DAEWOONG BIO BIOPLANT

One-Stop CDMO Service

Full CDMO Services in One Location

Bio Plant (Hyang-nam)

Biologics Manufacturing & Development CDMO Service

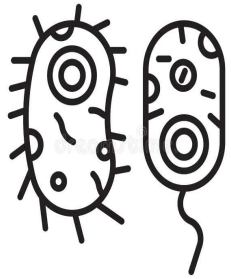
Daewoong Bio's bio-plant, located in Hyangnam, Gyeonggi-do, Korea, manufactures and supplies excellent biopharmaceuticals around the world, and was completed in the second half of 2024 to expand into overseas markets such as the United States.

It is a dedicated production plant for microorganism-based biopharmaceuticals. Drug Substance has large, state-of-the-art facilities with a capacity of up to 900 liter of working volume, while DP also has facilities for manufacturing various finished pharmaceuticals in the form of 2R vial 44,631 vials / 6R vial 23,247 vials (lyophilization), PFS, and Spray per year.

Location

Floor	Area size(m²)	Floor Activities
4F	4,092 m²	DS Manufacturing Line (900 L of Working volume)
3F	4,092 m²	DP Line #1 (Vial), DP Line #2 (PFS), DP Line #3 (Cartridge) DP Line #4 (Spray), Packaging Room
2F	4,092 m²	QA Office, Conference room, MSAT Lab
1F	4,092 m²	QC Laboratory, Warehouse, MCB/WCB Storage
Base	4,092 m²	PW/WFI System, HVAC, Bio-kill System, Emergency Generator
Total	~ 20,459 m² (연면적 6,200평)	

Production of Recombinant Protein Drug through Microbial Culture



Establishment of an economical and productive manufacturing process for global products and CDMO business

1) Technology transfer, process development and optimization of microorganism (E.coli)-based products

2) Manage the production process so that commercial products can be produced stably, and resolve problems based on process understanding when they occur.

3) Support for process validation including Process Design, PPQ, CPV, and CMC study including IND/IDE, BLA/PMA

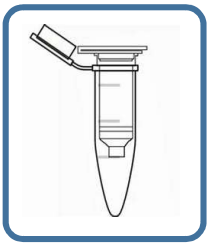
4) Cost reduction (CoGs) to improve price competitiveness and process improvement to improve process robustness

Fermentation: Equipped with state-of-the-art GMP facilities that provide services ranging from non-clinical, clinical and commercialization support based on microbial culture. In particular, Daewoong-Bio has a refolding tank (10,000 L) using multi-use incubators (50L, 1,350L) for US FDA approval preparation and is designed to minimize cross-contamination.

Purification: The purification process is optimized for scale-up, and chromatography and ultrafiltration (UF/DF) undiluted solution filling are operated using facilities optimized for GMP regulations. We have column controllers, columns, and UF/DF equipment of various sizes to secure a variety of products for our customers.

Aseptic Fill/Finish: The latest finished product facility connects the aseptic filling and freeze-drying processes of the product through one line, and is operated through each Vial/PFS/Cartridge automation system.

Analytical Laboratory: We carry out overall quality control of biopharmaceuticals in compliance with GMP guidelines and provide test performance, test method establishment, and test method validation through test method technology transfer procedures.

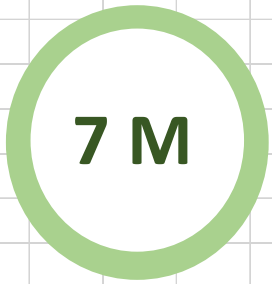


MSAT Lab: For products developed in research institutes or CDMO projects, we are responsible for pre-process review, transferring the developed biopharmaceutical/ medical device product production technology to the factory, and optimizing it to suit the facility. We provide process optimization services based on process understanding.

