

Shortcut to  
Official Channel



# CELL | ST<sup>TM</sup>

Cell culture media  
**For better lives**



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**Comprehensive Cell Culture Media Solutions**

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## ■ Ajinomoto CELLiST Korea Co., Inc.

Ajinomoto CELLiST Korea provides services, such as development and manufacture of animal cell culture media and contract manufacture of media.

Keeping pace with the growth of the Korean biopharmaceutical market, we will continue to grow as a company that contributes to the development of high-quality, high-value-added medicines by providing solutions with high satisfaction based on state-of-the-art technology.



### MISSION

We contribute to *medical advancement and better lives* by providing cell culture media



### VISION

We will become *the most preferred and trusted cell culture media supplier* in Asia.

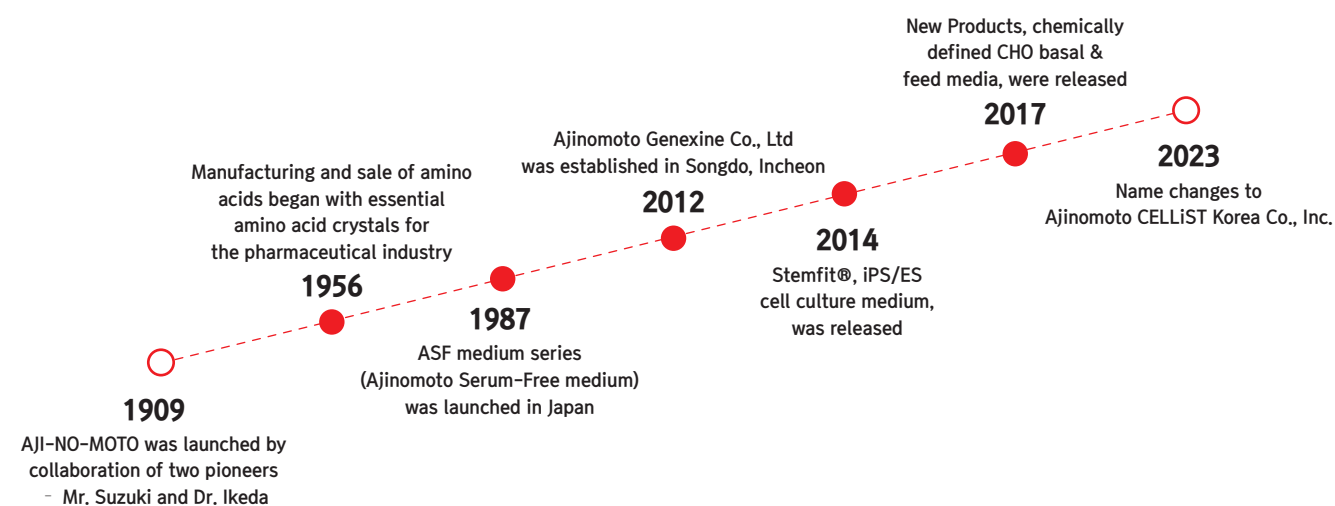


### VALUE

*Customer-centered culture,*  
Operational Excellence,  
Stable-Speedy-Superb quality

## ■ History Cell Culture Media Business History of Ajinomoto

As a leader in amino acid research, we have a long history of over 100 years and with over 30 years of experience in the research and development of cell culture media, we provide high-quality media to our customers.



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1. PRODUCTS

1-1. CELL CULTURE MEDIA FOR CHO CELLS

Overview

CELLiST provides an ‘all in one’ solution for all your biologics manufacturing needs.

CELLiST is a completely chemically-defined, animal origin-free medium.

CELLiST provides high yield and productivity in all CHO cell lines.

CELLiST incorporates Ajinomoto’s long history of know-how in the development and manufacturing of amino acids and amino acids-related products.



Product Line

CELLiST™ Basal media						
Model #	Format	Catalog #	Package type	Qty.	With Additives	W/O Additives
BASAL3	Powder	221AD1-1L	1L Aluminum Pouch	27.0g	D-Glucose	L-Glutamine, • Sodium hydrogen carbonate Thymidine Hypoxanthine • Poloxamer • Insulin and other growth factors
		211AD1-50L	50L Plastic Drum	1.35kg		
BASAL3P	Powder	221AD3-1L	1L Aluminum Pouch	28.0g	D-Glucose, Poloxamer	L-Glutamine, • Sodium hydrogen carbonate Thymidine Hypoxanthine • Insulin and other growth factors
		211AD3-50L	50L Plastic Drum	1.4kg		
BASAL10	Powder	221BS1-1L	1L Aluminum Pouch	24.3g	D-Glucose	L-Glutamine, • Sodium hydrogen carbonate Thymidine Hypoxanthine • Poloxamer • Insulin and other growth factors
		211BS1-50L	50L Plastic Drum	1.22kg		
BASAL10P	Powder	221BS4-1L	1L Aluminum Pouch	25.3g	D-Glucose, Poloxamer	L-Glutamine, • Sodium hydrogen carbonate Thymidine Hypoxanthine • Insulin and other growth factors
		211BS4-50L	50L Plastic Drum	1.27kg		
BASAL CHO MX	Powder	221BS3-1L	1L Aluminum Pouch	23.0g	D-Glucose, Poloxamer	L-Glutamine • Sodium hydrogen carbonate Thymidine • Hypoxanthine • Insulin and other growth factors
		211BS3-50L	50L Plastic Drum	1.15kg		

CELLiST™ Feed media						
Model #	Format	Catalog #	Package type	Qty.	With Additives	W/O Additives
FEED2	Powder	222FC1-0.2L	0.2L Aluminum Pouch	22.0g	-	L-Glutamine • D-Glucose • Insulin and other growth factors
		212FC1-10L	10L Plastic Drum	1.1kg		
F7	Powder	222FD3-0.2L	0.2L Aluminum Pouch	24.0g	-	L-Glutamine • D-Glucose • Insulin and other growth factors
		212FD3-10L	10L Plastic Drum	1.2kg		

CELLiST™ Perfusion media *Prototype			
Model #	Format	Concentration	With Additives
CHO Perfusion Media_P1	Powder	37.4g/L	Poloxamer

