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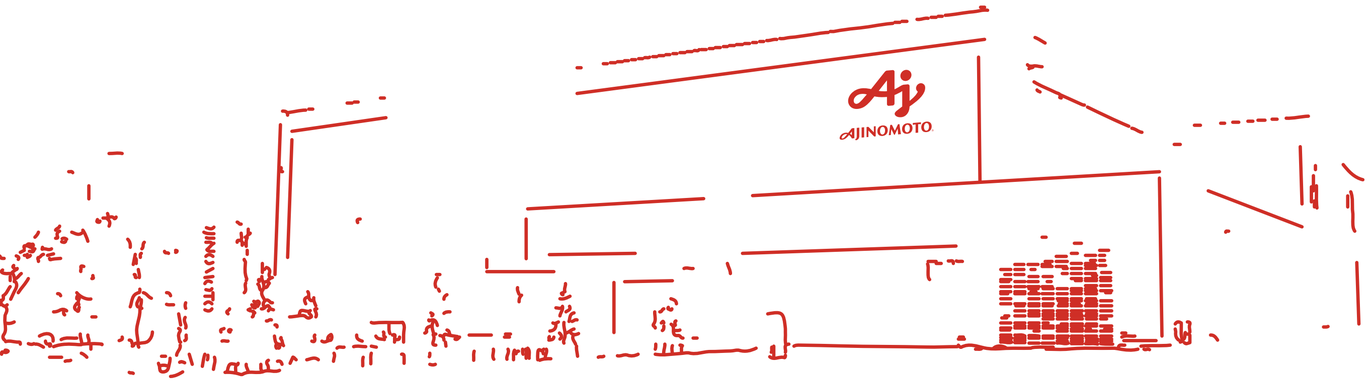
AJINOMOTO

SWITCH PROGRAM

CELLiST™

AJINOMOTO GENEXINE CO., LTD.

Ajinomoto Genexine is providing a wide range of services
including development and manufacturing of animal cell culture media
and consignment production of media, etc.
We will continue to grow as a company that makes
contributions towards the development of high quality
and high value-added medicine by provide highly satisfactory solutions
based on the most advanced technologies in concordance
with the growth of biopharmaceutical market in Korea.



MISSION

To make contributions towards medical advancements
and better life of mankind by supplying cell culture media.

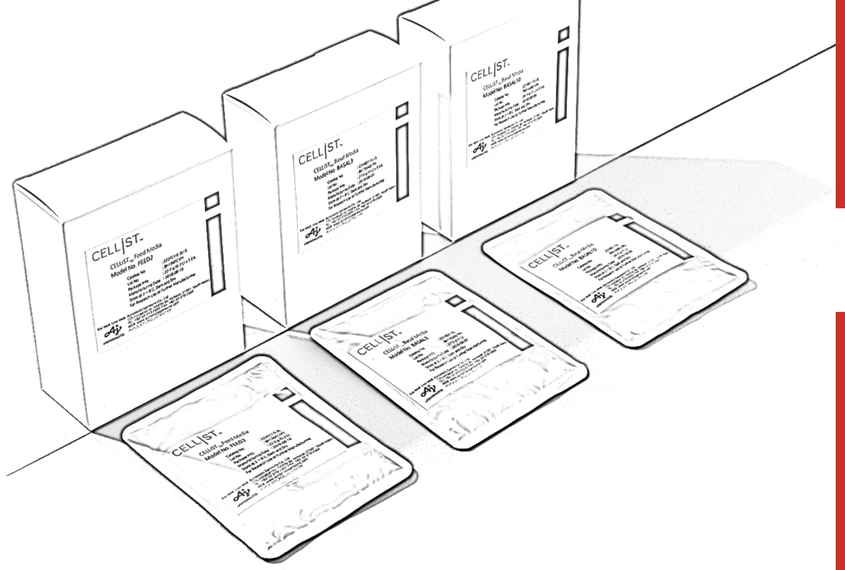
VALUE

Customer-oriented culture, Operational Excellence,
Stable-Speedy-Superb quality

VISION

To become the most preferred and trusted
cell culture media supplier with focus on the Asian market.

