1. Company Information

	Input Field
Company Name	CellSource Co., Ltd.
Address (Head Office)	11F SHIBUYA CAST, 1-23-21 Shibuya, Shibuya-ku, Tokyo 150-0002, Japan
Location (Manufacturing Site)	Haneda Global CPC, Life Innovation Center, 3-25-22 Tonomachi, Kawasaki-ku, Kawasaki, Kanagawa 210-0821, Japan
Business Start Year	30 November 2015
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	CellSource Co., Ltd. Executive Officer and General Manager of CPC Division Futa Asada Email: asada@cellsource.jp
Website	https://www.cellsource.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 operate a Cell Processing Center (CPC) holding a Manufacturing License for Specific Cell-Processed Products, dedicated to supporting high-quality regenerative medicine. Our CPC features a hygienically controlled manufacturing area, a quality control and testing area for rigorous evaluation, and a temperature-controlled cell storage area. Through our strict safety management system and advanced technology, we meet the diverse needs of medical and research institutions by delivering safe and reliable processed cell products.
CDMO Partnership Network	Undisclosed
Company Strengths	Located in the Life Innovation Center at KING SKYFRONT—a National Strategic Special Zone—our licensed CPC boasts an extensive track record in contract manufacturing, including the cultivation of adipose-derived stem cells. Supported by a rigorous quality control system ensuring high safety standards, we also offer dedicated assistance for the implementation of regenerative medicine, providing comprehensive support with regulatory applications and compliance.
Company Presentation Materials	None

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.)	We choose optimal transport methods and temperature control measures based on the specific characteristics and conditions of each product and service. Safety and reliability remain our highest priorities in every delivery.	
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	Yes (PMDA on-site inspections for new application and renewal of Manufacturing License for Specific Cell-Processed Products: 3 times in total / Shibuya Facility: 2, Tonomachi Facility: 1)	
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	