1. Company Information

	Input Field
Company Name	Japan Tissue Engineering Co., Ltd. (J-TEC)
Address (Head Office)	6-209-1 Miyakitadori, Gamagori, Aichi 443-0022, Japan
Location (Manufacturing Site)	6-209-1 Miyakitadori, Gamagori, Aichi 443-0022, Japan
Business Start Year	2014
Total Number of Employees in Cell & Gene Therapy CDMO Business	☐Less than 20 ☑20-49 ☐50-99 ☐100 or more
Number of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business	☐Less than 10 ☑10-29 ☐30-49 ☐50 or more
Contact Information	TEL:+81-533-66-2128 MAIL: jtec-cdmo@jpte.co.jp
Website	https://www.jpte.co.jp/en/business/cdmo-cro/index.html
Regenerative Medicine Product Manufacturing License (Japan PMD Act)	☑Yes ☐No ☐Planned (within approximately 1 year)
Specific Cell-Processed Products Manufacturing License (Japan RM Safety Act)	☑Yes ☐No ☐Planned (within approximately 1 year)
Facility & Equipment Overview (Manufacturing Area, QC Area, Storage Area, Others)	The manufacturing area and the quality control (QC) area are independent zones, with completely separate Heating, Ventilation, and Air Conditioning (HVAC) systems. The manufacturing area is designed to allow simultaneous production of multiple autologous cell products. It is equipped with safety cabinets (Class 100) within a cleanroom (Class 10,000). The operational status of HVAC systems, culture equipment, and storage facilities is monitored and recorded 24 hours a day. To ensure prompt response in case of equipment malfunction, the facility is equipped with an alarm notification system and a security system that restricts access.
CDMO Partnership Network	Teijin Limited, J-TEC, Mitsui Fudosan Co., Ltd. and the National Cancer Center (NCC) have established a regenerative medicine platform in Kashiwanoha Smart City, Japan. The platform supports the development of innovative treatments for diseases with unmet needs such as cancer. It serves a one-stop system supporting research and development, business plan formulation, and commercial production of regenerativemedicine products. Overseas, Teijin and J-TEC have entered into a Letter of Intent for a global strategic collaboration with Resilience US, Inc. (Resilience) .
Company Strengths	Our company leverages its extensive experience and expertise—acquired through the development, manufacturing, and marketing of its own products—in regulatory affairs, interactions with regulatory authorities, and GCTP-compliant manufacturing facilities. These strengths enable us to provide comprehensive support throughout the entire lifecycle of cell-based products, regardless of cell type or product format—from early-stage development to post-market sales and re-examination.To date, we have completed over 230 commissioned projects under contractual agreements. Our core strengths are as follows: 1. Development and commercialization of five approved autologous products: We have developed and launched five regenerative medical products in-house, with a proven track record of providing treatment to approximately 3,000 patients. 2. Ownership of the entire value chain: We possess the necessary functions, personnel, and experience for the development, manufacturing, and marketing of regenerative medical products, including research and development, clinical development, regulatory affairs, manufacturing, quality assurance, and sales. 3. Incorporating clinical feedback into product development (reverse translational research): Based on our experience working closely with physicians who use our products, we have established a system that reflects clinical insights into product design and development processes to optimize outcomes. A proper firewall is maintained between our in-house product development and our CDMO (Contract Development and Manufacturing Organization) business.
Company Presentation Materials	Links to Non-Confidential Company PDFs

2. Service Scope & Experience

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

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

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

Regulatory Approval Support in Japan	Experience	Capability
Regulatory Consulting Services for Approval Applications	☑Yes	☑Yes ☐No
Marketing Authorization Application Preparation Support	☑Yes	☑Yes ☐No
PMDA Interaction Support for Approval Applications	☑Yes	☑Yes ☐No

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 ☐Outsourced
	Cell Counting & Viability Assessment	☑In-house ☐Outsourced
	Flow Cytometry	☑In-house ☐Outsourced
	[Gene]	
	Biological Activity Assay	☐In-house ☑Outsourced
	Infectivity Titer Assay	☐In-house ☑Outsourced
	Identity Testing (Viral Genome, etc.)	☐In-house ☑Outsourced
	Purity Testing	☐In-house ☑Outsourced
	Residual & Impurity Testing	☐In-house ☑Outsourced
	Others	—
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	Our company introduces customers to experienced transportation providers with whom we have an established track record. Through close collaboration among the customer, the transportation company, and our company, we build the most suitable transportation solutions.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality System)	☑Established ☐Not established ☐Planned within approximately 1 year
	Quality Manual	☑Established ☐Not established ☐Planned within approximately 1 year
GCTP Compliance	☑Yes ☐No	
Experience with GCTP Compliance Inspection	☑Yes ☐No	
External Audit Experience	Our company has experience responding to compliance inspections (on-site investigations) conducted by regulatory authorities. We have undergone nine inspections based on the Pharmaceutical and Medical Device Act since 2007, and two inspections based on the Act on the Safety of Regenerative Medicine since 2015. In addition, we have experienced two document-only inspections (without on-site visits). We have been found to be fully compliant in all cases.	
Risk Assessment & Management	☑Yes ☐No	
Supply Chain Management (Including supplier evaluation and experience with client company audits)	☑Yes ☐No	
Experience with Import of Foreign Products (Materials, Reagents, etc.) including import procedures and communication with international suppliers	☑Yes ☐No	
Proprietary Regenerative Medicine Products	☑Yes ☐No	
Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement	☐ Selected	