1. Company Information

	Input Field
Company Name	Takara Bio Inc.
Address (Head Office)	Nojihigashi 7-4-38, Kusatsu, Shiga 525-0058, Japan
Location (Manufacturing Site)	Nojihigashi 7-4-38, Kusatsu, Shiga 525-0058, Japan
Business Start Year	2014
Total Number of Employees in Cell & Gene Therapy CDMO Business	100 or more
Number of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business	50 or more
Contact Information	TEL: +81-77-567-9262 CDM Business Development MAIL: nishikawasz@takara-bio.co.jp
Website	https://www.takarabio.com/
Regenerative Medicine Product Manufacturing License (Japan PMD Act)	Yes
Specific Cell-Processed Products Manufacturing License (Japan RM Safety Act)	Yes
Facility & Equipment Overview (Manufacturing Area, QC Area, Storage Area, Others)	The Center for Gene and Cell Processing (CGCP) I and II are multifunctional facilities compliant with ISO 9001 and GMP for investigational drugs. They are capable of manufacturing both drug substances and drug products of biopharmaceuticals, including regenerative / cell & gene therapy products, as well as conducting quality testing and storage. CGCP III has been selected for government subsidies for infectious disease emergencies. In the event of an emergency, it will manufacture active ingredients for viral vector vaccines and mRNA vaccines, and enzymes for use in mRNA production. In normal times, it will manufacture various viral vectors for gene therapy, mRNA active pharmaceutical ingredients, enzymes for use in mRNA production, and ancillary materials for gene therapy.
CDMO Partnership Network	1) We provide biopharmaceutical safety evaluation testing through SGS Vitrology, a UK-based company certified under GLP and GMP by the British regulatory authorities. 2) Leveraging advanced analytical technologies from U-Medico, we offer comprehensive, state-of-the-art quality testing services for viral vectors, including analytical ultracentrifugation, mass spectrometry, and particle and aggregate analysis. 3) By integrating Toshiba’s LNP design and manufacturing technologies with Takara Bio’s mRNA manufacturing capabilities, we provide end-to-end mRNA-LNP manufacturing services in Japan.

Company Strengths	At Takara Bio, we have been providing development, manufacturing, and quality testing services for regenerative/cell therapy and gene therapy products in Japan for over 20 years. In particular, for early-stage development projects, we work closely with our clients to support process and analytical method development as well as regulatory consultations with a view toward clinical trials. In recent years, we have expanded our capabilities to cover new modalities, including regenerative/cell therapy and gene therapy products, DNA/RNA vaccines, and antibody (protein-based) therapeutics, offering manufacturing and quality testing services—including viral safety evaluation testing. We are also advancing the development and manufacturing of enzymes and protein products used as raw materials for pharmaceutical production. Through these efforts, we provide a wide range of CRDMO (CRO + CDMO) services at one of the largest scales in Japan.
Company Presentation Materials	https://www.takarabio.com/services-and-support/gene-and-cell-therapy-manufacturing

2. Service Scope & Experience

Cell types & other Modalities	Experience	Capability
iPSC (Autologous/Allogeneic), ESC	Yes	No
Somatic Stem Cells (Autologous/Allogeneic)	Yes	No
Somatic Cells (Blood-derived/Tissue-derived)	Yes	No
CAR-T Cells, TCR-T Cells	Yes	No
Viral Vectors	Yes	Yes
Plasmids	Yes	Yes
mRNA	Yes	Yes

Regenerative Medicine Product Development (under Japan's PMD Act)	Experience	Capability
Process Development (Process Optimization)	Yes	Yes
Non-clinical Study (GLP) Product Manufacturing & Administration	Yes	Yes (excluding cell processing)
Clinical Trial Product Manufacturing	Yes	Yes (excluding cell processing)
Marketed Product Manufacturing & Administration	No	Yes (excluding cell processing)

Specific Cell-Processed Products Development (under Japan's RM Safety Act)	Experience	Capability
Process Development (Process Optimization)	Yes	Yes
Manufacturing for Clinical Application	Yes	No

Regulatory Approval Support in Japan	Experience	Capability
Regulatory Consulting Services for Approval Applications	Yes	Yes
Marketing Authorization Application Preparation Support	Yes	Yes
PMDA Interaction Support for Approval Applications	Yes	Yes

3. Manufacturing System & Others

	Input Field	
Representative Analytical Method Capabilities	[Cell]	
	Sterility Testing	In-house / Outsourced
	Mycoplasma Testing	In-house / Outsourced
	Endotoxin Testing	In-house
	Cell Counting & Viability Assessment	In-house
	Flow Cytometry	In-house
	[Gene]	
	Biological Activity Assay	In-house
	Infectivity Titer Assay	In-house
	Identity Testing (Viral Genome, etc.)	In-house
	Purity Testing	In-house
	Residual & Impurity Testing	In-house / Outsourced
	Others	(Free text)
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	From our investigational drug storage facility, we deliver products with shipping instructions to domestic and international medical institutions via partnered logistics providers, maintaining appropriate temperature conditions throughout transport. Transport validation can also be conducted upon request. We engage with multiple logistics companies in our CDMO business.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality System)	Established
	Quality Manual	Established
GCTP Compliance	Yes	
Experience with GCTP Compliance Inspection	Yes	
External Audit Experience	We handle approximately 20 external audits annually, primarily from domestic and international pharmaceutical companies, and have accumulated a total of around 200 audit experiences to date.	
Risk Assessment & Management	Yes	
Supply Chain Management (Including supplier evaluation and experience with client company audits)	Yes	
Experience with Import of Foreign Products (Materials, Reagents, etc.) including import procedures and communication with international suppliers	Yes	
Proprietary Regenerative Medicine Products	Yes	
Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement	Selected	