CELLiST Products Features

- High performance for both cell growth and protein expression
- Superior filterability and uniformity
- Trial and bulk size both available
- Flexible application as a new platform media
- Manufactured by a GMP compliant factory
- Rich formulation of high quality amino acids by Ajinomoto Group

Key Features of CELLiST™ F7

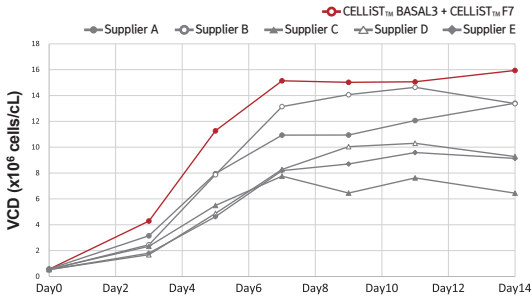
- Employing Ajinomoto Group’s proprietary cysteine-stabilization technology, high levels of readily available cysteine are achieved, allowing increased culture performance, while maintaining a hassle-free, single-agent feeding process at neutral pH.
- Amino acids and other medium components are optimized for increased process performance using cutting-edge ‘Digital Twin’ technology, through collaboration with the Bioprocess Technology Institute (BTI, A\*STAR).

CELLiST™ BASAL3/3P & F7 Media

Cell Culture Performance

Comparative studies show superior culture growth and productivity with the CELLiST™ BASAL3 + CELLiST™ F7 media combination. In a fed-batch process using a CHO-K1 cell line expressing IgG1 antibody, our media outperforms top global competitors in viable cell density and IgG titer.

Cell Growth



Protein Production

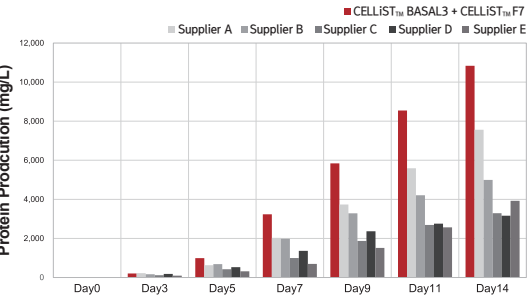
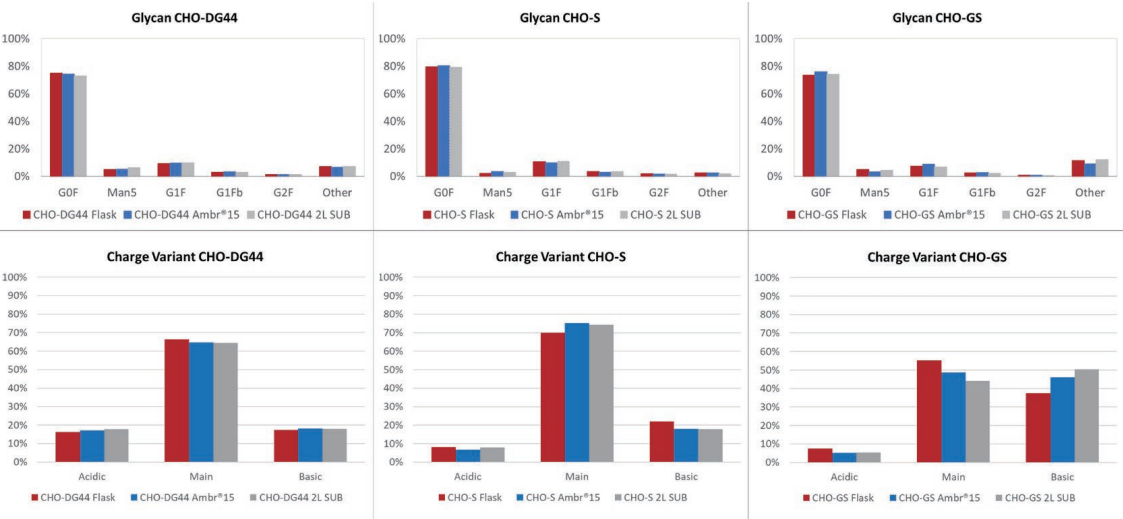


Figure 1: Fed-batch process was performed in an Ambr®15 microbioreactor system, using CHO-K1 cell line expressing IgG1 antibody. Feeding in CELLiST™ group was performed at a concentration of 6% (v/v) on day 3, 5, 7, 9 and 11. ‘Supplier A, B, C, D and E’ represent basal/feed media combinations from major media suppliers. Culture and feeding manners were performed according to each manufacturer’s recommendations.

Protein Quality Across Different Scales

CELLiST™ media maintains consistent protein quality from flask to bioreactor scale. Our data indicates reliable protein quality, making scale-up processes straightforward and efficient. Fed-batch process was performed in 125 mL Erlenmeyer flasks, Ambr®15 microbioreactor system, and 2L single-use bioreactor system (Sartorius, BioStat® B), using CHO-DG44, CHO-S and CHO-GS cell lines expressing IgG1 antibody. Feeding was performed at a concentration of 6% (v/v) on day 4, 6, 8, 10 and 12.



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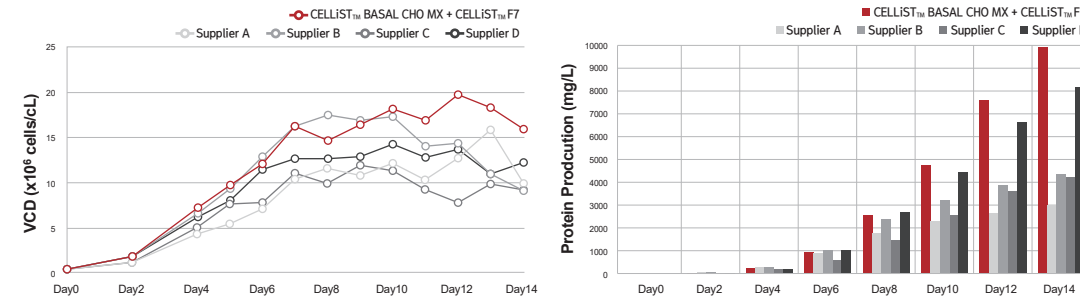


## ■ CELLiST™ BASAL CHO MX & F7 Media

### ■ Cell Culture Performance

Comparative studies show superior culture growth and productivity with the CELLiST™ BASAL CHO MX + CELLiST™ F7 media combination. In a fed-batch process using CHO-K1 and CHO-S cell lines expressing IgG1 antibody, our media outperforms top global competitors in viable cell density and IgG titer.

