1. Company Information

	Input Field
Company Name	S-RACMO Co.,Ltd.
Address (Head Office)	33-94, Enoki-cho, Suita, Osaka, Japan
Location (Manufacturing Site)	33-94, Enoki-cho, Suita, Osaka, 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	ml-contact@s-racmo.co.jp
Website	https://www.s-racmo.co.jp/
Regenerative Medicine Product Manufacturing License (Japan PMD Act)	Yes
Specific Cell-Processed Products Manufacturing License (Japan RM Safety Act)	No
Facility & Equipment Overview (Manufacturing Area, QC Area, Storage Area, Others)	We are currently operating two CPC (Cell Processing Centers), with plans to commence operations of a third facility within 2025. By staggering the scheduled maintenance periods for each CPC, we aim to ensure continuous manufacturing and product release throughout the year. Our manufacturing area is equipped with safety cabinets, incubators, centrifuges, and microscopes under Grade B cleanroom conditions, while isolators are installed in Grade C environments. The storage area is furnished with refrigerators, freezers (-30°C, -80° C, and -150°C), programmable freezers, and cryogenic storage tanks for cell preservation. We also maintain multiple warehouses for raw materials and finished products. In our QC laboratory, we have established facilities and equipment for physicochemical testing, biochemical assays, cell-based assays, and microbiological testing, including fluorescence microscopes, flow cytometers, and plate readers, among others.
CDMO Partnership Network	Non-disclosure
Company Strengths	Our company possesses advanced expertise in process development and manufacturing, cultivated through our experience at Sumitomo Chemical and Sumitomo Pharma. We have a proven track record in the manufacture of a wide range of cell types, including iPS cells, somatic stem cells, somatic cells, donor-derived cells, and patient-derived cells. We offer contract manufacturing services for products at all stages of development, including commercial products, investigational products for clinical trials, and materials for non-clinical studies. Leveraging our experience at Sumitomo Pharma, we also provide support for regulatory interactions with authorities such as the Pharmaceuticals and Medical Devices Agency (PMDA) and the U.S. Food and Drug Administration (FDA), including CMC regulatory consulting and assistance with regulatory submissions. In addition, we have established expertise and a proven track record in exporting products manufactured in Japan to the United States. We are also considering the utilization of Sumitomo Pharma's manufacturing facility, the CPC in North Carolina, as an overseas production site. We are currently building a framework that enables seamless manufacturing and product release in both Japan and the United States.
Company Presentation Materials	https://www.s-racmo.co.jp/

2. Service Scope & Experience

Cell types & other Modalities	Experience	Capability
iPSC (Autologous/Allogeneic), ESC	Yes	Yes

Somatic Stem Cells (Autologous/Allogeneic)	Yes	Yes
Somatic Cells (Blood-derived/Tissue-derived)	Yes	Yes
CAR-T Cells, TCR-T Cells	No	Yes
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	Yes	Yes

Specific Cell-Processed Products Development (under Japan's RM Safety Act)	Experience	Capability
Process Development (Process Optimization)	No	Yes
Manufacturing for Clinical Application	No	Yes

Regulatory Approval Support in Japan	Experience	Capability
Regulatory Consulting Services for Approval Applications	Yes	Yes
Marketing Authorization Application Preparation Support	Yes	Yes
PMDA Interaction Support for Approval	Yes	Yes

3. Manufacturing System & Others

	Input Field	
Representative Analytical Method Capabilities	[Cell]	
	Sterility Testing	In-house & Outsourced
	Mycoplasma Testing	In-house
	Endotoxin Testing	In-house
	Cell Counting & Viability Assay	In-house
	Flow Cytometry	In-house
	[Gene]	
	Biological Activity Assay	In-house
	Infectivity Titer Assay	Outsourced
	Identity Testing (Viral Genome, etc.)	In-house & Outsourced
	Purity Testing	In-house
	Residual & Impurity Testing	In-house & Outsourced
	Others	
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	Through collaboration with external partners, we are building a global logistics framework for the transportation of commercial and clinical trial products. We also have a proven track record of transporting non-frozen cell products within Japan and to the United States.	
Quality Assurance System (PQS System & Operation Status)	PQS (Pharmaceutical Quality System)	Established
	Quality Manual	Established
GCTP Compliance	Yes	
Experience with GCTP Compliance Inspection	Yes	
External Audit Experience	In accordance with the Pharmaceuticals and Medical Devices Act (PMD Act), our company underwent a compliance inspection conducted by the PMDA and was granted compliance status in 2023.	
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	No
Biopharmaceutical Manufacturing Base Development Project for Vaccine Production Capacity Enhancement	No