CDMO Timeline (Expected)

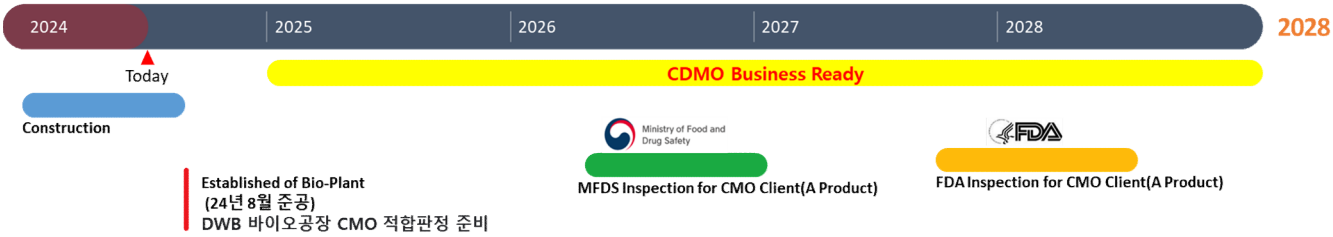
Below outlines an illustrative timeline showing the expected sequence and estimated duration of program stages

Task Name	Duration	1M	2M	3M	4M	5M	6M	7M	8M	9M	10M	11M	12M
Technology Transfer	1M												
Process Gap Risk Analysis	1M												
Analytical Method Transfer & Establishment	3M												
Process Transfer & Establishment	3M												
150 L Process Demontration Run (optional)	1M												
Analytical Method Validation/verification	3M												
Engineering run (1,500 L)	0.5M												
cGMP Manufacture (including PV/Comparability)	2M												
cGMP Conituous Manufacturing	-												



Bio Plant history & Plan

Continuous growth is expected due to the verification of international technology through an inspection by the U.S. FDA and increased demand for CDMO. The company plans to undergo an inspection by the U.S. FDA and have its technology verified to international standards, and based on this, CDMO services for multiple products will be possible.



Products and scope contracted to date (2024.05.20)

Product	A Product (Plan)	B Product (Plan)	C Product (Plan)	D Product (Plan)
Target Country	US, Korea, JP, China	Korea	US, Korea	Korea
Inspection	FDA, MFDS, PMDA, NMPA, etc	MFDS	FDA, MFDS	MFDS
Scope	DS DP (Lyophilized vial)	DS DP (PFS)	DS DP (PFS & Spray)	DS DP (Cartridge)

US FDA, MFDS (Korean Ministry of Food and Drug Safety), PMDA (Pharmaceuticals and Medical Device Agency), NMPA(National Medical Products Administration)

Production of Recombinant Protein Drug through Microbial Culture

● Drug Substance Main Equipment (Working Area: ~3,000 m²)

1,350 L Fermenter (Bioengineering)
(Max. 900 L of working volume)
10,000 L of Refolding Tank
Diameter max 1.4 m Column (Cytiva)

● Drug Product Main Equipment (Working Area: ~3,800 m²)

DP Line #1
(Vial & Lyophilization)

Vial Fill/Finish
(Syntegon, Germany)

Lyophilization
(Optima, Germany)

Vial Capping
(Syntegon, Germany)

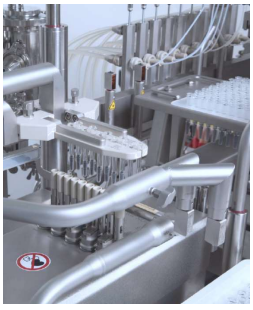
DP Line #2
(Cartridge)

Cartridge Washing
(DARA, Spain)

Cartridge Autoclave
(DARA, Spain)

Cartridge Fill & Finish
(DARA, Spain)

DP Line #3
(Pre-filled Syringe)



Pre-filled Syringe Fill & Finish
(Bausch + Stroebel, Germany)

