & Analytical Development
- GMP Manufacturing

### ● Billingham, UK

- Process & Analytical Development



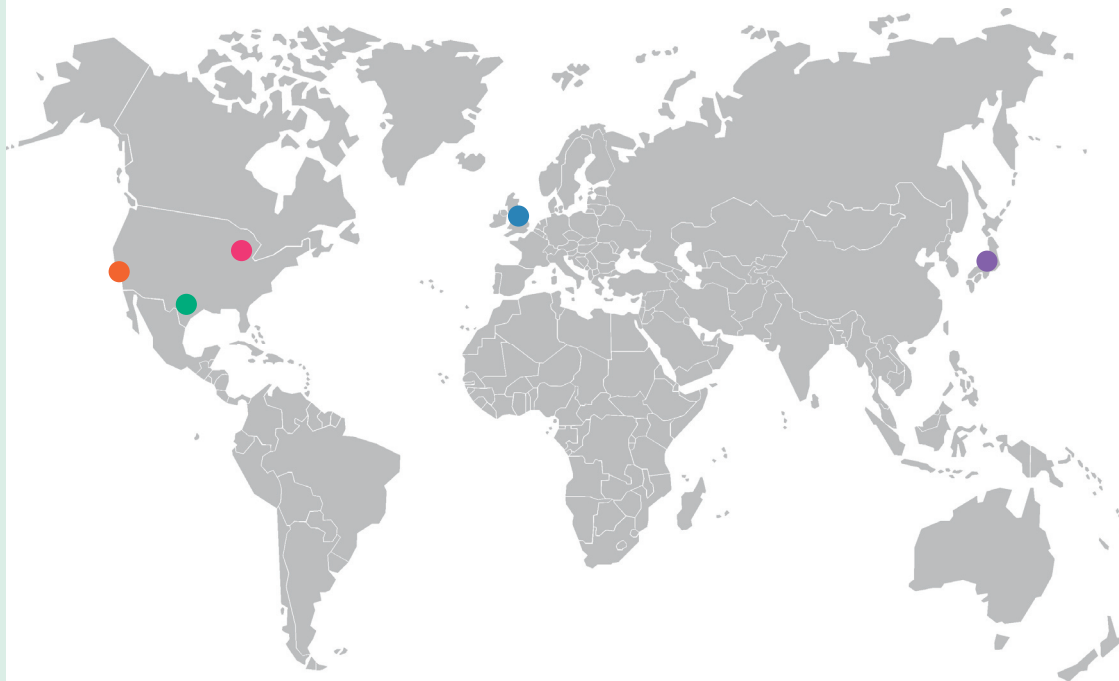
## Innovation Center

### ● Kaisei, Japan

- Innovation Center for Advanced Therapies

# kojoX™

Singular, global quality management system, procedures & modular way of working that encompasses all modalities & sites



World class advanced therapies network providing unrestricted access to key markets and supporting partners across a range of modalities

## Partners for *Life*™