CELL|ST™



It is a composite word of ‘CELL’ and ‘iST’, which a suffix to indicate a ‘specialist’, that illustrates the reliability and confidence of Ajinomoto on our specialized cell culture media products. In addition, it signifies the 1st cell culture media containing No. 1 technological capabilities of Ajinomoto on amino acids.

CELLiST is a brand name of cell culture media products that Ajinomoto Inc. manufactures and sells.
Cell culture media business of Ajinomoto Inc. began with the development of serum-free media (ASF media) for the first time in 1987.
Ajinomoto Inc. has been manufacturing and selling media for biopharmaceutical products for about 30 years and established Ajinomoto Genexine Co., Ltd. in 2012 for manufacturing and expanded sales of cell culture media.
Customers of CELLiST include the leading pharmaceutical and bio companies as well as bioengineering research institutes in the world.

1st cell culture media

Ajinomoto is providing the highest quality cell culture media that leads the cell culture media market in the world.

No.1 technological capabilities on amino acids

Ajinomoto is manufacturing and selling cell culture media products with the leading amino acid technologies and know-how in the world.

WHAT IS SWITCH PROGRAM?

‘Switching cell culture media’ is impossible? Difficult?

It is possible at any time!

SWITCH PROGRAM refers to our service that provides various benefits including improvement of productivity and antibody quality, and cost down, etc. through **switching of cell culture media (Media Switch)**, which is a key element in the biopharmaceutical product manufacturing process.

Cost

Product development cost for Media Change is not charged separately.

Time

Product development takes at least 6 months and it is generally possible to achieve Media Change within 1 year.

* If customer choose do Fine Tuning with the Catalog Media of CELLiST, it is possible to shorten the time required for product development to 3 months.

Resource

We support experiments by utilizing a wide range of devices that our research center has including ambr, HPLC and UPLC, etc.

Documentation

We provide assertive support including equivalence test and direct submission of formulation to the authority such as FDA, EMA, etc. at the time of Documentation Filing.

WHY SWITCH PROGRAM?

SWITCH PROGRAM

Cost down and securing of productivity are important factors in order to secure competitive superiority in the market.
It is possible to increase the development and manufacturing efficiency of your company quickly and conveniently
without separate cost at any stage if Media Change is implemented through SWITCH PROGRAM

i Bio Similar

Development Phase 1, 2

- Improve productivity (Titer, VCD improvement)
- Improve Protein Quality (CV, Glycan Profile adjustment)
- Speedy development support
  (utilization of ambr, HPLC and UPLC, etc.)

Phase 3 Commercial

- Cost Down
- Improve productivity (Titer, VCD improvement)
- Improve Protein Quality (CV, Glycan Profile adjustment)
- Analysis service (utilization of HPLC and UPLC, etc.)
- Support Process Development and Process Validation
- Support Documentation Filing (equivalence assessment, etc.)

i New Drug

Development Phase 1, 2

- Media Screening Service
- Improve productivity (Titer, VCD improvement)
- Speedy development support (utilization of ambr, HPLC and UPLC, etc.)
- Develop optimized media (utilization of QbD and OMICS, etc.)

Phase 3 Commercial

- Cost Down
- Improve productivity (Titer, VCD improvement)
- Analysis service (utilization of HPLC and UPLC, etc.)
- Support Process Development and Process Validation
- Support Documentation Filing

SWITCH PROGRAM PROCESS

01 CONTACT

- Get customer's requests
- Contract the NDA

02 DEVELOPING

- Contract the MTA
- Get customer's cell-line
- Media Screening
- Select candidate media
- Cell culture & check the antibody quality

03 FINE TUNING

- Media formulation adjustment
- Formulation confirmation
- Equivalence test

04 SCALE-UP TEST

- Set culture conditions
- Scale-up test

05 PV AND APPROVAL APPLICATION

- Change control
- Documentation Filing

CELLIST™

DEVELOPING

[If we can get your cell-line]

CELL IST™

Optimized media

Select optimized media candidates quickly by utilizing our in-house Media Library

Contract MTA and get the cell-line

After contract Material Transfer Agreement (MTA),
get the cell-line for the development

Media Screening

Do Media Screening by utilizing Media Library that
our R&D Lab has and the results of analysis of existing products.