DAEWOONG-BIO BIOPLANT / CDMO CAPABILITIES & Quality System

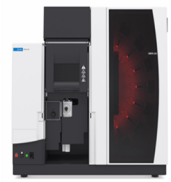
Analytical Laboratory

- Raw material control (Full Compendium) & Environmental Monitoring, MCB/WCB Test (Periodic)
- In-Process Control / Release Test : UV Absorbance, HPLC, Western blot, Microbial Identification, Sterility, Capillary Electrophoresis, etc.
- Method Development (Validation, Development, Optimization)
- Long-term/Accelerated/Stressed Stability Test

Fluorescence Spectroscopy

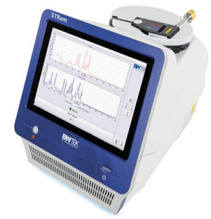
HPLC (Agilent)

GC (FID, ECD)

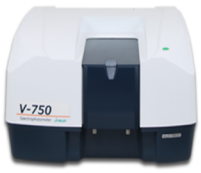


Atomic Absorption Spectrometry

Karl Fischer
(Colometric/Volumetric)



Raman Spectrophotometer



UV/VIS spectrophotometer

Capillary Electrophoresis

FACs

Stability Chamber

Manufacturing Science & Control (MSAT) Laboratory

- Process Optimization and Scale-up
- Process Improvement (Yield, Efficiency, Productivity, Safety, CoGs)
- Process Characterization & Range Studies
- Process Risk Assessment
- CMC Regulatory Packages
- Tech-transfer / Scale-up activities
- Review GMP Document (Change Control, Master Formula)
- Deviation, OOS Investigation
- Batch Record Revision / Review
- Support Clinical / Commercials Manufacturing

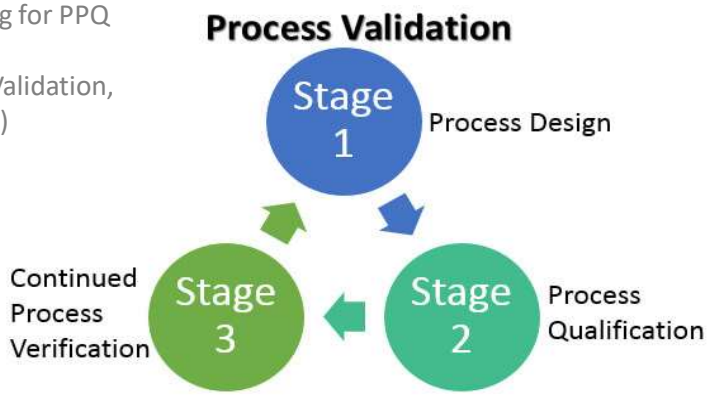
Fermentor
(6.7L, 150L Scale)

AKTA Avant (Cytiva)

HPLC (Agilent)

