1. Company Information

	Input Field
Company Name	Minaris Advanced Therapies Co., Ltd.
Address (Head Office)	#1, Shibusawa Bldg, 1, Ebisu-chou, Kanagawa-ku, Yokohama-shi, Kanagawa 221-0024, Japan
Location (Manufacturing Site)	#1, Shibusawa Bldg, 1, Ebisu-chou, Kanagawa-ku, Yokohama-shi, Kanagawa 221-0024, Japan
Business Start Year	2017
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	TEL: +81-45-620-9280　Business Development Department MAIL: mrj_contact@rm.minaris.com
Website	https://minaris.com/
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)	The manufacturing site covers approximately 9,000 square meters and houses six Grade B cleanrooms. Our quality testing facilities are equipped to perform most standard tests for cell therapy products in-house, including rapid sterility testing using systems such as BACT/ALERT. The storage area includes five large liquid nitrogen tanks, providing sufficient capacity for commercial-scale manufacturing. Additionally, there are three development rooms available for process and analytical method development. We also have an unutilized area of over 3,000 square meters, which can be expanded in the future to meet customer needs.
CDMO Partnership Network	Our company is headquartered in the United States and has group companies in Europe, operating more than 60 cleanrooms worldwide. In addition to being a CDMO for cell-based therapies, we also provide testing service and development, manufacturing for viral vectors. To provide our clients with a “Total Supply Chain as a Service”, we have formed a strategic partnership with Alfresa Holdings Corporation and Cell Resources Corporation. Other key partners include: VectorBuilder Inc. and TFBS Bioscience Inc. (vector CDMO) Myoridge Co., Ltd. (media development and optimization) Cryoport Systems, LLC (cell product transportation) Locus Cell Co., Ltd. (cell therapy CDMO in Taiwan) Cell Tech Innovation Venture Studio Co., Ltd. (accelerator based in Taiwan)

	Input Field
Company Strengths	Our group operates sites in Japan, the United States, and Europe, and serves as a CDMO with commercial manufacturing experience in each of these markets for cell therapy products. We have successfully undergone inspections by the FDA, EMA, and PMDA as part of the regulatory approval processes in each region. Representative achievements include the commercial manufacturing of CAR-T and MSC products in Japan, LYFGENIA by bluebird bio and AMTAGVI by Iovance Biotherapeutics in the United States, and SKYSONA and ZYNTEGLO by bluebird bio in Europe. We also support smooth global technology transfers between our international sites, helping clients reduce lead times and costs for overseas expansion. Our Japan site is located in Yokohama, offering excellent access by both land and air. This enables faster delivery of products to patients and shorter lead times for sample transportation and processing. We also possess our own large-scale cultivation technology platform, including 3D bioreactors with capacities up to 50 liters.
Company Presentation Materials	-

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)	No	Yes
CAR-T Cells, TCR-T Cells	Yes	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	No
Manufacturing for Clinical Application	No	No

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 Applications	Yes	Yes

3. Manufacturing System & Others

	Input Field	
Representative Analytical Method Capabilities	[Cell]	
	Sterility Testing	In-house
	Mycoplasma Testing	In-house
	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, etc.)	Outsourced
	Purity Testing	Outsourced
	Residual & Impurity Testing	Outsourced
	Others	-
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	While we do not offer proprietary logistics services, we are able to provide comprehensive domestic and global transportation support through our partners, Alfresa Holdings and Cryoport, enabling a one-stop solution. In collaboration with other strategic partners, we also support the import/export and transportation of raw materials, intermediates, and final products, helping clients build and manage a global product development and supply chain.	
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	We have undergone three inspections by the PMDA in 2020, 2021, and 2022, resulting in the approval of targeted products, including autologous CAR-T and allogeneic MSC therapies. In addition, we have experience with audits conducted by various clients, including global pharmaceutical companies and major domestic manufacturers. As a group, we also have a proven track record of inspections by the FDA and EMA, and are able to leverage that experience to support regulatory compliance.	
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	Not selected	