#### CHO-K1



#### CHO-S

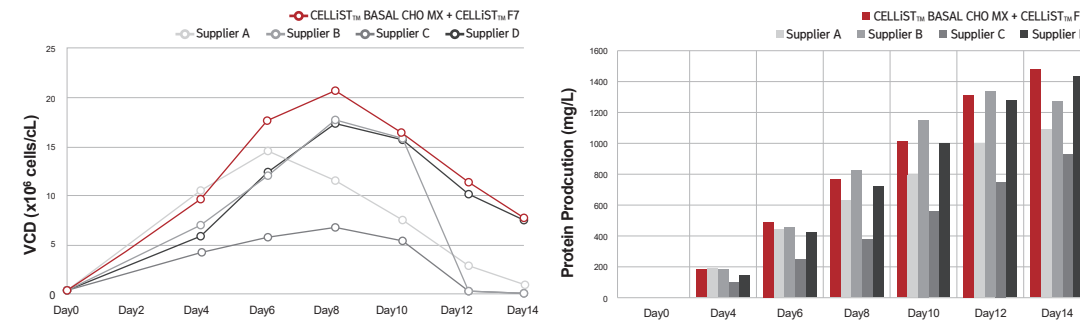


Figure 1: Fed-batch process was performed in an Ambr®15 system (CHO-K1) and 125 mL flasks (CHO-S), respectively. Feeding in CELLiST™ group was performed at a concentration of 6% (v/v) on days 4, 6, 8, 10, and 12. 'Supplier A, B, C and D' represent basal/feed media combinations from major media suppliers. Culture and feeding manners for supplier A, B, C and D were performed according to each manufacturer's recommendations.

### ■ Scalability

As can be seen below, CELLiST™ BASAL CHO MX medium is suitable for use in various culture scales from small scale microbioreactors to larger scale 200L bioreactors. CELLiST™ BASAL CHO MX medium shows consistent performance in terms of cell growth and productivity regardless of scale.

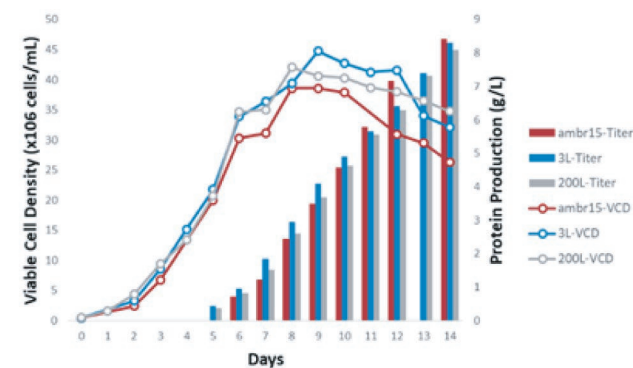


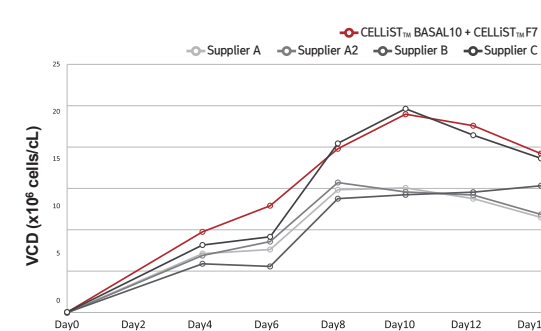
Figure 2. Viable cell density and IgG titer profiles during the 14 days of fed-batch culture. Three types of bioreactors were used: microbioreactors (Ambr®15), 3L bench-top reactor and 200L bioreactor.

## ■ CELLiST™ BASAL10/10P & F7 Media

### ■ Cell Culture Performance

Comparative studies show superior culture growth and productivity with the CELLiST™ BASAL10 + CELLiST™ F7 media combination. In a fed-batch process using a CHO-K1 cell line expressing IgG1 antibody, our media outperforms top global competitors in viable cell density and IgG titer.

#### Cell Growth



#### Protein Production

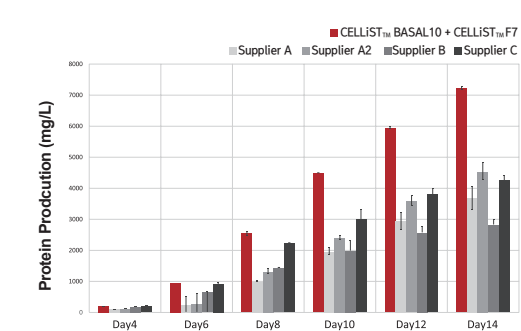
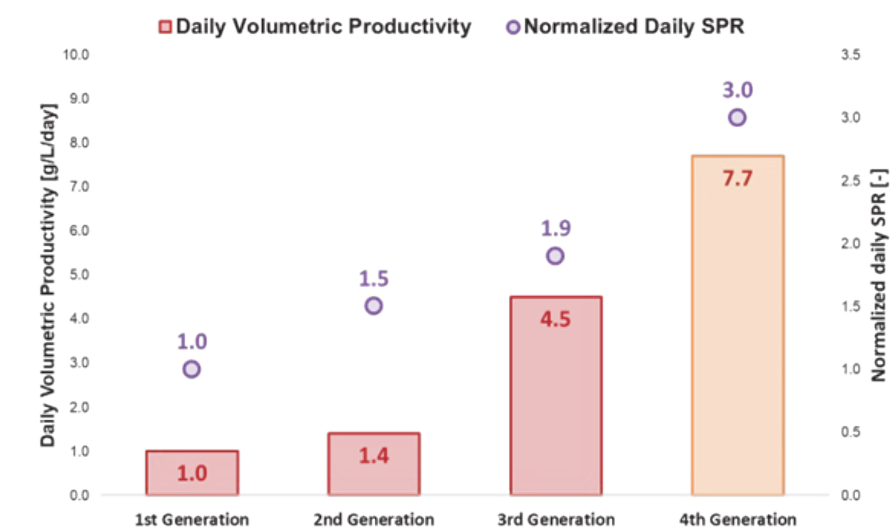


Figure 1. Fed-batch process was performed in a 125 mL Erlenmeyer flask system, using CHO-K1 cell line expressing IgG1 antibody. Feeding in CELLiST™ group was performed at a concentration of 6% (v/v) on day 4, 6, 8, 10 and 12. A, A2, B and C represent basal/feed media combinations from major media suppliers. Culture and feeding manners were performed according to each manufacturer's recommendations.