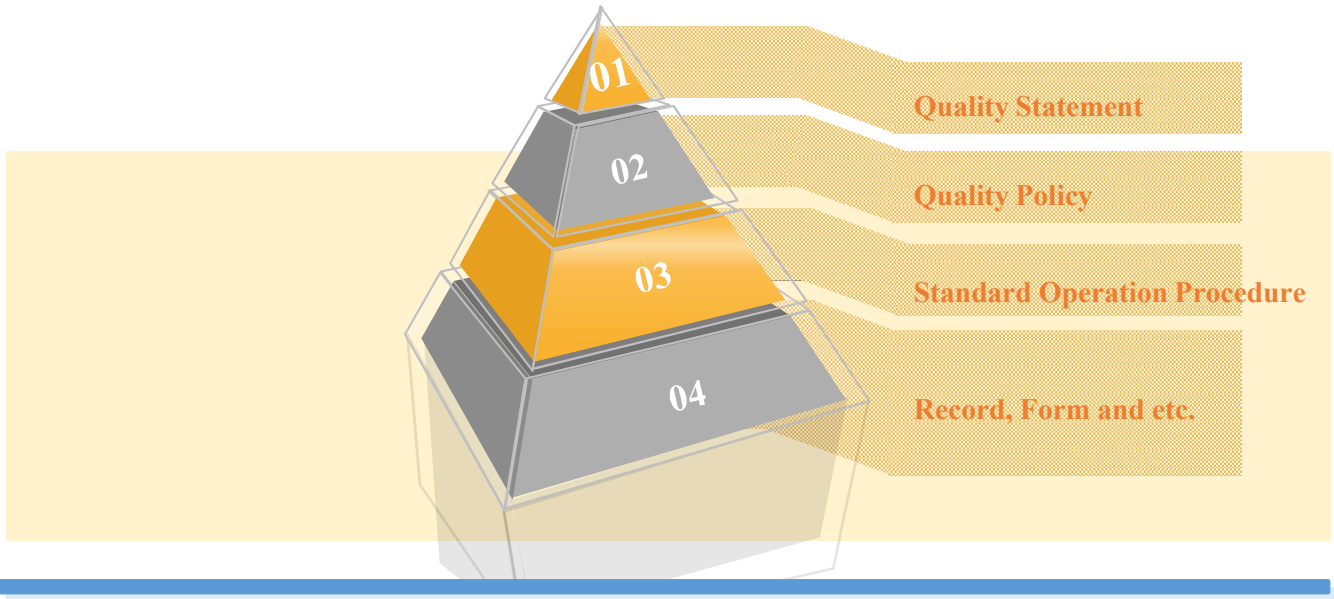
Provide Successful Tech-transfer & Process Validation

- Process Quality Risk Assessment (CPP, KPP, IPC Setting)
- Scale Down Model (SDM) Qualification
- Process Characterization Study using SDM (DoE, optional)
- Acceptance Criteria/Acceptance Range setting for PPQ
- CMC Study (Resin/Membrane Lifetime study, Buffer/Intermediate Holding Time, cleaning Validation, Impurity Clearance, Comparability Study, etc.)
- CPV (Continued Process Verification)



Quality Management System

On the basis of quality statement, we build our quality management system.
Our quality policy meets regulatory authority's requirements and can encourage to continuous improvement.
Management should provide appropriate resources and trainings for quality system. And issues related to product and PQS are reported to the management to review and secure continuous effectiveness of PQS.



Contact us

DAEWOONG-BIO

Hyangnam Bio-Plant, 35-14,
Jeyakgongdan 4-gil, Hyangnam-
eup, Hwaseong-si, Gyeonggi-do,
18623

+82-10-8339-5827
hojinlee@daewoong-bio.co.kr
+82-10-7614-7277
2230674@daewoong-bio.co.kr

DAEWOONG BIO BIOPLANT

One-Stop CDMO Service

Full CDMO Services in One Location

DAEWOONG-BIO BIOPLANT / OVERVIEW

Bio Plant (Hyang-nam)

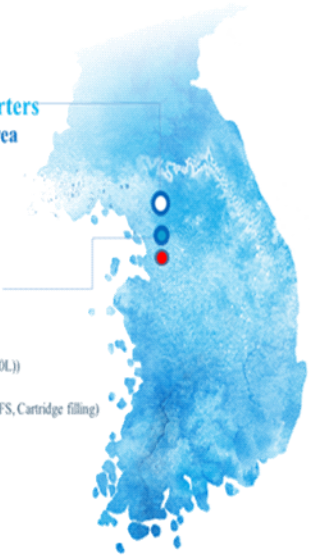
Biologics Manufacturing & Development CDMO Service

Daewoong Bio's bio-plant, located in Hyangnam, Gyeonggi-do, Korea, manufactures and supplies excellent biopharmaceuticals around the world, and was completed in the second half of 2024 to expand into overseas markets such as the United States.

It is a dedicated production plant for microorganism-based biopharmaceuticals. Drug Substance has large, state-of-the-art facilities with a capacity of up to 900 liter of working volume, while DP also has facilities for manufacturing various finished pharmaceuticals in the form of 2R vial 44,631 vials / 6R vial 23,247 vials (lyophilization), PFS, and Spray per year.

