1. Company Information

	Input Field
Company Name	PharmaBio Corporation
Address (Head Office)	Life Innovation Center, 3-25-22, Tonomachi, Kawasaki-Ku, Kawasaki,
Location (Manufacturing Site)	Life Innovation Center, 3-25-22, Tonomachi, Kawasaki-Ku, Kawasaki,
Business Start Year	2011
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	info@pharmabio.co.jp
Website	https://www.pharmabio.co.jp/
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)	We are located adjacent to Haneda International Airport, making it an ideal site for the transportation of regenerative medical products. Within our 1,500-square-meter premises, we have established facilities that allow in-house operations from manufacturing to shipment. These include a manufacturing area (10 Cell Prpcessing Rooms), a quality control area (capable of conducting tests required for shipment decisions), a storage area, and a development area. We have also established a quality assurance system compliant with GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice).
CDMO Partnership Network	A2 Healthcare Corporation (A2) A2 is a Contract Research Organization (CRO) that plays a central role in the healthcare division of the Itochu Group. Through our partnership with A2 in the field of regenerative medicine, we contribute the accelerated development of regenerative medicine products.
Company Strengths	We have been engaged in the CDMO business for over 10 years and have established a robust team of experts in medicine, pharmaceuticals, clinical development, and quality engineering. By responding to the diverse needs of domestic and international clients, we have contributed to the advancement of the field of regenerative medicine. Additionally, based on the knowledge and experience gained through our CDMO business, we have also expanded into the drug discovery business. Currently, we are taking on the challenge of novel drug discoveries in regenerative medicine, leveraging our unique cell sheet manufacturing technology as our strength. [Results of CDMO Business] -Outsourcing agreement signed with a global pharmaceutical company -Other contract achievements with several domestic companies [Strengths and Progress in Drug Discovery Business] -Unique Cell Sheet Manufacturing Technology: Overcoming the fragility of conventional cell sheets, our product has significantly improved functionality, shape memory, and adhesion rate. Since the cell sheets are composed solely of collagen produced by the cells themselves, immune reactions are minimized, ensuring high safety. -Development Achievements of Regenerative Medicine Product: Currently conducting Phase 1/2a clinical trials with two studies in the ophthalmology field and one study in dermatology. GMP certification for investigational drugs has been obtained, enabling the supply of produnts for overseas clinical trials.
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	(Free text)
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	(Free text)	
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 experience undergoing GMP inspections for investigational products, and other external audits conducted by both domestic and global 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	