

Cell culture media For better lives

**CMO Service** 

Shortcut to Official Channel

### Who is Ajinomoto CELLiST Korea



# **Major History**

#### 2012 ■ Established as a joint venture between Ajinomoto and Genexine

Started commercial production

2014

#### 2017 • CELL ST.

CHO Cell Culture Media brand launched

#### 2019

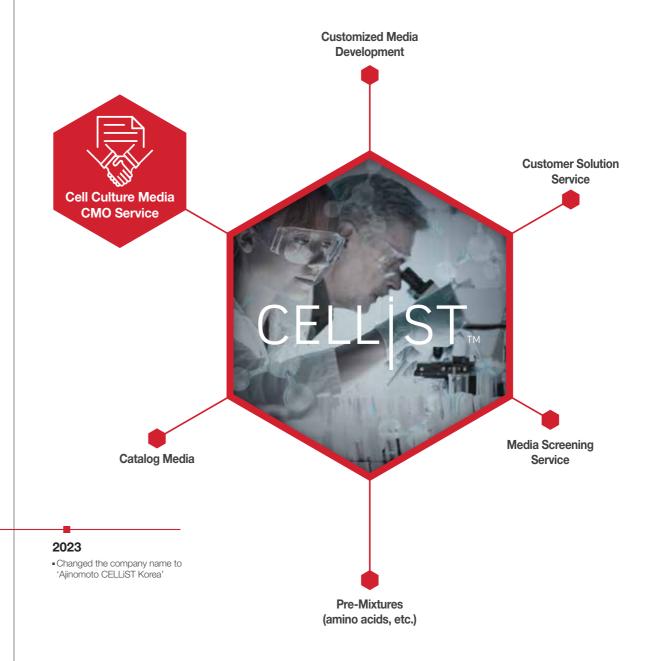
Osong Customer Service

### 2022 • Changed the name from

- Osong Customer Service to CELLIST Solution Center (CELL ST | Solution Center)
- China CSC scheduled to open
- Preparing to open CSC in India

## What Ajinomoto CELLiST Korea can do

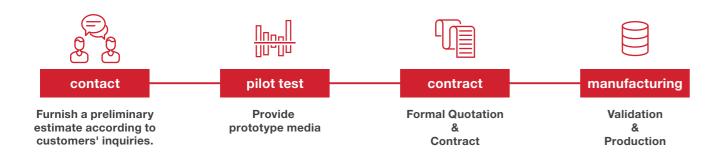
Creating new value for the customer through cutting-edge bioscience and fine chemical technologies



CELL ST.

### **CMO Service**

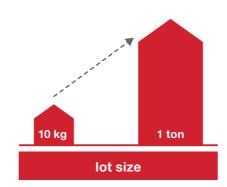
Ajinomoto CELLiST Korea offers contract manufacturing services for cell culture media using customers' formulations. Leveraging Ajinomoto's expertise in nutritional knowledge and advanced control technology over physical properties, we can ensure the delivery of superior quality and cost-competitive solutions.











#### grinding

Item	Model Manufacturer	Spec/ Capacity	
Pin Mill	UPZ100 Hosokawa Micron	~50kg /hr	
Pin Mill	UPZ160 Hosokawa Micron	~140kg /hr	
Pin Mill	UPZ250 Hosokawa Micron	~750kg /hr	

#### mixing

Item	Model Manufacturer	Spec/ Capacity
Container	PM100	~50kg
Mixer	Hiroshima M&M	/Lot
Container	PM400	~250kg
Mixer	Hiroshima M&M	/Lot
Container	PM1000	~500kg
Mixer	Hiroshima M&M	/Lot
Container	PM2000	~1,100kg
Mixer	Hiroshima M&M	/Lot

#### packaging

Item	Model Manufacturer	Spec/ Capacity	
Powder filling machine (Large)	TM-F31M7-L Toyo Machinery	~20kg /package (±5.0g)	
Powder filling machine (Small)	LFS100G-AM GS	~30g /package (±0.002g)	

## **Manufacturing Capacity**

Ajinomoto CELLIST Korea possesses expansive production facilities and adheres to the lates Good Manufacturing Practice (cGMP) standards in its management systems.

We specialize in tailored manufacturing services for a wide range of powdered formulations, catering to individual customer requirements. Our offerings span from uniquely customized amino acid mixture supplements to the large-scale production of growth and feed media for commercial purposes.

#### **Manufacturing Capability**

: Diverse production capacities and packaging alternatives are at your disposal.