Location

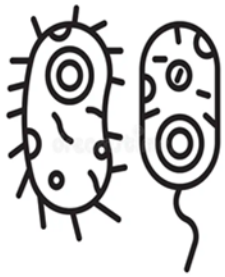
Headquarters
Seoul, Korea



Hyangnam Factory
- Biologic CDMO Service
- Drug Substance
  (Microbial Fermentation (~900L))
- Aseptic Fill/Finish Service
  (Liquid & Lyophilized vial, PFS, Cartridge filling)

Floor	Area size(m²)	Floor Activities
4F	4,092 m²	DS Manufacturing Line (900 L of Working volume)
3F	4,092 m²	DP Line #1 (Vial), DP Line #2 (PFS), DP Line #3 (Cartridge) DP Line #4 (Spray), Packaging Room
2F	4,092 m²	QA Office, Conference room, MSAT Lab
1F	4,092 m²	QC Laboratory, Warehouse, MCB/WCB Storage
Base	4,092 m²	PW/WFI System, HVAC, Bio-kill System, Emergency Generator
Total	~ 20,459 m² (연면적 6,200평)	

Production of Recombinant Protein Drug through Microbial Culture



Establishment of an economical and productive manufacturing process for global products and CDMO business

1) Technology transfer, process development and optimization of microorganism (E.coli)-based products

2) Manage the production process so that commercial products can be produced stably, and resolve problems based on process understanding when they occur.

3) Support for process validation including Process Design, PPQ, CPV, and CMC study including IND/IDE, BLA/PMA

4) Cost reduction (CoGs) to improve price competitiveness and process improvement to improve process robustness

Fermentation: Equipped with state-of-the-art GMP facilities that provide services ranging from non-clinical, clinical and commercialization support based on microbial culture. In particular, Daewoong-Bio has a refolding tank (10,000 L) using multi-use incubators (50L, 1,350L) for US FDA approval preparation and is designed to minimize cross-contamination.

Purification: The purification process is optimized for scale-up, and chromatography and ultrafiltration (UF/DF) undiluted solution filling are operated using facilities optimized for GMP regulations. We have column controllers, columns, and UF/DF equipment of various sizes to secure a variety of products for our customers.

Aseptic Fill/Finish: The latest finished product facility connects the aseptic filling and freeze-drying processes of the product through one line, and is operated through each Vial/PFS/Cartridge automation system.

Analytical Laboratory: We carry out overall quality control of biopharmaceuticals in compliance with GMP guidelines and provide test performance, test method establishment, and test method validation through test method technology transfer procedures.

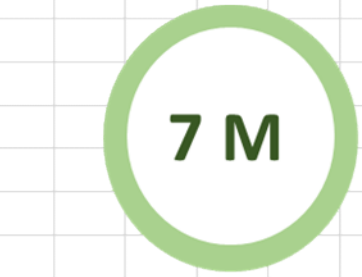
MSAT Lab: For products developed in research institutes or CDMO projects, we are responsible for pre-process review, transferring the developed biopharmaceutical/ medical device product production technology to the factory, and optimizing it to suit the facility. We provide process optimization services based on process understanding.

DAEWOONG-BIO BIOPLANT / CDMO CAPABILITIES

CDMO Timeline (Expected)

Below outlines an illustrative timeline showing the expected sequence and estimated duration of program stages

Task Name	Duration	1M	2M	3M	4M	5M	6M	7M	8M	9M	10M	11M	12M
Technology Transfer	1M												
Process Gap Risk Analysis	1M												
Analytical Method Transfer & Establishment	3M												
Process Transfer & Establishment	3M												
150 L Process Demontration Run (optional)	1M												
Analytical Method Validation/verification	3M												
Engineering run (1,500 L)	0.5M												
cGMP Manufacture (including PV/Comparability)	2M												
cGMP Conituous Manufacturing	-												



Bio Plant history & Plan

Continuous growth is expected due to the verification of international technology through an inspection by the U.S. FDA and increased demand for CDMO. The company plans to undergo an inspection by the U.S. FDA and have its technology verified to international standards, and based on this, CDMO services for multiple products will be possible.

