

# Minaris Regenerative Medicine

Creating Future Cell Therapy Miracles Together





**VISION**

Creating future cell therapy miracles together

We commit our experience to our clients, by providing global manufacturing services, development solutions, and technologies for cell and gene therapies to improve society's well-being

**MISSION**

# Consolidation of Industry Expertise

1999

Founding of **Progenitor Cell Therapy (PCT)** as first cell therapy-focused CDMO



2016

Hitachi Chemical undergoes strategic expansion into **Regenerative Medicine Business Sector**

2018

Hitachi Chemical launches **dedicated Yokohama CDMO facility**

Sep 2020/Aug 2021

Renamed business to **Minaris Regenerative Medicine**



2007

Establishment of **apceth Biopharma** – a pioneering cell and gene therapy company



2017

Hitachi Chemical **acquires PCT and rebrands to HCATS**

**HCATS**

2019

Hitachi Chemical **acquires apceth Biopharma**

Apr 2020

Hitachi Chemical becomes a **consolidated subsidiary of Showa Denko K.K.** and changes name to **Showa Denko Materials**



# Minaris Regenerative Medicine's Global Services For Our Clients

Reaching out to patients world-wide

- **Supplying patients worldwide**
- **Region-specific regulatory expertise**
- **Access to technology and know-how**
- **Major market access across three continents**
- **More than 500 employees worldwide**



More than 30 grade B clean rooms worldwide

# Why Our Clients Choose Us

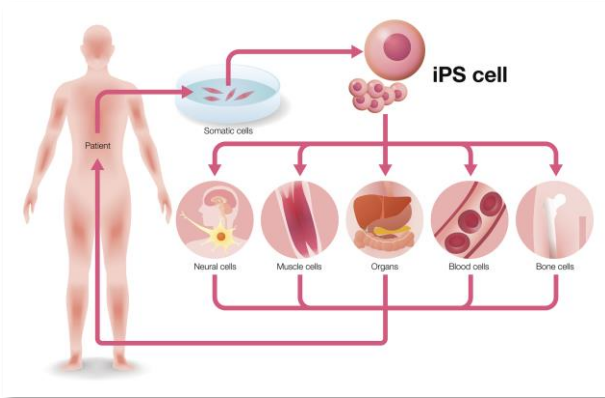
---

- Global footprint
- Outstanding quality systems and reliability
- Experience with a vast variety of cell types
  - Autologous and allogeneic
  - Genetically modified and native
  - T-Cells (CAR-T, TCRs, Tregs...)
  - TILs
  - CD34+ cells
  - Mesenchymal stem cells (MSC)
  - Hematopoietic stem cells (HSC)
  - Lymphocytes & monocytes
  - NK cells, dendritic cells
  - iPSCs technologies
- Donor material procurement in Europe
- Commercial manufacturing track record (2 commercial products to the market, 2 products under marketing review and preparing for market launch)





# Minaris iPSC Experience



- Generation of MCB/WCB from iPSC clones
- Culture, cryopreservation, long term culture and expansion of iPSCs
- Lentiviral and retroviral transduction of iPSCs and analysis for long term transgene expression.
- Analysis of genetic stability
- GMP compatibility testing for clinical supply
- Upscaling of iPSCs to bioreactors
- Characterization of starting material for iPSC generation
- Flow cytometric characterization of pluripotency
- Differentiation of iPSCs into MSCs followed by trilineage differentiation

# Expert Services and Operational Capabilities

More than 30 grade B clean rooms worldwide



## Development and Innovation

- Manufacturing process
- Analytical methods
- Consulting

## Clinical manufacturing

- Technology transfer
- Global logistics and storage
- Region-specific expertise
- Compliant to cGMP (FDA) and GMP (EMA)
- Donor material procurement EU

## Commercial manufacturing

- Regulatory support
- Transfer between regulatory environments
- In-house Qualified Person (EU)

# Stringent Quality Control and Comprehensive Quality Management System

Essential elements of our production, ensuring the quality and consistency of every batch

## Quality Control

- Identity (e.g. flow cytometry, qPCR)
- Purity (e.g. ELISA)
- Potency (cell-based potency assays, cell count and viability)
- Safety (e.g. sterility, endotoxin, mycoplasma) partly with accredited external laboratories
- Stability (ICH guidelines)

## Quality Management

- Quality-by-design concept
- Risk based approach
- Meeting regulatory standards
- And our own strict requirements



# Extensive Process Development Expertise

Vast experience with allogeneic and autologous settings as well as native and genetically modified cells

## Technologies

- 2D bioreactors
- 3D bioreactors (2L & 50L)
- Microcarriers
- Automated systems
- Closed systems
- Fill and Finish
- iPSC