## ■ CELLiST™ CHO Perfusion Media\_P1

### ■ Media Performance



- Increasing poloxamer concentration enhanced cell-specific productivity and viability by protecting cells from shear stress.
- Changing the iron source controlled cell proliferation rate, which helped maintain appropriate VCD.
- Improvements in the media composition, including L-Cystine, enhanced productivity.  
[https://www.ajinomotocellistkorea.com/en/technicalmaterial\\_en](https://www.ajinomotocellistkorea.com/en/technicalmaterial_en)



# 1. PRODUCTS

## 1-2. SUPPLEMENT

### Overview

CELLiST provides an 'all in one' solution for all your biologics manufacturing needs. CELLiST is a completely chemically-defined, animal origin-free medium. CELLiST provides high yield and productivity in all CHO cell lines. CELLiST incorporates Ajinomoto's long history of know-how in the development and manufacturing of amino acids and amino acids-related products.



### Product Line

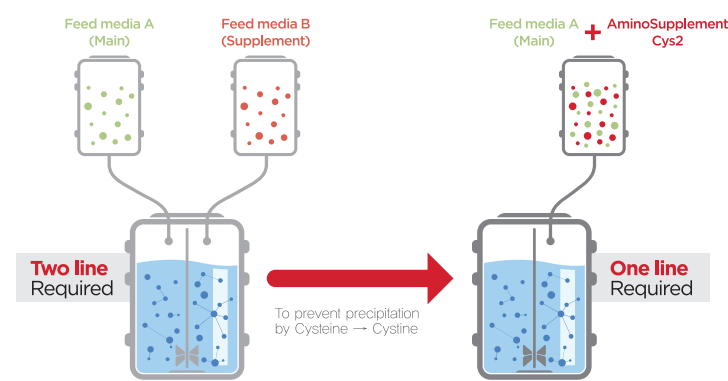
#### CELLiST™ AminoSupplement

Model #	Format	Catalog #	Package type	Qty.
Cys1	Powder	225SP1-1L	1L Aluminum Pouch	6.61g
Cys2	Powder	225SP2-1L	1L Aluminum Pouch	17.0g

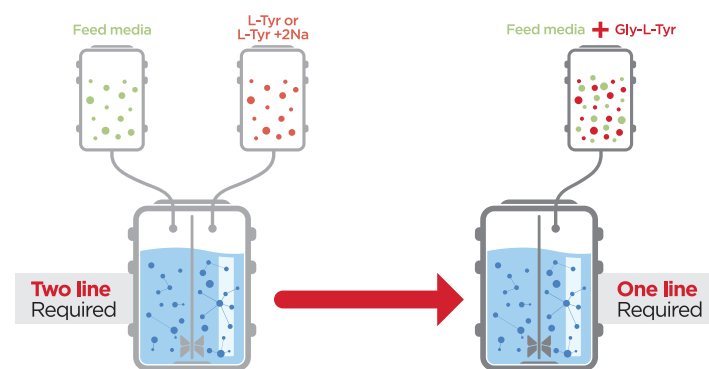
#### CELLiST™ Supplement

Model #	Format	Catalog #	Package type	Qty.	Main Target
Glycyl L-Tyrosine Dihydrate	Powder	215GLT-20KG	20kg Plastic Drum	20kg	Using this in place of L-Tyr or Tyr-2Na allows a single agent with higher solubility of Tyr, leading to process simplification.

### Cost-cutting by improved stability



### Cost-cutting and high solubility



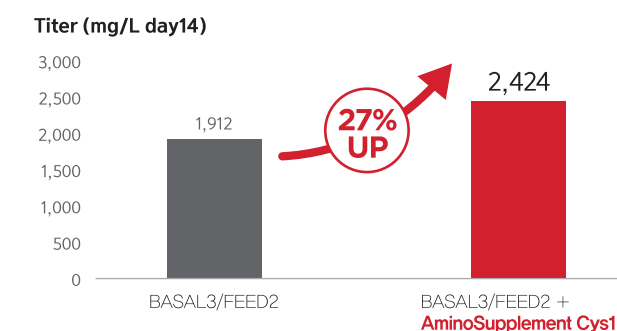
## CELLiST™ AminoSupplement Cys1/Cys2

### Overview

CELLiST AminoSupplement Cys1/Cys2 can help customers improve titer and reduce initial & running costs for cell culture by just adding AminoSupplement Cys1/Cys2 into feed media. Our proprietary formulation inhibits cystine formation / precipitation and enhances the Cys source concentration in the media

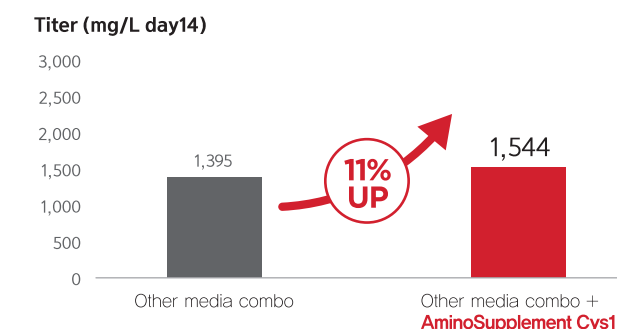
### Titer improvement

#### CHO-DG44/ambr®



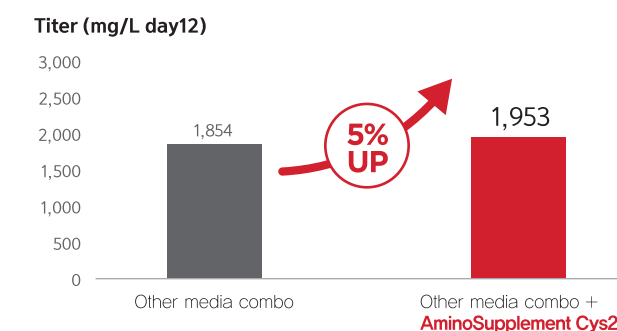
Fed-batch cultures were compared using cells of CHO-DG44. FEED2 was added 5.25% on days 4, 6, 8, 10, and 12 of culture.