Products and scope contracted to date (2024.05.20)

Product	A Product (Plan)	B Product (Plan)	C Product (Plan)	D Product (Plan)
Target Country	US, Korea, JP, China	Korea	US, Korea	Korea
Inspection	FDA, MFDS, PMDA, NMPA, etc	MFDS	FDA, MFDS	MFDS
Scope	DS DP (Lyophilized vial)	DS DP (PFS)	DS DP (PFS & Spray)	DS DP (Cartridge)

US FDA, MFDS (Korean Ministry of Food and Drug Safety), PMDA (Pharmaceuticals and Medical Device Agency), NMPA(National Medical Products Administration)

Production of Recombinant Protein Drug through Microbial Culture

● Drug Substance Main Equipment (Working Area: ~3,000 m²)

1,350 L Fermenter (Bioengineering)
(Max. 900 L of working volume)
10,000 L of Refolding Tank
Diameter max 1.4 m Column (Cytiva)

● Drug Product Main Equipment (Working Area: ~3,800 m²)

DP Line #1 (Vial & Lyophilization)

Vial Fill/Finish (Syntegon, Germany)

Lyopilization (Syntegon, Germany)

Vial Capping Syntegon, Germany)

DP Line #2 (Cartridge)

Cartridge Washing (DARA, Spain)

Cartridge autoclave (DARA, Spain)

Cartridge Fill & Finish (DARA, Spain)

DP Line #3 (Pre-filled Syringe)

Pre-filled Syringe Fill & Finish (Bausch + Stroebel, Germany)

DAEWOONG-BIO BIOPLANT / CDMO CAPABILITIES & Quality System

Analytical Laboratory

- Raw material control (Full Compendium) & Environmental Monitoring, MCB/WCB Test (Periodic)
- In-Process Control / Release Test : UV Absorbance, HPLC, Western blot, Microbial Identification, Sterility, Capillary Electrophoresis, etc.
- Method Development (Validation, Development, Optimization)
- Long-term/Accelerated/Stressed Stability Test

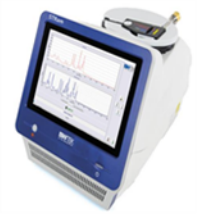
Fluorescence Spectroscopy

HPLC (Agilent)

GC (FID, ECD)

Atomic Absorption Spectrometry

Karl Fischer
(Colometric/Volumetric)



Raman Spectrophotometer

UV/VIS spectrophotometer

Capillary Electrophoresis

FACs

Stability Chamber

Manufacturing Science & Control (MSAT) Laboratory

- Process Optimization and Scale-up
- Process Improvement (Yield, Efficiency, Productivity, Safety, CoGs)
- Process Characterization & Range Studies
- Process Risk Assessment
- CMC Regulatory Packages
- Tech-transfer / Scale-up activities
- Review GMP Document (Change Control, Master Formula)
- Deviation, OOS Investigation
- Batch Record Revision / Review
- Support Clinical / Commercials Manufacturing

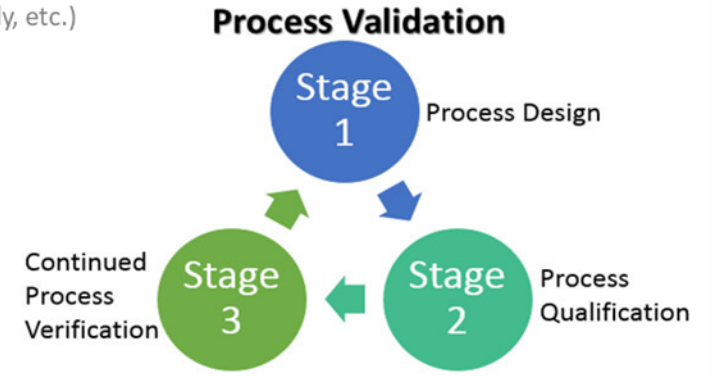
Fermentor
(6.7L, 150L Scale)

