1. Company Information

	Input Field
Company Name	Cellafa Bioscience Inc.
Address (Head Office)	M&D Tower 20th Floor, 1-5-45 Yushima Bunkyo-ku Tokyo, 113-8510, Japan
Location (Manufacturing Site)	Research, development, and manufacturing: 5-2-3 Tokodai, Tsukuba City, Ibaraki Prefecture (inside Astellas Pharma Tsukuba Bio Research Center) Research and development*: Nakanoshima Qross Mitsui Link Lab Nakanoshima, 4F, 4-3-51 Nakanoshima, Kita-ku, Osaka City, Osaka Prefecture *Operations scheduled to begin in March 2026
Business Start Year	2025
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	Yuki Hayashi, Head of Business Management (℡+81-70-2830-9204, ✉:yuki.hayashi@cellafa.com)
Website	https://cellafa.com/
Regenerative Medicine Product Manufacturing License (Japan PMD Act)	☐Yes ■No** ☐Planned (within approximately 1 year) **We are currently (as of January 2026) building GMP facilities and a production system. We will be able to confirm GMP compliance for investigational drugs manufacturing by early 2028. We will consider obtaining business licenses by the time commercial production of the products under contract is required.
Specific Cell-Processed Products Manufacturing License (Japan RM Safety Act)	☐Yes ■No*** ☐Planned (within approximately 1 year) ***Currently (as of January 2026), we are building GMP facilities and a production system, and are currently planning to obtain certification.
Facility & Equipment Overview (Manufacturing Area, QC Area, Storage Area, Others)	・GMP manufacturing: The manufacturing area (robotic cell culture automation system using the Laboroid "Maholo" in a aseptic environment), QC area, and storage area are currently being set up, and preparations are underway to enable clinical trial drug manufacturing in early 2028. ・Process research and development functions: Equipped with a robotic cell culture automation system using the Laboroid "Mahoro" in a non-sterile environment equivalent to GMP. One line is currently installed, with another line scheduled for installation in March 2026.
CDMO Partnership Network	We are expected to be contracted by our parent company, Astellas Pharma, for several cell therapy development projects. We are also in negotiations with over 10 other biotech ventures and academic startups for contract work.

Company Strengths	Cellafa Bioscience is building a highly accurate and reproducible cell manufacturing platform to accelerate the social implementation of regenerative medicine. This platform combines Astellas' regulatory and GMP compliance capabilities with Yaskawa Electric's advanced automation using AI and labo-roid "Maholo." Furthermore, cloud-based "One Click Transfer" enables rapid deployment of optimized manufacturing processes to GMP facilities. This eliminates the variability and high costs associated with traditional manual processes, enabling reliable and efficient cell therapy manufacturing. In December 2025, the manufacturing technology received Advanced Manufacturing Technology (AMT) certification from the U.S. FDA. The company aims to become the world's first Partnership Research, Development & Manufacturing Organization (PRDMO) model, combining pharmaceutical expertise and robotics technology. The company's strength lies in its advanced platform, which meets FDA AMT designation, enabling efficient manufacturing while maintaining reproducibility and sterility.
Company Presentation Materials	https://storage.googleapis.com/studio-design-asset-files/projects/NxqgY2xDW1/s-1x1_f0e2696f-27de-42ad-a160-52ab4cb2b886.pdf

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	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 (early 2028) ☐No
Marketed Product Manufacturing & Administration	☐Yes	☐Yes ■No (under discussion)

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 (early 2028) ☐No

Regulatory Approval Support in	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 &

	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	(Free text)
Transportation Services Details & Experience (In-house/Outsourced, temperature control, international shipment handling etc.)	We can handle temperature control, international transportation, etc by outsourcing.	
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	The company is expected to be audited by its parent company, Astellas Pharma, within approximately one year.	
Risk Assessment & Management	■Yes ☐No	
Supply Chain Management (Including supplier evaluation and experience with client company	☐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