1. Company Information

	Input Field
Company Name	FUJIFILM Toyama Chemical Co., Ltd.
Address (Head Office)	14-1, Kyobashi 2-Chome, Chuo-Ku, Tokyo 104-0031 Japan
Location (Manufacturing Site)	8-70, Chiharazaki 1-chome, Toyama-shi, Toyama 931-8334 Japan
Business Start Year	1936
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	
Website	https://www.fujifilm.com/fftc/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)	
CDMO Partnership Network	Synplogen Co., Ltd. Strategic Business Alliance Agreement on CDMO Services for mRNA therapeutics TriLink BioTechnologies Non-exclusive License and Supply Agreement for CleanCap® mRNA capping technology
Company Strengths	FUJIFILM Toyama Chemical has been providing one-stop shop CDMO services from mRNA synthesis to lipid nanoparticle (LNP) formulation to meet the needs of pharmaceutical companies and biotech startup companies engaged in mRNA therapeutics.
Company Presentation Materials	https://www.fujifilm.com/fftc/en/what-we-do

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	[Biological testing]	
	Sterility Testing	■In-house ☐Outsourced
	Microbial Limit Test	■In-house ☐Outsourced
	Mycoplasma Testing	☐In-house ■Outsourced
	Endotoxin Testing	■In-house ☐Outsourced
	Biological Activity Assay	☐In-house ■Outsourced
	[Physical and chemical testing]	
	Identification (mRNA)	■In-house ☐Outsourced
	Identification (Lipids)	■In-house ☐Outsourced
	mRNA Integrity Assay	■In-house ☐Outsourced
	Residual & Impurity Testing	■In-house ☐Outsourced
	3' poly(A) tail length	■In-house ☐Outsourced
	5' capping Efficiency	■In-house ☐Outsourced
	Particle size	■In-house ☐Outsourced
	Quantitative Analysis	■In-house ☐Outsourced
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	individual support	
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		
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	