#### CHO-S/ambr®



Fed-batch cultures were compared using cells of CHO-S. Feed media from other companies was added 6% to the basic media from other companies on culture days 4, 6, 8, 10, and 12.

#### CHO-S/ambr®



Fed-batch cultures were compared using cells of CHO-S. Feed media from other companies was added 4.5% to the basic media from other companies on cultures 4, 6, 8, 10, and 12 days.



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■ CELLiST™ Glycyl-L-Tyrosine Dihydrate

■ Overview

CELLiST™ offers a comprehensive solution for all your biologics manufacturing requirements. CELLiST™ Glycyl-L-Tyrosine Dihydrate (Gly-L-Tyr) provides exceptional solubility, enhancing the overall available tyrosine source, which is a critical component for cell growth and productivity. Gly-L-Tyr solubility surpasses that of traditional L-Tyrosine. Incorporating CELLiST™ Gly-L-Tyr into the manufacturing processes removes the need for two separate feeding lines, resulting in a simple, robust and cost-effective workflow. This product was developed by Ajinomoto Group, leveraging years of experience in amino acids science and bioprocess design, as well as high-quality raw materials production capabilities.

■ Advantages

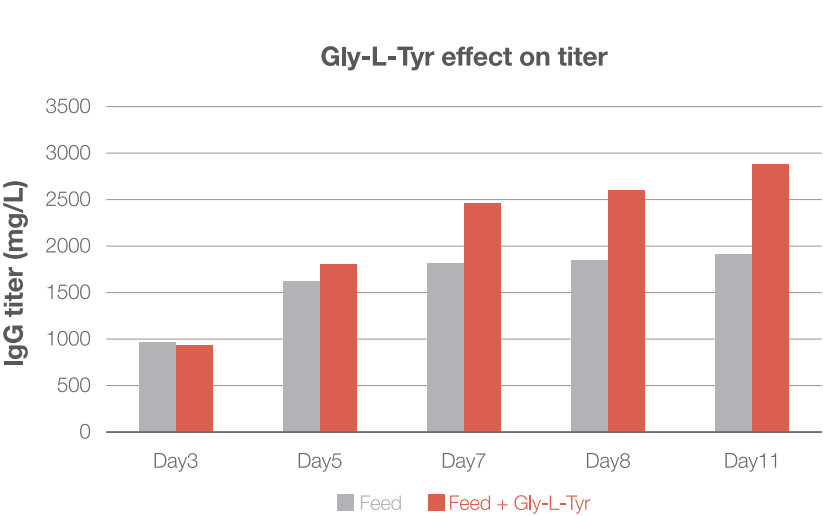
Gly-L-Tyr is an effective tyrosine source with high solubility

CELLiST™ Glycyl-L-Tyrosine Dihydrate is a highly-soluble and effective tyrosine source, which is an essential ingredient for biologics manufacturing. Unlike other tyrosine sources, such as L-Tyrosine disodium salt dihydrate (L-Tyr+2Na), which requires an alkaline pH and presents challenges during dissolution, Gly-L-Tyr provides optimal solubility without compromising pH conditions.

	L-Tyrosine	Gly-L-Tyr
Solubility at 25°C	0.479g/L	36.9g/L

Optimized tyrosine source for improved productivity

The addition of Gly-L-Tyr to the process optimizes tyrosine source supply to the cell culture and results in significant improvement to the performance and productivity of the fed-batch process. The graph below shows the increase in productivity (titer) for a fed-batch CHO cell culture.



1. PRODUCTS

1-3. CELL CULTURE MEDIA FOR HEK293 CELLS

■ CELLiST™ HEK293 Vaccine Media for Viral Vaccine Production

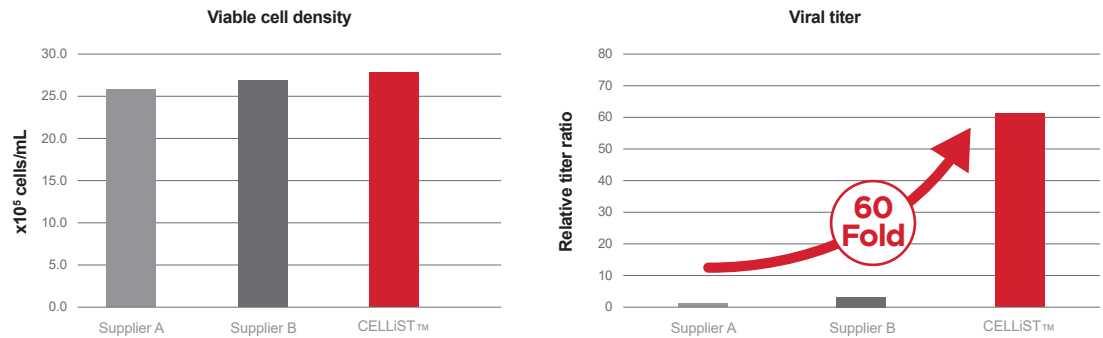
■ Overview

CELLiST™ HEK293 Vaccine Media	CELLiST™ HEK293 Vaccine Supplement
Stand-alone medium for viral vaccine production at any scale.	Designed to be added to any other HEK293 medium, for enhancing viral production at any scale.
<ul style="list-style-type: none"><li>Chemically-defined, protein-free medium without animal-derived components, hydrolysates, extracts or any other undefined components.</li><li>High performance for optimal viral vaccine production.</li><li>Based on Ajinomoto Group's proprietary AminoScience technology.</li><li>Test samples as well as bulk size orders are available.</li><li>Flexible application allowing easy substitution of any current media platform.</li><li>Manufactured in a GMP-compliant factory.</li></ul>	

■ Media Performance

Performance of CELLiST™ HEK293 Vaccine Media

Below figures are viable cell density and virus production results for CELLiST™ HEK293 Vaccine Media compared with several other commercially available media. This performance data was obtained using HEK293.2sus cell line infected with Human adenovirus 32. Cells were cultured for 3 days on petri dish and cultured for additional 2 days after virus infection. Virus production was measured following Plaque-forming assay.