Select candidate media

Select 1~2 candidate media
on the basis of Screening results

Cell culture and check the antibody quality

Basic culture test (check VCD and titer),
and analysis of CV and Glycan Profile

CUSTOMER

- Provide cell-line
- Select items and standards for antibody quality
- Select candidate media

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- Media Screening
- Set basic culture conditions
- Analyze antibody quality
- Report results

DEVELOPING

[If we cannot get your cell-line]

CELL IST™

Optimized media

Select optimized media candidates quickly by utilizing our in-house Media Library

Contract MTA

Contract Material Transfer Agreement (MTA)

Media Screening

Do Media Screening by providing Media Library
that our R&D Lab has to the customer.

Select candidate media

Select 1~2 candidate media
on the basis of Screening results

Assessment of qualities of culturing and antibody

Basic culture test (check VCD and titer),
and analyze CV and Glycan Profile

* It is possible to analyze at the research center also if customer can send supernatant.

CUSTOMER

- Media Screening
- Share Media Screening results and select candidate media
- Analyze antibody quality

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- Send Media Library sample
- Set basic culture conditions after having reviewed the Media Screening results
- (If customer send supernatant to research center) analyze antibody quality at the same time.

Maximize Cell Performance

Fine Tuning to improve antibody quality and productivity

Media formulation adjustment

Detailed adjustment of formulation
in accordance with culture and
antibody quality test results

Confirmation of formulation

CUSTOMER

- Select final media
- Reproduction experiment

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- Report final candidate test results
- Provide media sample
- (If needed,) submit equivalence test results

From Media to Culturing

Set culture conditions

- Set basic culture conditions including temperature and pH management, etc.

Scale-up Test

- Culture test in diversified scales
- Set culture conditions and adjust formulation additionally in accordance with the Scale-up Test results
- Provide support when customers do additional Scale-up Test by themselves.

CUSTOMER

- Review culture conditions
- Review Scale-up Test results
- Additional Scale-up Test

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- Set culture conditions
- Scale-up Test
- Support customer’s Scale-up Test
- (If needed,) Additional test and Fine Tuning

Change Control Supporting

Provide assertive supports for Change Control including submission of formation to approving authority, and provision of equivalence test data and experimental raw data, etc.

Change Control

Change Control for Media Switch

Documentation Filing

Prepare data and materials
to be submitted to approving authority

CUSTOMER

- Change Control PV
- Media Switch
- Documentation Filing

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- Provide media/raw materials for Change Control PV
- Support Documentation Filling
  (submission of experimental raw data
  and equivalence test data, etc.)

CASE STUDY

We have numerous experiences in Media Switch for **Biosimilar** and **New Drug Pipeline**

i A (Bio Similar)

Stage	Content	Current Status
· Phase3 → Commercial	· Manufacture various raw materials used in the past into a single mixture format to enhance convenience and productivity	· Completed raw material change after verification of equivalence Currently being used in manufacturing

i A (Bio Similar)

Stage	Content	Current Status
· Phase3 → Commercial	· Media Switch to enhance productivity	· Completion of equivalence verification and media development Preparing Change Control

i B (New Drug)

Stage	Content	Current Status
· Development	· Media Switch to enhance productivity and improvement of Product Quality	· Fine tuning of final candidate media is in progress.

i C (New Drug)

Stage	Content	Current Status
· Development	· Media Switch to enhance productivity and improvement of culture conditions	· Completion of media change Currently being used in development

i D (New Drug)

Stage	Content	Current Status
· Development → Phase1	· Media Switch to enhance productivity	· Final candidate media culture test is in progress.

TIME LINE

At the time of Custom Media development

	1M	2M	3M	4M	5M	6M	7M	8M	9M	10M	11M	12M
Media Screening												
Media development after having selected candidate media												
Scale-Up Test and set culture conditions												
Culture test and Fine Tuning												
Prepare Change Control												

At the time of using CELLiST Catalog Product

	1M	2M	3M	4M	5M	6M	7M	8M	9M	10M	11M	12M
Media Screening												
Fine tuning after having selected candidate media												
Scale-Up Test and set culture conditions												
Prepare Change Control												

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