## Manufacturing Development

- Cell isolation
- Cell selection & sorting
- Gene modification (viral vectors, CRISPR/Cas9)
- Cell expansion/upscaling
- Volume reduction
- Formulation
- Cryopreservation
- Process Characterization

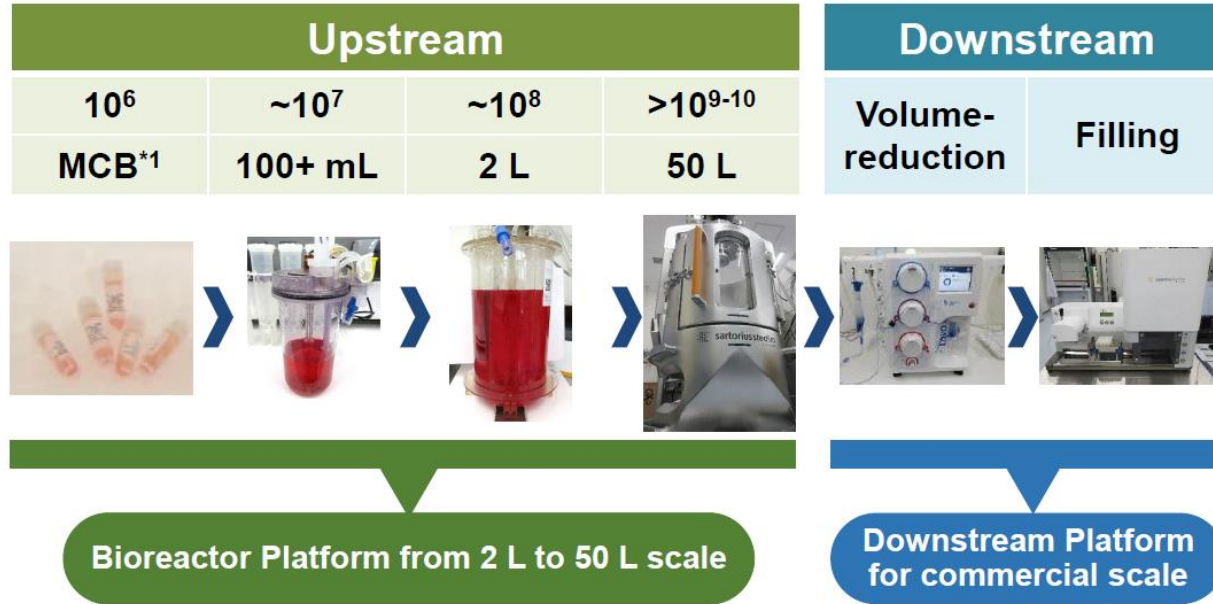
## Analytical Development

- Cell count
- Flow cytometry
- PCR technologies
- Potency assays
- ELISA
- Assay validation



# 3D 50L Bioreactor

MRJ



- Proof-of-concept: MSC with microcarrier, T-cells in suspension without microcarrier
- In-line Monitoring with perfusion system, automated High throughput filling process (about 450 vials/h) based on semi-closed process
- System could be closed and could be performed in grade C room

# Quality Assurance

---



## US facilities

---

- FDA compliant
- cGMP compliant
- EU ATMP compliant (NJ)
- QP release available

## EU facilities

---

- EU ATMP compliant
- GMP certification
- BSL2
- Clinical and commercial manufacturing authorizations
- In-house qualified persons (QP)
- Preparing for FDA compliance

## Japan facilities

---

- Manufacturing license for Regenerative Medicine
- GCTP compliant (PMDA)

# NEW: Capacity Expansion Planned to Grow for the Future of Our Clients

---

## Europe

- Greenfield expansion located 2.5 km from existing facilities
- 14 additional clean rooms
- Modular cleanroom design

## Japan

- Expansion of existing facilities
- 2 additional new cleanrooms available in 2023
- Additional cleanrooms possible depending on client demand

## North America

- Expansion of existing facilities
- Doubling our clean room capacity for late stage and commercial products

# Broad International Client Base

Small, mid-size and large biotech/pharma

---



## Clients *(selected few)*

- **GSK** (Clinical supply in US & EU)
- **Daiichi Sankyo** (Japan)
- **Bluebird Bio** (Clinical and commercial supply)
- **SanBio** (MSC in US & Japan)
- **Mustang Bio** (Clinical supply EU)
- **MaxiVax SA** (clinical supply EU)
- **Large International Pharmas**
- **NASDAQ-listed US based biotechs**
- **Biotech start-ups**

## Client Satisfaction

- Minaris builds **long lasting alliances** with its clients
- **Repeat business** - additional GMP-manufacturing projects by clients
- Positive client **testimonials and referrals**

Thank you

[www.rm.minaris.com](http://www.rm.minaris.com)