**Figure 1.** Performance of CELLiST™ compared with two other commercially available HEK293 vaccine media. Viable cell density was measured on day 3 and virus production (Plaque-forming units, PFU) was evaluated 2 days after transfection. Measured PFU values were normalized relative to Supplier A.



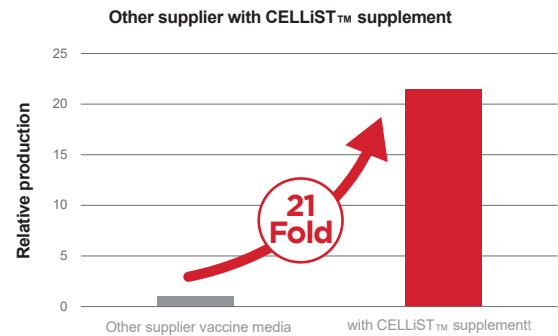
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**Performance of CELLiST™ HEK293 Vaccine Supplement**

CELLiST™ HEK293 Vaccine Supplement was developed for customers who do not wish to replace their existing base vaccine medium but want to improve their process productivity. Addition of this supplement to any commercially available vaccine medium will dramatically improve productivity, as shown below.



**Figure 2.** Relative virus production of CELLiST™ HEK293 Vaccine Supplement with another supplier’s commercially available vaccine media. Measured PFU values were normalized relative to vaccine medium without the supplement.

■ **CELLiST™ HEK293 AAV Production Media**

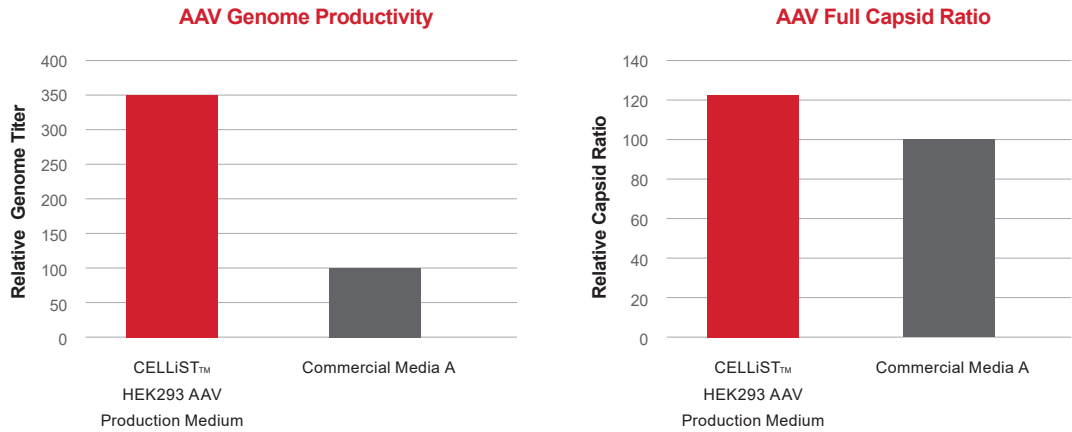
■ **Overview**

Product	Catalog No.	Specifications	Amount	Packaging Information
CELLiST™ HEK293 AAV Production Medium	-	Contains poloxamer Contains 7.5 g/L D-Glucose Contains 4mM L-Alanyl-L-Glutamine <b>Does not</b> contain thymidine and hypoxanthine <b>Does not</b> contain sodium bicarbonate	19.6 g/L	1L / 50L

Features	Benefits
Enriched with amino acids for enhanced cell growth.	Rapid cell proliferation, achieving higher cell densities faster.
Optimized for high performance AAV production	Optimized composition for maximizing cellular energy production to enhance AAV productivity, utilizing Ajinomoto Group's proprietary AminoScience technology
Versatile application	Versatility across cell culture processes and scales, enabling easy substitution of any currently-used media platform.
Chemically defined, protein-free, animal component-free	Reduces risk of viral contamination and ensures batch-to-batch consistency.
Supplied in fine powder form.	Easy to dissolve and allows for prolonged shelf life and ease of transportation.
Available in both test samples and bulk sizes.	Flexibility according to usage requirements.

■ **Cell Culture Performance**

CELLiST™ HEK293 AAV Production Medium demonstrates superior genome productivity in comparative studies. In a viral production process using a HEK293 cell line, our media consistently outperforms competitor media in both AAV productivity and full capsid ratio.



**Figure 1.** AAV production was carried out using HEK293 cells adapted to CELLiST and competitor media over five passages prior to transfection. AAV genome titers were measured by qPCR, and the full capsid ratio was calculated from the number of AAV particles (vp/mL) measured by ELISA and AAV genome titer (vg/mL) following transfection. Results are shown as relative values, with competitor media set to 100.





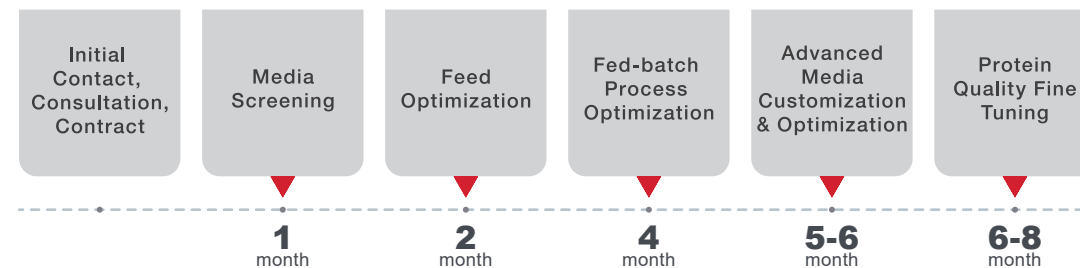
## 2. SERVICES

### ■ Custom Media Development

With over 60 years of experience in amino acids science, the Ajinomoto Group has advanced cell culture media development capabilities backed by bioprocess development technologies, allowing complete support for both media and process optimization to our Biopharma customers.

