

CELL | ST™

Cell culture media
For better lives

CMO Service

Shortcut to
Official Channel

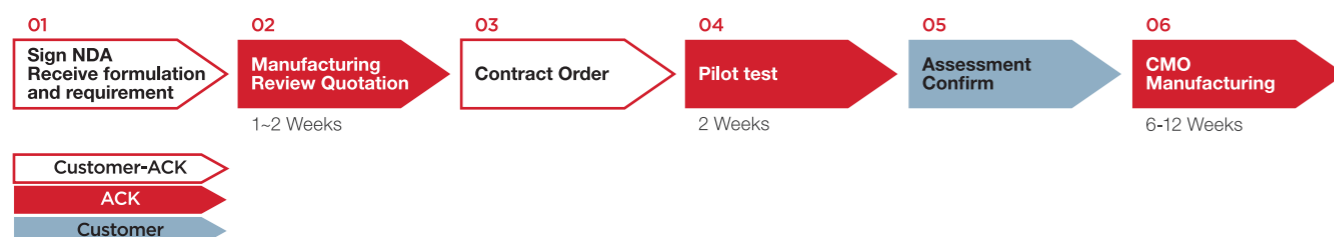


What we can offer

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.

- Flexible small to large scale media or supplement production
- Provide prototype media or supplement usually in 10 business days after order in a non-GMP environment
- Provide media or supplement usually in 6-12 weeks after order in a GMP compliant environment
- Offer competitive price

Overall Process



Service Features / Reference

Our strengths

- 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.)

Our reference

- Continuous 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 customized pre-mixture blends of over 10 different raw materials.

Supported Items

We specialize in tailored manufacturing services for a wide range of powdered formulations, catering to individual customer requirements.

- Powder Media / Supplement in lots up to 10kg, packaged in aluminum pouch or plastic pail by weight

Container(L)	5L	10L	20L	80L	250L	1,000L	2,000L
non-GMP	~2kg	~5kg	~10kg				
cGMP			~10kg	~50kg	~100kg	~450kg	~1,000kg

- Annual maximum production capacity: 200 ton (1 ton x 200 batches)
- Various kinds of formulas includes:
 - Customer-developed formulas
 - Classical formulas with or without modifications (e.g. DMEM with low NaCl)
- Media are packaged in aluminum pouch or plastic pail by weight

	Aluminum pouch	6L Plastic drum	20L Plastic drum	60L Plastic drum
Amount(kg)	~0.050kg	~3kg	~10kg	~20kg
Amount(L)	~1L	~50L	~500L	~1,000L

Quality Control Testing

- Product quality are evaluated by the following tests

- 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

- Result of Analysis is available for prototype.
- Testing includes Appearance, Solubility, pH and Osmolality.
- TAMC/TYMC, Endotoxin, Mycoplasma and Cell culture are optional, requiring more lead-time to the delivery.




Manufacturing Process

Production at our technical laboratory and GMP-compliant factory is well-established, allowing efficient & speedy manufacturing with high quality for ranging from small scale to industrial supply.

All processes are controlled by MES (Manufacturing Execution System)

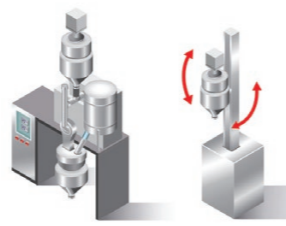
1. Weighing

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



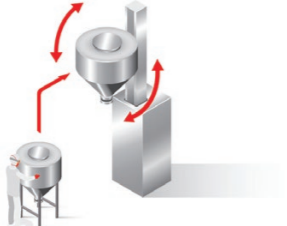
2. Pulverization

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.



milling

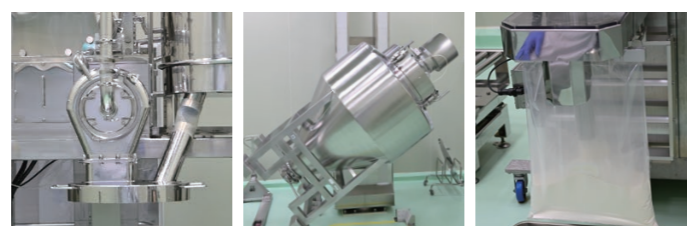
Item	Model Manufacturer	Spec/ Capacity
Pin Mill	UPZ100 Hosokawa Micron	~50kg /hr
Pin Mill	UPZ160 Hosokawa Micron	~140kg /hr
Pin Mill	UPZ250 Hosokawa Micron	~750kg /hr

mixing

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

packaging

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



Quality System

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



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



Manufacturing management standards
HACCP GMPs

The international quality management system standard
ISO 9001

GMPs / ICH Q7 / 21CFR Part 820

ISO9001

Eat Well, Live Well.



Who is Ajinomoto CELLiST Korea



Major History

- 2012**
 - Established as a joint venture between Ajinomoto and Genexine
- 2014**
 - Started commercial production
- 2017**
 - **CELLiST.** CHO Cell Culture Media brand launched
- 2019**
 - Osong Customer Service
- 2022**
 - Changed the name from Osong Customer Service to CELLiST Solution Center (**CELLiST** Solution Center)
 - China CSC scheduled to open
 - Preparing to open CSC in India
- 2023**
 - Changed the company name to 'Ajinomoto CELLiST Korea'

What Ajinomoto CELLiST Korea can do

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

