1. Company Information

	Input Field
Company Name	TAIYO Pharma Tech Co., Ltd.
Address (Head Office)	4-38,Aketa-cho, Takatsuki-Shi, Osaka 569-0806, Japan
Location (Manufacturing Site)	4-38,Aketa-cho, Takatsuki-Shi, Osaka 569-0806, Japan
Business Start Year	2019
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: +81-72-682-1181 Business Development Section, Management Strategy Department
Website	https://www.taiyo-pt.co.jp/en/business/modality.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)	Both of our cell processing facility (CPF) and gene therapy product manufacturing area comply with PIC/S GMP. The CPF has two separate rooms, and each room has a Grade A safety cabinet installed inside a Grade B clean room. The gene therapy product manufacturing area also has two separate rooms. Each of these rooms is equipped with single-use equipment for 200-liter suspension cultures in a Grade C clean room. In both areas, temperature, humidity, dust and other environmental factors are continuously monitored and recorded 24 hours a day.
CDMO Partnership Network	Synplogen Co., Ltd., Cyfuse Biomedical K.K., Gene Therapy Research Institution Co.,
Company Strengths	Our company has extensive experience in manufacturing aseptic injectable products and has complied with both PMDA and PIC/S GMP. In addition, we have successfully passed several inspections by healthcare authorities without any critical observations. For the manufacturing of regenerative medicine and gene therapy products, we have established facilities that meet both GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice) and PIC/S GMP. With the quality management system (QMS) we have developed through our experience in aseptic manufacturing, we produce regenerative medicine and gene therapy products in compliance with GMP. Our operators receive dedicated training in GMP aseptic injectable manufacturing background. In addition to this, with specific manufacturing techniques training for regenerative medicine and gene therapy, our team maintain stable and consistent production. Based on our knowledge and experience with aseptic injectable products, we are committed to supply high-quality regenerative and gene therapy products.
Company Presentation Materials	-

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	**In-house:** Compendial tests (Our expertise in analytical testing for the Japanese Pharmacopoeia, developed through our solid oral and injectable formulation manufacturing operations, enables us to support release testing in the field of gene therapy as well.) We can perform partially of the above-mentioned identity and purity tests as well. **Outsourced:** Some of the above-mentioned identity and purity tests are performed by our external partners.
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	-	
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	We have undergone inspections by PMDA, Osaka Prefecture Pharmaceutical Affairs Division, Ibaraki Health Center of Osaka Prefecture, and our customer Pharmaceutical companies.	
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	