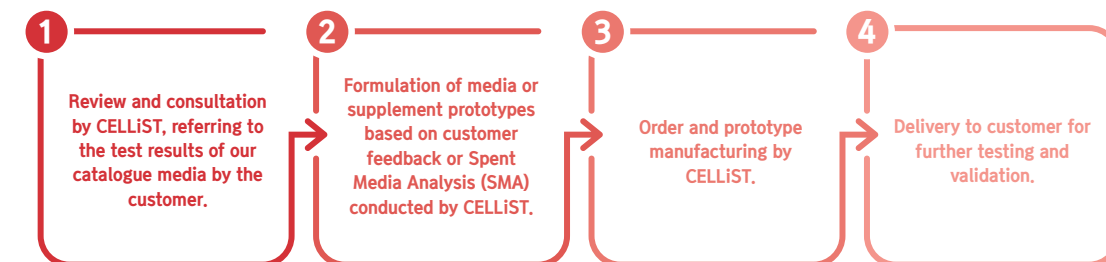
#### ■ For comprehensive media customization

Custom media totally optimized for your process in 6 to 8 months, based on the following process.

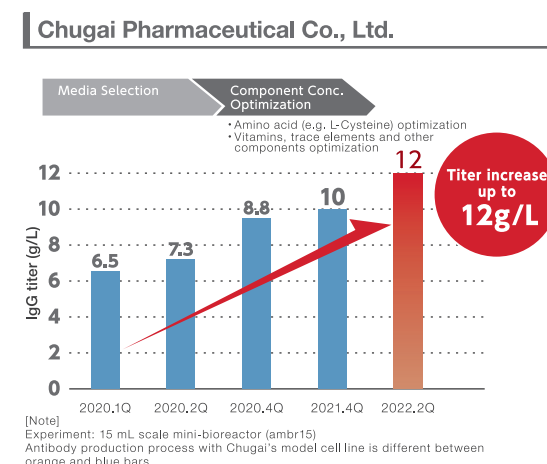
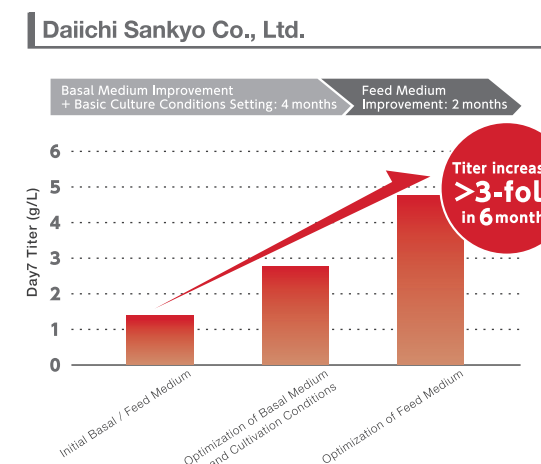


#### ■ For swift media refinement

Custom media or supplement optimized for your process by fine-tuning catalogue media, with swift prototype production and delivery, typically completed within 10 business days.



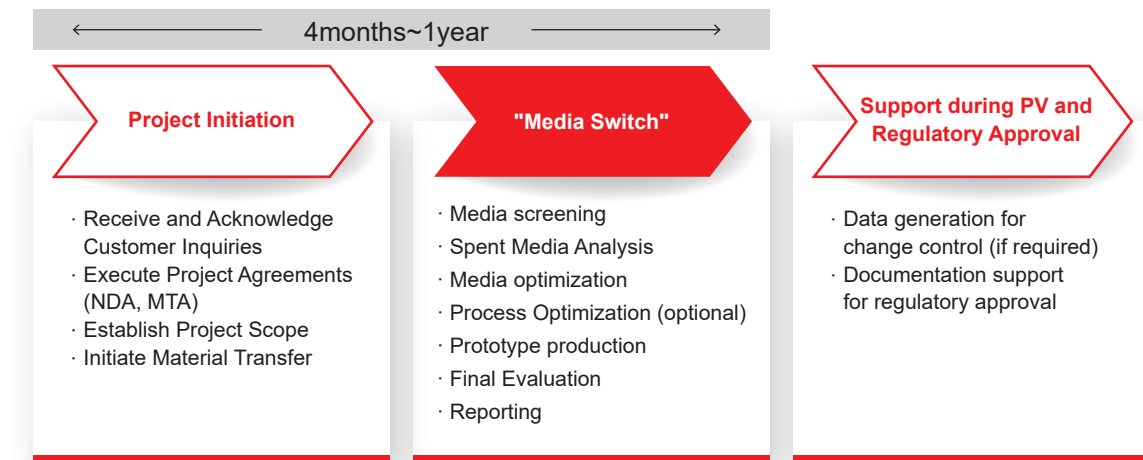
### ■ Our Service Track Record



### ■ Switch Program

Our end-to-end Switch Program supports the seamless transition to new CELLIST™ cell culture media, reducing production costs and ensuring optimal compatibility with your biopharmaceutical processes. Our dedicated team partners with you to ensure your goals are met seamlessly and efficiently.

#### ■ End-to-end Service



### ■ Case Study

#### 1. Media Development

Effort was put to maximize yield and match the glycosylation and charge variants (CV) profiles of the original drug. To develop the media, we created a starting medium from our in-house media library and utilized Ajinomoto Group's expertise in cell culture media to determine the final media composition. In addition, candidate components were tested for adjusting glycosylation and CV profiles. This process ensured not only consistent production of the target protein but also similarity of glycosylation and CV profiles to those of the original drug. Finally, subsequent process optimization led to a 27% increase in yield compared to the original media.

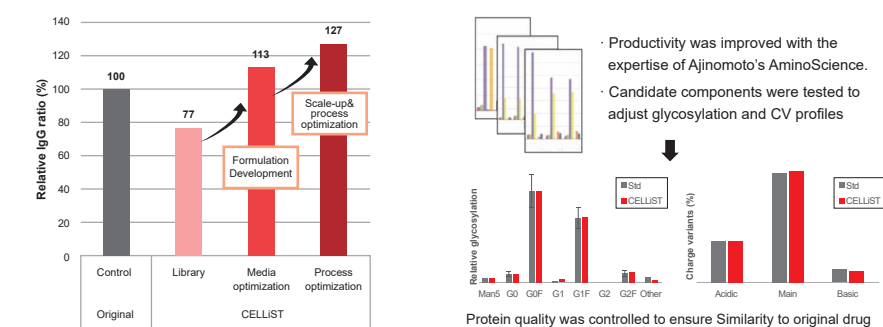


Figure 1. Process of media development for enhancing productivity and matching protein quality attributes.

