Company Name Address (Head Office) - C292-1 Myakidadori, Camagori, Alaki 43-0022, Japan Lication (Manufacturing Site) - C292-1 Myakidadori, Camagori, Alaki 43-0022, Japan Lication (Manufacturing Site) - C292-1 Myakidadori, Camagori, Alaki 43-0022, Japan Lication (Manufacturing Site) - C292-1 Myakidadori, Camagori, Alaki 443-0022, Japan - Camagori, Marchi 444-002 - Camagori, Marchi 444-002 - Camagori, Marchi 444-002 - Camagori, March	1. Company Information	Input Field	
Address (Head Office) Location (Manufacturing Site) 6-209-1 Mywikitadori, Gamagori, Aichi 443-0022, Japan Location (Manufacturing Departments for Cell & Gene Therapy CDMO Business Mumber of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business  Contact Information  MELI: tec-cdmo@tyte.co.jp  Mobile Regenerative Medicine Product Manufacturing License (Japan PMD Act)  Specific Cell-Processed Products Manufacturing License (Japan PMD Act)  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 and the quality control (QC) area are independent zones, with completely separate Heating, Ventilation, and Air Conditioning (HVAC) systems.  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 cabines (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 maifunction, the facility is equipped with an alarm notion products.  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 maifunction, the facility is equipped with an alarm notion is ror disease.  Teljin Limited, 3-TEC, Milesui Fudosan Co., Ltd. and the National Cancer Center (NCC) have established a regenerative medicine pitatom in Kashiwanoha Smart City, Japan. The platform supports the development of regulatory fariaris, interactions with regulatory ariaris, interactions with regulatory ariaris, interactions with regulatory ariaris, increactions with regulatory ariaris, increactions with r	Company Name		
Location (Manufacturing Site)  Business Start Year  2014  Total Number of Employees in 6el & Gene  Chrespy CDMO Business  Number of Employees in R&O and Manufacturing Departments for Cell & Gene Therapy CDMO Business  Contact Information  TEL:+81-533-66-2128  MAIL: (tec-domo@pite.co.ip)  Mebaite  Regenerative Medicine Product Manufacturing Decense (Japan RM Safety Act)  The manufacturing area and the quality control (QC) area are independent zones, with completely separate Heating, Ventilation, and Air Conditioning (HAC) systems.  The manufacturing area is designed to allow simultaneous production of multiple autologous cell products. It is equipped with safety calculation of multiple autologous cell products. It is equipped with safety calculation of multiple autologous cell products. It is equipped with safety calculation of multiple autologous cell products. It is equipped with safety calculation of multiple autologous cell products. It is equipped with safety cabinets (Calculation) (Calcula			
Business Start Year Total Number of Employees in Real and Manufacturing Departments for Cell & Gene Therapy CDMO Business Contact Information Malt; rec-cdmo@jpte.co.jp Mebate Regenerative Medicine Product Manufacturing License (Japan PMD Act) Specific Cell-Processed Products Manufacturing License (Japan PMD Act) 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 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 autologues 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.  Teijin Limited, 3-TEC, Mitsui Fudosan Co., Ltd. and the National Cancer Center (NCC) have established a regenerative medicine platform in Kashiwannha Smart City, Japan. The platform supports the development of innovative treatments for clisases with unmant needs such as cancer. It serves a one-stop system supporting research and development, pusiness for disease map production of regenerative medicine platform in Kashiwannha Smart City, Japan. The platform supports the development of innovative treatments for clisases with a malarm nether of the platform of the development of the platform of the pla	, ,		
Total Number of Employees in Cell & Gene Diseases Number of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business  Contact Information  Elected Haman Section of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business  Contact Information  TEL:+81-533-66-2128 MAIL: jtec-cdmo@pipte.co.jbp  Regenerative Medicine Product Manufacturing Decesses (Japan PMD Act)  Specific Cell-Processed Products Manufacturing Decesses (Japan PMD Act)  The manufacturing area and the quality control (QC) area are independent zones, with completely separate Heating, Ventilation, and Air Conditioning (HrAC) 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.  Teljin Limited, J-TEC, Mitsui Fudosan Co., Ltd. and the National Cancer Center (NCC) have established a regenerative medicine platform in Kashiwanoab Smart City, Japan. The platform supports the development of business plan formulation, and commercial products on repearerative medicine products.  Overseas, Teljin and J-TEC have entered into a Letter of Intent for a global strategic collaboration with Resilience US, Inc. (Resilience) .  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 Cell-based products, regardless of cell bype or products in-froness, with a provent randcurring and marketing of revokuts in house, with a provent randcurring and marketing of reporture in fevy, with a provent rack record of providing treatment to approxima			
