1. Company Information

	Input Field
Company Name	Alfresa Holdings Corporation / Cell Resources Corporation
Address (Head Office)	101-8512 7 Kanda Mitoshirocho, Chiyoda-ku, Tokyo
Location (Manufacturing Site)	9630551 15-1 Aza-Matsugasaku Kikutamachi, Koriyama, Fukushima 2100821 3-25-22 Tonomachi Kawasaki-ku, Kawasaki, Kanagawa
Business Start Year	2024
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: 0355777291 Corporate Planning Dept. MAIL: akira-suzuki@cellresources.co.jp
Website	https://cellresources.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)	Koriyama CPC: 2 rooms for Manufacturing Area, 1 room for QC Area, 1 room for Storage Area Tonomachi CPC: 1 room for Manufacturing Area, 1 room for QC Area, 1 room for Storage Area
CDMO Partnership Network	No
Company Strengths	We work on installing automated equipments, and we have published business partnerships with Miltenyi and Thermo Fisher installing their equipments
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.)	N/A	
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	Experienced of inspections by PMDA and a local Breau of Health and Welfare to obtain business licenses for Manufacturing License for Specific Cell-Processed Products under Japan's Act on the Safety of Regenerative Medicine	
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	