1. Company Information

	Input Field
Company Name	REPROCELL Inc.
Address (Head Office)	MetLife Shin-yokohama Bldg. 9F, 3-8-11 Shin-yokohama, Kohoku-ku, Yokohama, Kanagawa 222-0033, Japan
Location (Manufacturing Site)	3-25-22 Tono-machi, Kawasaki-ku, Kawasaki, Kanagawa 210-0821
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	+81454753887
Website	https://www.reprocell.com/
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 facility has a manufacturing license for specific cell processing products, and it has two cell culture rooms as a cleanliness controlled area (Grade B) and one cleanroom for compounding and packaging. The facility is not equipped with testing and inspection facilities, and it is premised on outsourcing all in-process control tests, safety tests, environmental bacteria identification tests, etc. The storage area is equipped with liquid nitrogen tanks, freezers, and refrigerators in Grade C support areas and general areas, making it possible to store products at various temperature ranges.
CDMO Partnership Network	We have partnerships with BioBridge Global (USA), Histocell (Spain), and Texcell (France).
Company Strengths	We have diverse development pipelines, including iPSC establishment, differentiation induction, mesenchymal stem cells, and cancer immunotherapy. This allows us to provide seamless services from technology transfer to manufacturing. In addition, we have extensive experience collaborating with third parties on services such as virus safety testing, enabling us to offer one-stop services from manufacturing to quality control.
Company Presentation Materials	N/A

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.)	Transportation services/track record (in-house/outsourced, temperature control, international transport, etc. free description) For manufactured products, we can coordinate transportation with a third-party transportation service or store them at an external facility.	
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 with external inspections from domestic 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	