Container(L)	20 L	80 L	250 L	1,000 L	2,000 L
Scale(kg)	~10 kg	~50 kg	~250 kg	~450 kg	~1 ton

#### Annual production amount

: Approximately 200 ton (based on 1 ton x 200 batches)

#### **QC Test Item**

- Appearance (powder, after dissolving)
- Loss on drying
- pH (after dissolving)
- Osmotic pressure (after dissolving)
- Cell culture test
- Endotoxin test
- Microbial limit testing (TAMC / TYMC)
- Mycoplasma



## **Manufacturing Process**

Production within a GMP-compliant facility - ranging from laboratory scale to industrial supply Meet clients needs - efficient & speed development with high productivity & quality

All processes are controlled by MES (Manufacturing Execution System)

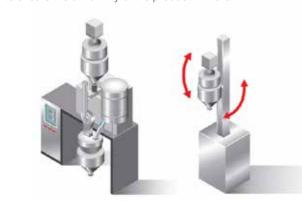
### 1. Weighing

In accordance with MES direction, raw materials are precisely measured, spanning from milligrams to kilograms.



### 2. Pulverization

Prior to blending, each material undergoes pulverization to ensure the uniformity of the product mixture.



#### 3. Mixing

A consistent blend of individual raw materials is achieved through multi-step mixing utilizing a container mixer.



#### 4. Packaging

Packaging materials undergo processing and cleaning before being brought into a clean area. The end products are then filled and stored in cold storage until they are ready for shipment.



# **Quality System**

Benefit from Ajinomoto's extensive experience in manufacturing pharmaceutical-grade amino acids over the years

**Quality Control** 

**Quality Assurance** 

#### ASQUA

Ajinomoto Group Quality Assurance System -

- ✓ Validated and controlled manufacturing process
- ☑ Quality review of batch records
- ☑ Qualified and Validated analytical methods
- ☑ Raw material characterization and management
- ☑ Certificate of Analysis, Certificate of Origin and MSDS available

ASQUA

Rules and requirements of the Ajinomoto Group

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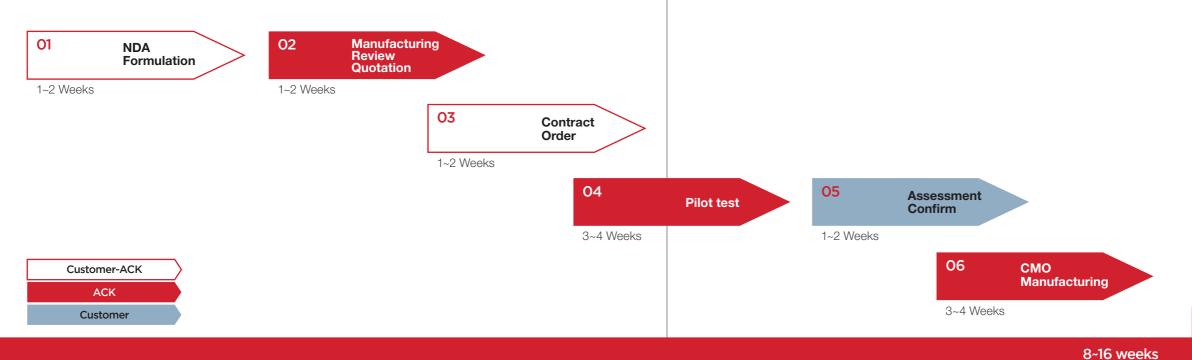
Manufacturing management standards HACCP GMPs

The international quality management system standard ISO 9001

GMPs / ICH Q7 / 21CFR Part 820

ISO9001

### **CMO Process and Lead Time**



The lead time could be modified based on the availability of raw materials and the assessment status from the customers, reflecting the supply and demand conditions.

### | Service Features / Reference



- Expertise in sourcing raw materials
- Rapid production response in emergency situations
- Swift shipping response leveraging geographical advantage (within Asia)
- Creating proprietary manufacturing processes and testing methodologies for our media
- Adaptable approach to diverse customer needs through inter-departmental collaboration (such as tailgate samples, trace metal measurements, etc.)



- Continuosly supply of media products for blockbuster pipelines with the lowest prices
- Meeting urgent CMO (Contract Manufacturing Organization) requests (Customer Inquiry - Raw Material Preparation - Pilot Production - Evaluation - Manufacturing - Delivery: 3 months)
- CMO request response for Classical Media (under 2 months)
- Lowered the customer's production expenses by delivering customiozed pre-mixture blends of over 10 different raw materials.

CELL ST<sub>m</sub>

Eat Well, Live Well.

AJINOMOTO.