#### 2. Process optimization using QbD approach

##### 2.1 Risk assessment

Risk assessment involves procedures to ensure that the manufacturing process of pharmaceutical products does not compromise product quality and that the process consistently produces products meeting intended quality characteristics and specifications.

Failure Mode and Effects Analysis (FMEA) was employed to identify potential risk factors and critical process parameters (CPPs). The potential impact of critical quality attribute (CQA) failures was also evaluated, and prioritized CQAs were identified for subsequent experiments.





## Unit operation risk assessment



Figure 2. Unit operation risk assessment. Potential risk factors were assessed using FMEA method.

### Purpose

- Check potential risk factors
- Assess potential CPPs
- Discuss ways to reduce risks

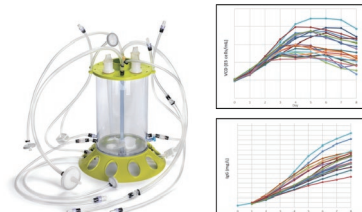
### Method

- Failure Mode Effects Analysis (FMEA)
- $RPN = P/U \times S/I \times D$

## 2.2 Design of Experiment (DoE) study

The objective of this stage was to conduct a DoE study of the main culture process as part of the QbD framework, within the process characterization studies of biopharmaceuticals. This study evaluated four different parameters: temperature, agitation, dissolved oxygen and pH, based on the results from the operational unit risk assessment of the main culture process. Cell cultures were performed accordingly, and CQAs were analyzed. This led to the development of a statistical model, investigating the relationship among CQAs, CPPs, and the identified design space. Finally, Monte Carlo simulations confirmed that the process is robust at the set point, along with the proven acceptable range (PAR) and normal operating range (NOR).

### Cell culture



### 3L bench-top bioreactor cultivation

Custom design (# of runs=17)

#### Process parameters

- Temperature
- Agitation
- Dissolved oxygen
- pH

#### Critical quality attributes

- Productivity
- Cell growth
- Glycosylation
- Charge variants

### CPP confirmation

Parameter	Unit	Value
Temperature	°C	37.0
Agitation	rpm	120
Dissolved oxygen	%	50
pH		7.2

- CPPs and corresponding design space were set according to DoE analysis
- PAR and NOR were identified, which satisfy product quality

### Design space confirmation

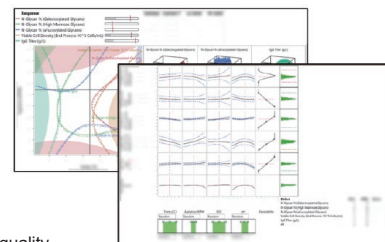


Figure 3. Design of Experiment (DoE) study conditions and analyzed entities including (1) CPPs confirmation and (2) Design space confirmation.

## 3. Conclusion

With the implementation of QbD approach and enhanced-performance customized media, this project not only achieved the optimization of the culture process but also ensured that the product consistently met its predefined quality criteria with greater predictability. As a result, production costs were reduced, and optimal compatibility was achieved, resulting in approval by the regulatory body.

## ■ 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.

- 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

## ■ Overall Process



## ■ We provide

- Powder Media / Supplement 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				
GMP			~10kg	~50kg	~100kg	~450kg	~1,000kg

\* The figures above may vary depending on the formulation and are for reference only.

- 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	5L Plastic drum	20L Plastic drum	50L Plastic drum
Amount(kg)	~0.050kg	~1.5kg	~10kg	~20kg

## ■ 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.



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## ■ Trace Element Analysis

The addition of trace elements through formulation is deemed crucial. Variations in these critical components have been associated with unintended impurities in the prevailing supply chain of cell culture raw materials. Our dedicated focus on trace metal analysis reflects our commitment to offering our clients solution with pioneering capabilities

## ■ What we can do

- Quantitative Testing by Inductively Coupled Plasma Mass Spectrometry (ICP-MS).
- For 18 different trace elements/impurities: Magnesium, Aluminum, Calcium, Vanadium, Chromium, Manganese, Iron, Cobalt, Nickel, Copper, Zinc, Selenium, Molybdenum, Silver, Cadmium, Tin, Barium and Lead
- Results reported without specification (data for informational purpose only)



## ■ Sales Support

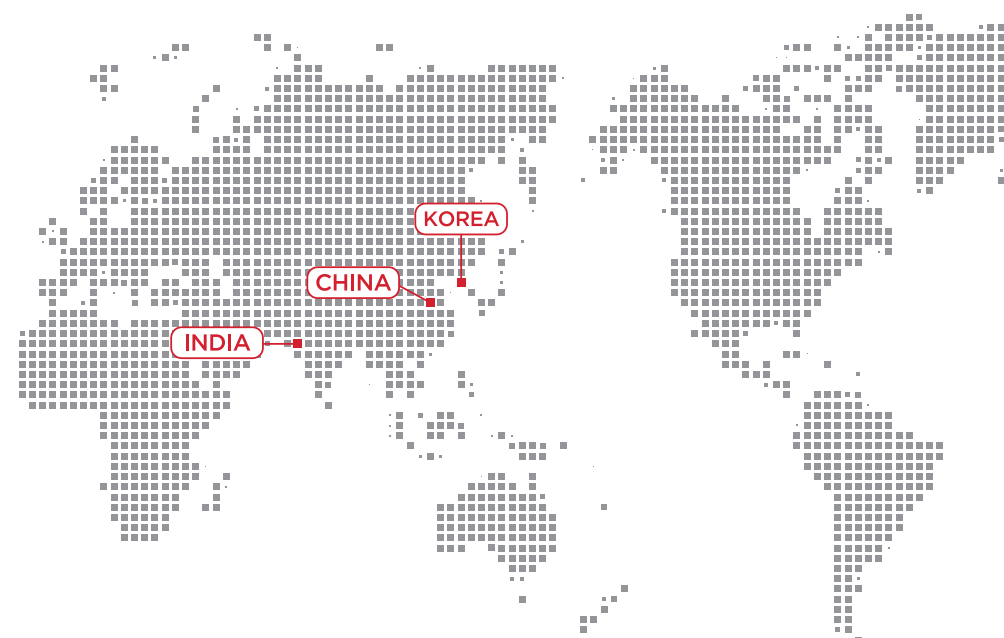
For quoting, ordering, product sample request

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