1. Company Information

	Input Field
Company Name	TEIJIN REGENET CO., LTD.
Address (Head Office)	Kasumigaseki Common Gate West Tower, 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585, Japan
Location (Manufacturing Site)	MITSUI LINK-Lab Kashiwanoha1-201, 6-2, Kashiwanoha 6-chome, Kashiwa city, Chiba 277-0882, Japan
	2-1, Hinode-cho, Iwakuni city, Yamaguchi 740-8511, Japan
Business Start Year	2023
Total Number of Employees in Cell & Gene Therapy CDMO Business	50-99
Number of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business	30-49
Contact Information	https://www.teijin-cdmo.com/form/
Website	https://www.teijin-regenet.com/en/
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)	Teijin Regenet provides seamless, one-stop support services from the early stages of research and development to commercial production at two locations: the Kashiwanoha Facility (800 m² of floor space) and the Iwakuni Factory (2,400 m²). The Kashiwanoha Facility serves as a CDO (Contract Development Organization) site, equipped with four Grade B cell culture rooms, general laboratories, storage areas and other facilities. The Iwakuni Factory functions as a CMO (Contract Manufacturing Organization) site, featuring four manufacturing rooms, one QC (Quality Control) room, general laboratories, and storage areas and other facilities. Furthermore, expansion work is underway to meet diverse needs and improve efficiency. Starting in February 2026, the facility will operate with seven manufacturing rooms and two QC rooms.
CDMO Partnership Network	Teijin Regenet, in collaboration with J-TEC, Mitsui Fudosan and the National Cancer Center Japan, has established the “Kashiwanoha Regenerative Medicine Platform”. This initiative supports the resolution of challenges faced by seed technology holders working on therapies for unmet medical needs, including assistance with clinical trial preparation. Through strategic partnerships with TFBS Bioscience Inc. and Mediridge Co., Ltd, Teijin Regenet also supports the supply of viral vectors and plasmids, essential components in advanced regenerative medicine. To foster a global collaborative framework, Teijin Regenet is actively pursuing strategic alliances with international CDMOs, including National RESILIENCE, Inc. (USA), Hilleman Laboratories (Singapore), and other overseas partners.

Company Strengths	Teijin Regenet offers comprehensive CDMO (Contract Development and Manufacturing Organization) services that cover the entire process—from research and development of regenerative medicine products to business planning and commercial manufacturing—all in a seamless, one-stop manner. Within the Teijin Group, J-TEC has a proven track record in obtaining manufacturing and marketing approvals for five regenerative medicine products, along with a history of successful product supply. Additionally, Teijin Pharma Limited holds licenses for the manufacture and sale of pharmaceuticals and medical devices. Leveraging the capabilities, technologies, and expertise of both companies, Teijin Regenet is able to provide tailored services and business proposals. As an independent entity, Teijin Regenet ensures robust security and information management systems to protect customer data. Furthermore, the company actively pursues strategic partnerships with overseas firms to support the supply of viral vectors and plasmids, which are essential for regenerative medicine, and to facilitate global expansion. These unique strengths and initiatives distinguish Teijin Regenet, enabling us to deliver services that go beyond conventional CDMO offerings.
Company Presentation Materials	Links to Non-Confidential Company PDFs

2. Service Scope & Experience

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

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

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

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	Yes	Yes

3. Manufacturing System & Others

	Input Field	
Representative Analytical Method Capabilities	[Cell]	
	Sterility Testing	In-house
	Mycoplasma Testing	In-house
	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
	Others	-
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	Through a transportation system jointly developed with our logistics partners, Teijin Regenet optimizes delivery routes and methods for each product to medical institutions. This ensures that our customers' products are reliably delivered to their designated destinations with precision and care.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality System)	Established
	Quality Manual	Established
GCTP Compliance	Yes	
Experience with GCTP Compliance Inspection	No	
External Audit Experience	Teijin Regenet has undergone PMDA inspections for the Manufacturing License for Specific Cell-Processed Products under Japan's Act on the Safety of Regenerative Medicine and the ATMP Manufacturing License under Japan's Pharmaceuticals and Medical Devices Act. In addition, we have successfully responded to various inspections from both domestic and international clients, demonstrating our commitment to compliance, quality, and transparency.	
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	No	
Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement	-	