1. Company Information

	Input Field
Company Name	H.U.Cells, Inc.
Address (Head Office)	50 Fuchigami, Akiruno, Tokyo, Japan
Location (Manufacturing Site)	24-7 Hirai, Hinode-cho, Nishitama-gun, Tokyo, Japan
Business Start Year	2023
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	+81-80-2174-1930 SRL, Inc. Research & Development Division
Website	https://www.hucells.com/en/index.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)	Two manufacturing areas, one QC area, one storage area, and one materials area.
CDMO Partnership Network	H.U. Group Holdings, Inc. encompasses group companies such as Fujirebio Inc. (including shared raw material operations) and SRL, Inc. H.U. Group also operates H.U. Cells, Inc., which functions as a manufacturing hub and coordinates projects for external clients.
Company Strengths	H.U. Group Holdings, Inc., the parent company, comprises core businesses spanning three major domains: Lab Testing and related Services (LTS), In Vitro Diagnostics (IVD), and Healthcare-related Services (HS). Through seamless collaboration across its group companies and integrated research and development, H.U. Group continues to drive innovation. Building on its foundation in clinical laboratory testing—ranging from the development of novel testing technologies and automation support, to a customer base that includes major core hospitals (with an 80% market share) and an associated transport network—H.U. Group also contributes to the advancement of regenerative medicine.
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	☐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 ■Cannot undertake
	Infectivity Titer Assay	☐In-house ☐Outsourced ■Cannot undertake
	Identity Testing (Viral Genome, etc.)	☐In-house ☐Outsourced ■Cannot undertake
	Purity Testing	☐In-house ☐Outsourced ■Cannot undertake
	Residual & Impurity Testing	☐In-house ☐Outsourced ■Cannot undertake
	Others	In-house: Specialized testing by our group company SRL, such as karyotyping. Outsourced: Viral exclusion testing, including in vivo studies and electron microscopy.
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	Medisket Co., Ltd. (https://www.medisket.co.jp/company/profile/), a member of the HU Group Holdings, provides transportation services for clinical and investigational specimens related to cell-processed products regulated under the Pharmaceuticals and Medical Devices Act (PMD Act) and the Act on Ensuring the Safety of Regenerative Medicine.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality System)	■Established ☐Not established ☐Planned within approximately 1
	Quality Manual	■Established ☐Not established ☐Planned within approximately 1
GCTP Compliance	■Yes ☐No	
Experience with GCTP Compliance Inspection	☐Yes ■No	
External Audit Experience	On-site inspection related to Manufacturing License for Specific Cell-Processed Products by PMDA	
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	Not a selected business operator	