AKTA Avant (Cytiva)

HPLC (Agilent)

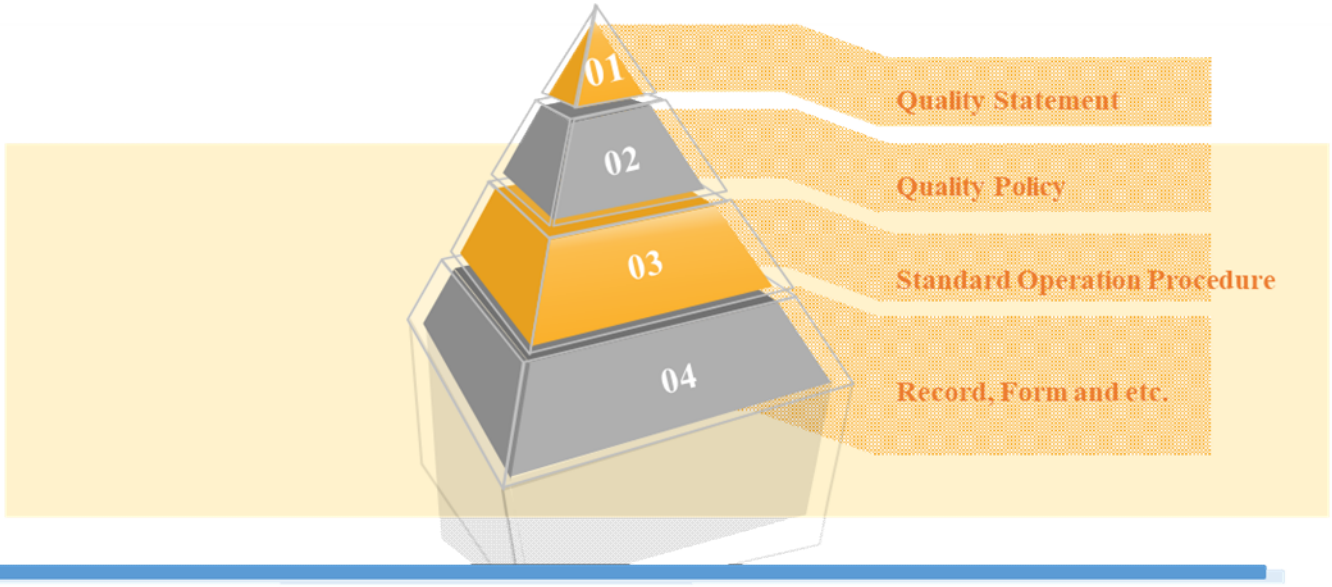
Provide Successful Tech-transfer & Process Validation

- Process Quality Risk Assessment (CPP, KPP, IPC Setting)
- Scale Down Model (SDM) Qualification
- Process Characterization Study using SDM (DoE, optional)
- Acceptance Criteria/Acceptance Range setting for PPQ
- CMC Study (Resin/Membrane Lifetime study, Buffer/Intermediate Holding Time, cleaning Validation, Impurity Clearance, Comparability Study, etc.)
- CPV (Continued Process Verification)



Quality Management System

On the basis of quality statement, we build our quality management system.
Our quality policy meets regulatory authority's requirements and can encourage to continuous improvement.
Management should provide appropriate resources and trainings for quality system. And issues related to product and PQS are reported to the management to review and secure continuous effectiveness of PQS.



Contact us

DAEWOONG-BIO

Hyangnam Bio-Plant, 35-14, Jeyakgongdan 4-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, 18623

+82-10-8339-5827
hojinlee@daewoong-bio.co.kr
+82-10-7614-7277
2230674@daewoong-bio.co.kr