1. Company Information

	Input Field
Company Name	ARCALIS, INC.
Address (Head Office)	320-20 Kawauchisaku Shimoota Haramachi-ku, Minamisoma-shi, Fukushima
Location (Manufacturing Site)	Same as above
Business Start Year	2021
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	Corporate Planning GM Katsunori Kawai
Website	https://corp.arcalis.co.jp/en/
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)	Manufacturing Area, QC Area, Storage Area, and Others
CDMO Partnership Network	Meiji Seika Pharma Co., Ltd.
Company Strengths	・Providing consistent services from target discovery to actual manufacturing. ・Japan's only and world-leading GMP facility capable of integrated mRNA production, with a proven track record of commercial manufacturing. ・Accumulated cutting-edge mRNA drug discovery know-how and proprietary technologies
Company Presentation Materials	Links to Non-Confidential Company PDFs

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	RNA Structural Features and Property Analysis
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	No	
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	
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	