1. Company Information

	Input Field
Company Name	ROHTO Pharmaceutical Co., Ltd.
Address (Head Office)	1-8-1 Tatsuminishi, Ikuno-ku, Osaka 544-8666, Japan
Location (Manufacturing Site)	Kyoto Facility (Cell Factory Kyoto): 6-5-4 Kunimidai, Kizugawa, Kyoto 619-0216, Japan Tokyo Facility (ROHTO Stem Cell Processing Center Tokyo): TIME24 Bldg. 1F 2-4-32, Aomi, Koutou-ku, Tokyo 135-0064, Japan
Business Start Year	2020
Total Number of Employees in Cell & Gene Therapy CDMO Business	100 or more
Number of Employees in R&D and Manufacturing Departments for Cell & Gene Therapy CDMO Business	50 or more
Contact Information	E-mail : rm-cdmo_info@rohto.co.jp
Website	https://www.rohto.co.jp/global/company/business/#cdmo
Regenerative Medicine Product Manufacturing License (Japan PMD Act)	Yes
Specific Cell-Processed Products Manufacturing License (Japan RM Safety Act)	Yes
Facility & Equipment Overview (Manufacturing Area, QC Area, Storage Area, Others)	There are three CDMO-related facilities: Cell Factory Kyoto, ROHTO Stem Cell Processing Center Tokyo, and Rohto Cross Innovation Lab (CPC under construction). All facilities have manufacturing areas for cell products, QC areas, and storage areas. Additionally, there is a separate facility for the development and manufacturing of media tailored to user requirements, which is a feature of ROHTO CDMO.
CDMO Partnership Network	Except for some testing and inspection, all CDMO operations utilize in-house resources.
Company Strengths	In ROHTO’s regenerative medicine, media, detachment solutions, tissue transport solutions, and tissue dispersion enzyme solutions used for the development and manufacturing of cell products are all self-developed and manufactured at their own factories. This strength is also applied to CDMO business, supporting the development and manufacturing of media and other solutions according to the client’s needs, allowing for joint pursuit of the required cell performance. Furthermore, they leverage the knowledge, technology, and know-how cultivated through their own product development to support a wide range from formulation development to clinical trial product manufacturing and non-clinical or regulatory application support for CDMO clients.
Company Presentation Materials	https://www.rohto.co.jp/global/ir/news/

2. Service Scope & Experience

Cell types & other Modalities	Experience	Capability
iPSC (Autologous/Allogeneic), ESC	No	Yes
Somatic Stem Cells (Autologous/Allogeneic)	Yes	Yes
Somatic Cells (Blood-derived/Tissue-derived)	No	Yes
CAR-T Cells, TCR-T Cells	No	No
Viral Vectors	No	No
Plasmids	No	No
mRNA	No	No

Regenerative Medicine Product Development (under Japan's PMD Act)	Experience	Capability
Process Development (Process Optimization)	Yes	Yes
Non-clinical Study (GLP) Product Manufacturing & Administration	Yes	Yes
Clinical Trial Product Manufacturing	Yes	Yes
Marketed Product Manufacturing & Administration	No	Yes

Specific Cell-Processed Products Development (under Japan's RM Safety Act)	Experience	Capability
Process Development (Process Optimization)	Yes	Yes
Manufacturing for Clinical Application	Yes	Yes

Regulatory Approval Support in Japan	Experience	Capability
Regulatory Consulting Services for Approval Applications	Yes	Yes
Marketing Authorization Application Preparation Support	No	Yes
PMDA Interaction Support for Approval	Yes	Yes

3. Manufacturing System & Others

	Input Field	
Representative Analytical Method Capabilities	[Cell]	
	Sterility Testing	In-house
	Mycoplasma Testing	In-house / Outsourced
	Endotoxin Testing	In-house
	Cell Counting & Viability Assessment	In-house
	Flow Cytometry	In-house
	[Gene]	
	Biological Activity Assay	Outsourced
	Infectivity Titer Assay	Outsourced
	Identity Testing (Viral Genome,	Outsourced
	Purity Testing	Outsourced
	Residual & Impurity Testing	Outsourced
	Others	Virus Testing: Outsourced
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	Capable of packaging products using equipment that maintains ultra-low temperature, and shipping in cooling containers using external transport agencies.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality	Established
	Quality Manual	Established
GCTP Compliance	Yes	
Experience with GCTP Compliance Inspection	No	
External Audit Experience	ATMP Manufacturing License under Japan's Pharmaceuticals and Medical Devices Act (PMD Act): PMDA Manufacturing License for Specific Cell-Processed Products under Japan's Act on the Safety of Regenerative Medicine: PMDA, Kyoto Pharmaceutical Affairs Division	
Risk Assessment & Management	Yes	
Supply Chain Management (Including supplier evaluation and experience with client company audits)	Yes	
Experience with Import of Foreign Products (Materials, Reagents, etc.) including import procedures and communication with international suppliers	Yes	
Proprietary Regenerative Medicine Products	Yes	
Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement	Not selected	