Departments for Cell & Gene Therapy CDMO Business  Contact Information  MalL: (sec-demo@)pte.co.)p  Website  Regenerative Medicine Product Manufacturing  Decense (Japan PMD Act)  Drocessed Products Manufacturing  Decense (Japan RM Safety Act)  The manufacturing area and the quality control (CC) area are independent zones, with completely separate Heating, Ventilation, and Air Conditioning (HVAC) systems.  The manufacturing area and the quality control (CC) 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.  Teijin Limited, 3-TEC, Mitsui Fudosan Co., Ltd. and the National Cancer Center (NCC) have established a regenerative medicine platform in Rashiwanoba Smarta (TC), Japan: The piletform supports tine development of innovative treatments for diseases with unnet needs such as cancer. It serves a one-stop system supporting research and development, business plan formulation, and commercial products of regenerative medicine products.  Overseas, Teijin and J-TEC have entered into a Letter of Intent for a global strategic collaboration with Resilience US, Inc. (Resilience).  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 GCP. The opital manufacturing and marketing of products in Probuse, with a provent race of laye or product format—from early-stage development to post-market sales and re-examination. To date, we have compl	Total Number of Employees in Cell & Gene	□Less than 20 ☑20-49 □50-99 □100 or more	
Mebsite Regenerative Medicine Product Manufacturing Dicense (Japan PMD Act) Dicense (Japan PMD Act) Dicense (Japan PMD Act)  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 100, With) 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 maffunction, the facility is equipped with a later of monitored and recorded 24 hours a day. To ensure prompt response in case of equipment maffunction, the facility is equipped with an alarm notification system and a security system that restricts access.  Teijin Limited, 3-TEC, Mitsul 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-story system supporting research and development, business plan formulation, and commercial production of regenerative-medicine products.  Overseas, Teijin and 3-TEC have entered into a Letter of Intent for a global strategic collaboration with Resilience US, Inc. (Resilience).  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 and marketing of its own products—in regulatory affairs, interactions with regulatory authorities, and GCTP-compliant manufacturing and marketing of regenerative medical products in-house, with a proven track record of providing treatment to approximately 3,000 pastiens.  Our core strengths are as follows:  1. Developme	Departments for Cell & Gene Therapy CDMO		
Regenerative Medicine Product Manufacturing License (Japan RM Safety Act)  Description Cell-Processed Products Manufacturing Description Cell-Processed Products Description Cell-Processed Products Description Cell-Processed Products Description Cell-Processed Processed Products Description Cell-Processed Processed			
Regenerative Medicine Product Manufacturing License (Japan RM Safety Act)  Description Cell-Processed Products Manufacturing Description Cell-Processed Products Description Cell-Processed Products Description Cell-Processed Products Description Cell-Processed Processed Products Description Cell-Processed Processed	Website	https://www.jpte.co.jp/en/business/cdmo-cro/index.html	
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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) .  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, 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 treverse 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 Manufacturing Organization) b		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	
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Company Presentation Materials Links to Non-Confidential Company PDFs	Company Strengths	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	
	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	
Developer Assessed Consent in James	Considerate	Completition	
Regulatory Approval Support in Japan Regulatory Consulting Services for Approval	Experience	Capability	
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		
	[Cell]		
	Sterility Testing	☑In-house □Outsourced	
	Mycoplasma Testing	☑In-house □Outsourced	
	Endotoxin Testing Cell Counting & Viability	☑In-house □Outsourced	
	Assessment Flow Cytometry	☑In-house □Outsourced ☑In-house □Outsourced	
Representative Analytical Method Capabilities	[Gene]	Em nouse Eoutsburged	
	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	<u> -</u>	
Transportation Services Details & Experience (Inhouse/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		

☐ Selected

Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement