

Bio-Support

Introduction of Company and Business

우리는 삶의 가치를 높이는 기술과 미래를 실현하는 솔루션으로, 사람과 건강한 삶을 연결한다.

We connect people to healthier lives through technologies that enhance the quality of life and solutions that realize the future.

Bio-Support

GMP Justice
Advanced Quality Culture

Innovative Value Chain
Collaboration Biz of Bio-Support

한국제약기술교육원
Korea Pharm Tech Education Center

Survival GMP Workshop
Knowledge Sharing of Bio-Support

GMP Platform
GXP Value Chain Solution

- BS Document No: BS-BBB-001E
- Revision No: 10
- Revision Date: 2026-02-06
- Written by: KM Kim, Bio-Support
- Security: Confidential!!!

Bio-support has been growing together
with our valued customers and partners since 2000!!!.

Introduction of Bio-Support

Bio-Support

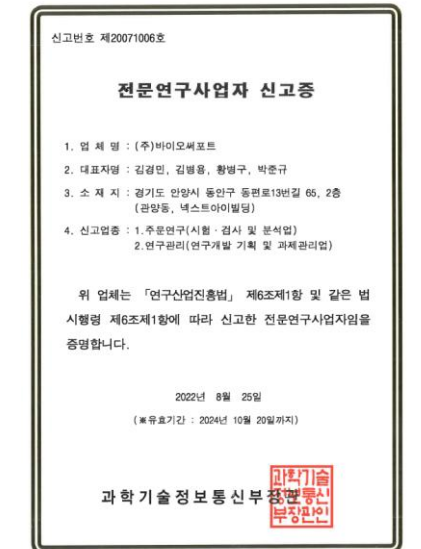
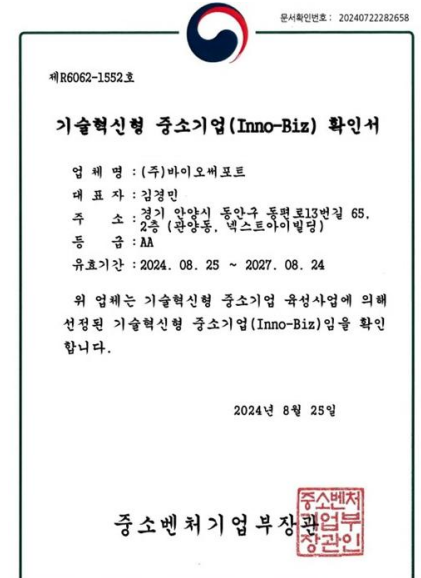
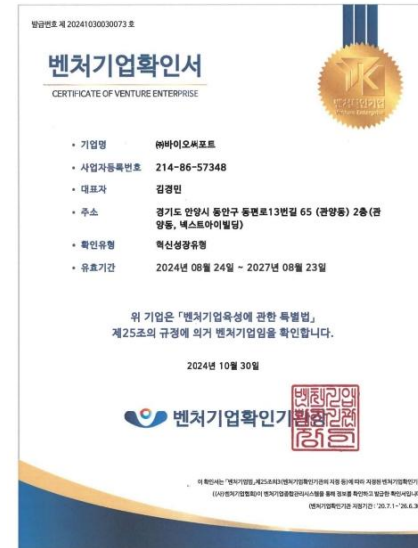


We start with value, grow through challenge,
act with sincerity and energy,
and fulfill through wisdom

and fulfill through wisdom
act with sincerity and energy
We start with value, grow through challenge

Company Overview

ITEM	DESCRIPTION
Name	Bio-Support Co., Ltd
Founded	Apr. 19, 2000
CEO	Kim Kyung-min
Address	65, Dongpyeon-ro 13beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
Employee	61 Persons(GMP Consultant 50, GEP Engineer 2)(as of Jan 2026)
Main business	<ul style="list-style-type: none"> [GMP & Validation Solution Consulting Biz] [PharmaBio Value Chain Collaboration Biz] <i>GMP (Good Manufacturing Practices, pharmaceutical manufacturing management and quality control standards) for pharmaceuticals, biopharmaceuticals, ATMP, veterinary drugs, medical devices, and health functional foods</i>
Main Certificates	<ul style="list-style-type: none"> Venture Business Verification (2006~), Gov. Promising SME Certification (2008) Technology Innovation SME (Innobiz) Verification (2008~) Professional Research Biz. Certificate(Ministry of Science & ICT)(2007~) ISO 9001 Quality Management System (2009~), Ministry of Employment and Labor SME Verification (2024~)
Contact us	www.biosupport.co.kr , gmp@biosupport.co.kr



**Established in 2000, Bio-Support is Korea's leading GMP and Validation consulting firm.
We are committed to advancing GMP excellence and quality
across the pharmaceutical, biotechnology, and healthcare industries.
Bio-Support delivers a comprehensive portfolio of GMP and Validation consulting services tailored
to the unique needs of these sectors..**

We develop and implement future-oriented GMP and Validation technologies to drive sustainable quality excellence.

We are committed to acting responsibly and contributing positively to society.

Bio-Support
As a trusted leader in GMP solution consulting and value chain collaboration, we are committed to setting the standard of excellence.

We look beyond today, driving innovation through leading-edge technologies and forward-thinking business models.

Delivering tangible business value with partners through pharmaceutical and biotechnology value chain collaboration

Policy for Corporate Management

Version 06(Revision Date: 2025-04-04, Effective Date : 2025-04-11)

The Motto of Company

With creativity and boldness, we envision our dreams and pursue them with joy. To us, dreaming is not a goal - it is our responsibility.

Why!!! Why have we gathered?

Mission	<ul style="list-style-type: none">❖ We connect people to healthier lives through technologies that enhance the quality of life and solutions that realize the future.
Vision	<ul style="list-style-type: none">❖ A company that goes beyond the boundaries of imagination with pharmaceutical, biotech, healthcare, and digital technologies and solutions - turning a healthier future for humanity into reality.
Product & Service	<ul style="list-style-type: none">❖ [GMP & Validation Solution Consulting Biz]❖ [PharmaBio Value Chain Collaboration Biz]

How!!! How do we work?

Work Way	<ul style="list-style-type: none">❖ Creative Value Design & Continuous Challenge Based on Positive Thinking and Leadership❖ Leadership is about more than just skills and abilities. It's about having the right mindset to inspire and empower others.❖ Either lead, follow or get out of the way.❖ Throw it away properly and fill it more properly to grow
People Code	<ul style="list-style-type: none">❖ Challenge, Leadership & Energy❖ Knowledge, Creativity & Wisdom

품질 선언문 - Quality Statement -

GMP Justice
Advanced Quality Culture

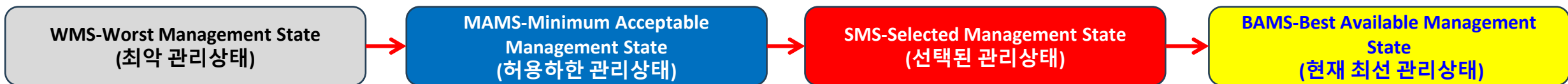
우리는 고객과 환자를 우리의 가족으로 생각하면서 GMP/GXP를 준수한다.
Our commitment to GMP/GXP compliance is rooted in a patient- and customer-first mindset, where safety and quality are treated as personal responsibilities.

우리는 위험, 시스템 및 과학을 기반으로 하여 GMP/GXP 활동을 실시한다.
Our GMP/GXP activities are performed based on risk-based, system-based, and science-based approaches.

Document No: POL-QM-0111-A-001(Ver. 01)

Effective Date: 2023-09-01

Bio-Support's Realization- and Risk-Based Quality, Management, and Business Framework



FY2026 Management Goals

By strategically decoupling the business value chain,
We will promote 'moving management' and 'value-oriented business innovation'
that change the combination according to changes in the environment.
= Value Creation + Value Extraction + Value Erosion(Strategic De-emphasis)

GMP & Validation Solutions
Consulting Business

GEP Realization Project

Value Chain Collaboration
Business

Advanced Regenerative
Medicine Solution Business

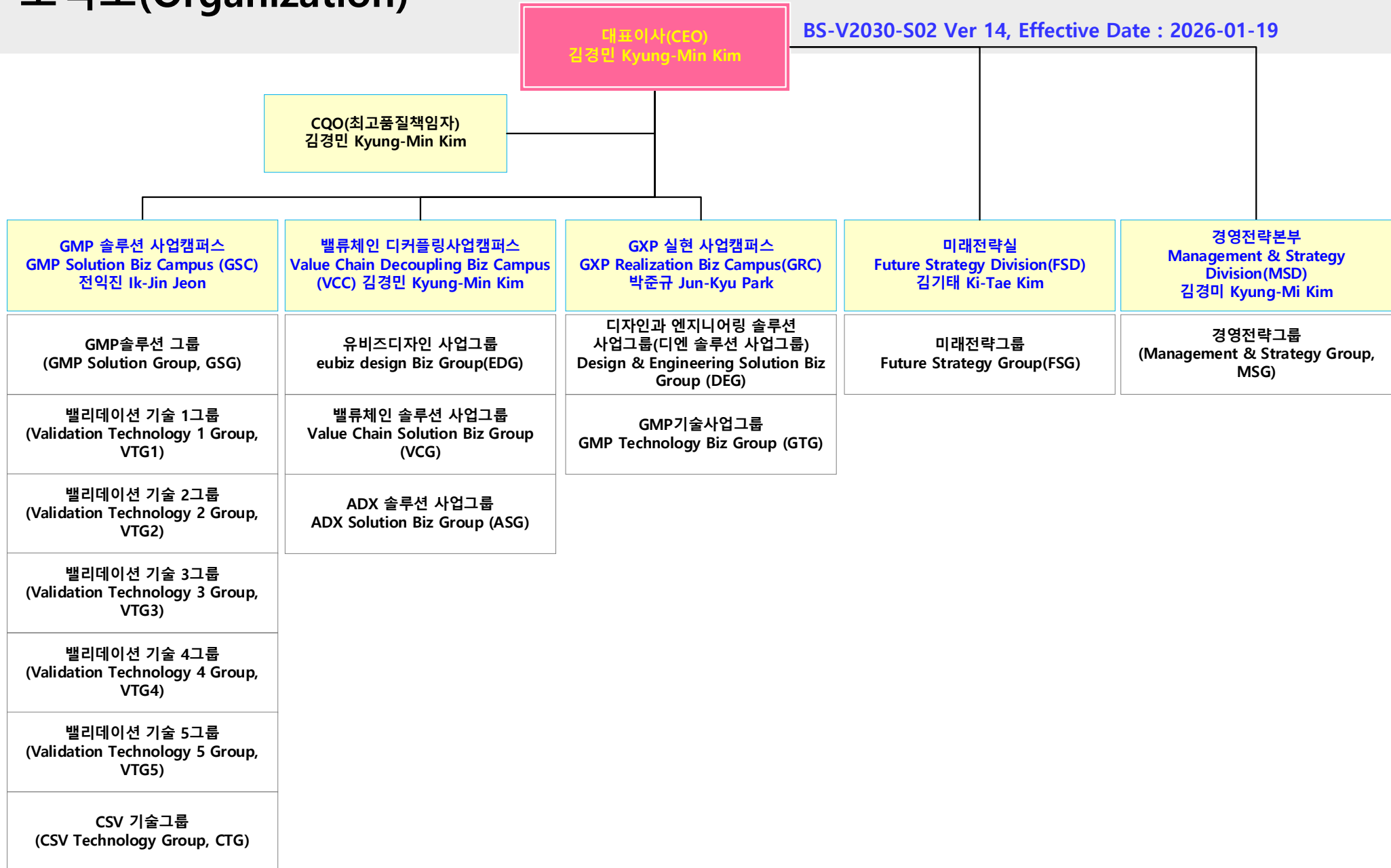
가치로 시작하고, 도전으로 성장하며, 정성과 에너지로 실행하고, 지혜로 완성한다.

We start with value, grow through challenge, act with sincerity and energy, and fulfill through wisdom.

- 가치 (Value)~~Management and business centered on value
- 도전 (Challenge)~~Courage to try the impossible
- 정성 (Sincerity)~~The attitude of putting your soul into even the smallest things
- 에너지 (Energy)~~The passion of a leader is the driving force of an organization
- 지혜 (Wisdom)~~Knowledge is to accumulate, wisdom is to share

회사 조직도(Organization)

BS-V2030-S02 Ver 14, Effective Date : 2026-01-19



Company Key-Personal Profile



Kyung-Min Kim

- CEO & Chief Consultant of Bio-Support
- Campus Leader, Value Chain Decoupling Biz Campus
- Co-CEO, Korea Pharm Tech Education Center(KPETC)
- Senior Vice-Chairman, PDA Korea Chapter
- GMP & Validation Consulting Specialist (handle over 300 Projects)
- ATMP GMP & Conceptual Design Specialist
- Advisor/Instructor, K-NIBRT(Yonsei Univ.)
- Instructor, College of Pharmacy Pharmaceutical Practice Education Program of Ehwa Womans Univ.
- Award of Korea Drug Research Association (2023)
- GMP Instructor/Speaker(KOHI, MFDS, KDRA,PSK, APQA, KAHPA, Dongkook Univ, Yonsei Univ, SungKyunKwan Univ Etc.,)



Jun-Kyu Park

- Chief Consultant & CTO of Bio-Support
- Campus Leader, GXP Realization Biz Campus
- Senior Instructor, KPTEC
- Conceptual Design & Process Design Specialist, Global DS(API) and DP GMP Manufacturing plant
- Conceptual Design Project(Handle over 80 Projects)



Ik-Jin Jeon

- Principal Consultant & Vice President of Bio-Support
- Campus Leader, GMP Solution Biz Campus
- Senior Instructor, KPTEC
- EU ECA Certified Validation Manager
- Project Specialist of Qualification & Validation Consulting of New GMP Manufacturing Plant(handle over 350 Projects)



Ji-Min Kim

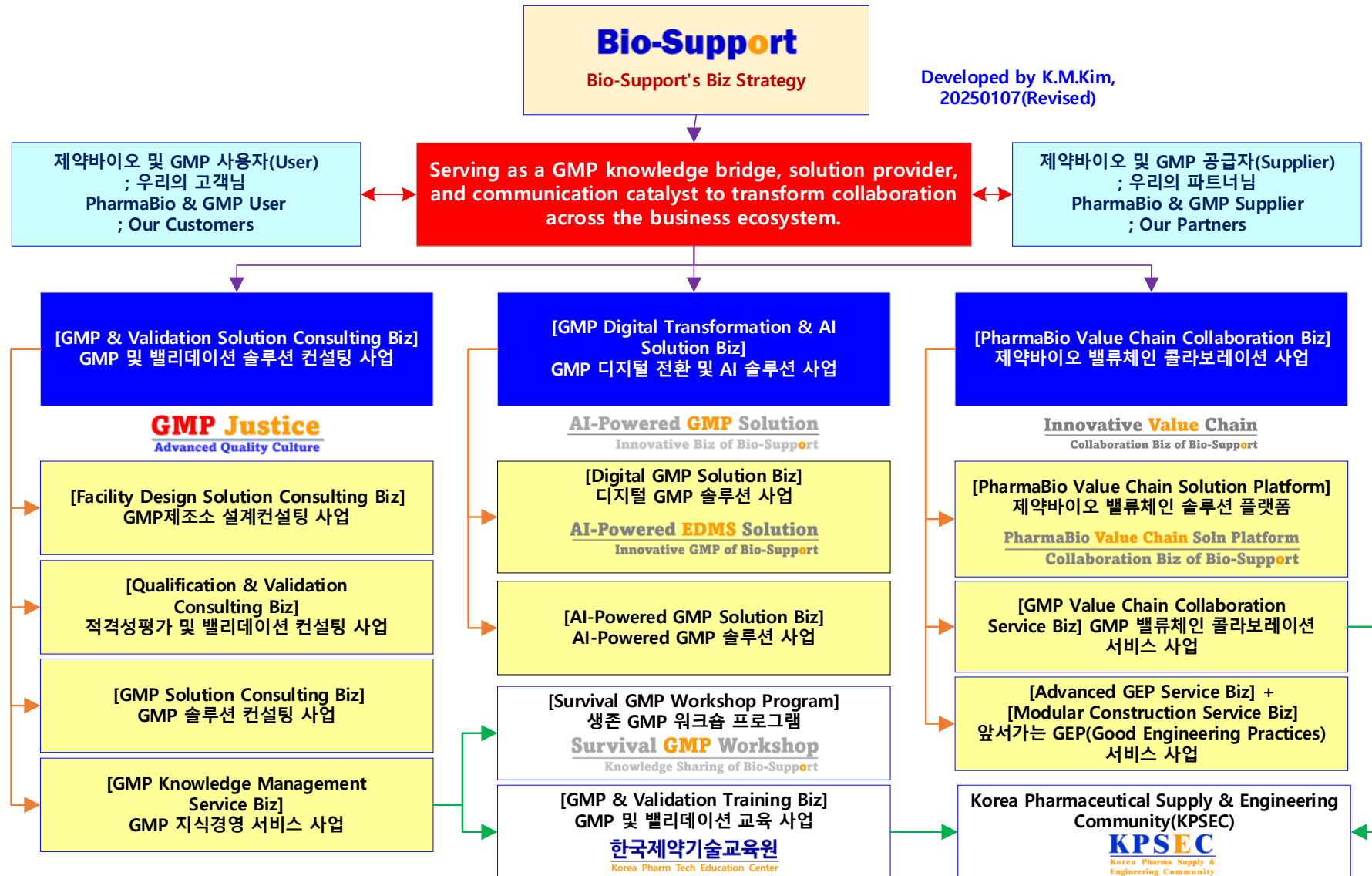
- Senior Engineer & Managing Director of Bio-Support
- Group Leader, Value Chain Decoupling Biz Campus
- SHI-ASIA (FORMAL SAMSUNG HEAVY (THAILAND) Managing Director, Project Director(PD)
- CEO, MTM C & T COMPANY LIMITED
- SAMSUNG C&T Site Manager
- Manufacturing Support Equipment Qualification Assessment Expert
- GPP Specialist/GEP Specialist



Kyung-Mi Kim

- Managing Director of Bio-Support
- Division Leader, Managing Strategy Division
- A.I.C.P.A.
- Formal Management Consultant, KPMG Shandong Accounting Firm
- Formal Team Chief., Univera's Strategy Planning Team.
- Performed numerous management consulting services including financial, H/R, and business planning

Bio-Support Business Overview



Bio-support has been growing together
with our valued customers and partners since 2000!!!.

Bio-Support

Introduction of GMP & Validation Solution Consulting Biz

GMP & Validation Solution Consulting Services

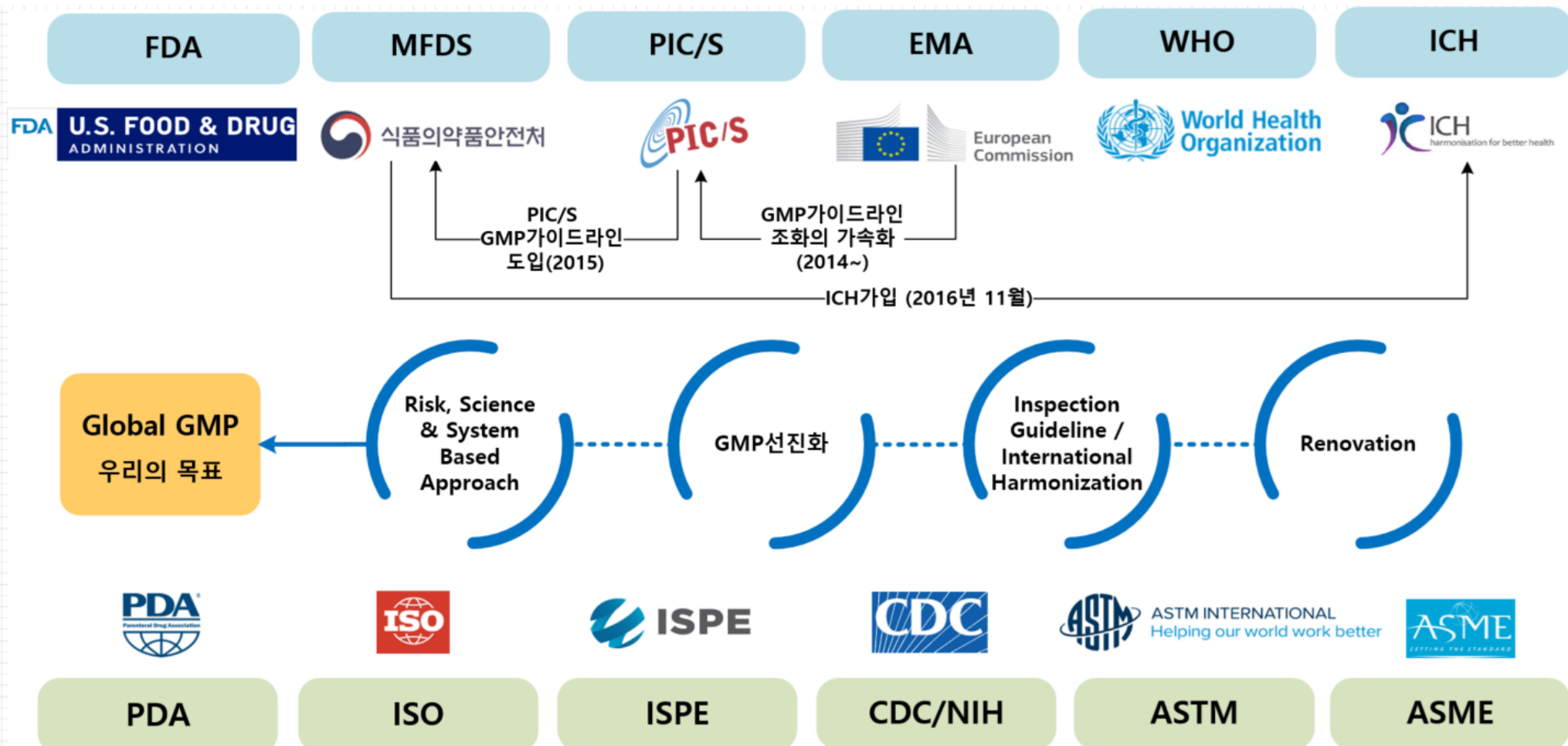
- *Your challenges in GMP and Validation are our priority.*
- *We offer a full spectrum of GMP and Validation solution consulting services to support your success.*



GMP & Validation Consulting/Solution Project Reference: More than total 1,290 projects

Realize Global GMP through forward-looking consulting

To ensure our clients' objectives are fully aligned with global GMP standards, Bio-Support continuously monitors, reviews, and analyzes regulatory requirements and standards across regions, proactively integrating them into our consulting services



[GMP & Validation Solution Consulting Biz]



New/Remodeling GMP Facility Consulting(Turnkey Project); [Conceptual Design Execution, VMP, QRM(RA), URS, DQ, IQ, OQ, PQ, CSV, CV, PV and/or PQS Consulting]	
GMP Facility Design Solution (Conceptual Design)	GMP Facility for Oral Solid Dosage Form, Liquids, Ointments, Eye Drops, Injections
	GMP Facility for API
	GMP Facility for Biopharmaceuticals, Cell Therapy & Gene Therapy(ATMP, CGT)
	GMP Facility for Health Functional Food & Medical Devices
Good Engineering Practice(GEP) Solution	Enhanced Design Review of Basic & Detailed Design/Facility Design
	GMP Facility Commissioning Consulting + Planning Execution & Reporting
	Utility System and Equipment Functional & Design Specification(FDS) Analysis & Documentation
	FAT / SAT and Pre-Delivery Inspection Planning, Execution & Reporting
	GMP Facility Engineering Management & Supervision Service
Qualification Consulting	Validation Master Planning + Quality Risk Management Master Planning
	QRM Planning, Execution & Reporting(Facility, Utility System, Equipment, Process etc.)
	URS & Design Qualification Execution & Documentation
	Installation & Operational Qualification Execution & Documentation
	Performance Qualification Consulting, Execution & Documentation
	Requalification & Revalidation Consulting, Execution & Documentation
Validation Solution	Cleaning Validation Consulting & Documentation
	Process Validation Consulting & Documentation
	Computerized System Validation Consulting, Execution & Documentation
GMP Solution Consulting	Validation Management System & Quality Risk Management System Consulting & Documentation
	GMP & Validation Training + Survival GMP Workshop(Knowledge Sharing)
	Data Integrity Management System & SOPs Consulting + Data Integrity Mock Inspection
	GMP Mock Inspection/ Vendor Audit
	Pharmaceutical Quality System(PQS) Consulting(Policy, SOPs, Form; Preparation, Review, Training)
GMP Innovation	QbD Consulting(Partnership)
	Contamination Control Strategy (CCS) + Advanced EMP & Bioburden Control Consulting
	GMP Digital Transformation Solution Consulting

[GMP & Validation Solution Consulting Biz]

Global GMP Trend Keyword





Advanced GMP by Design 개념도

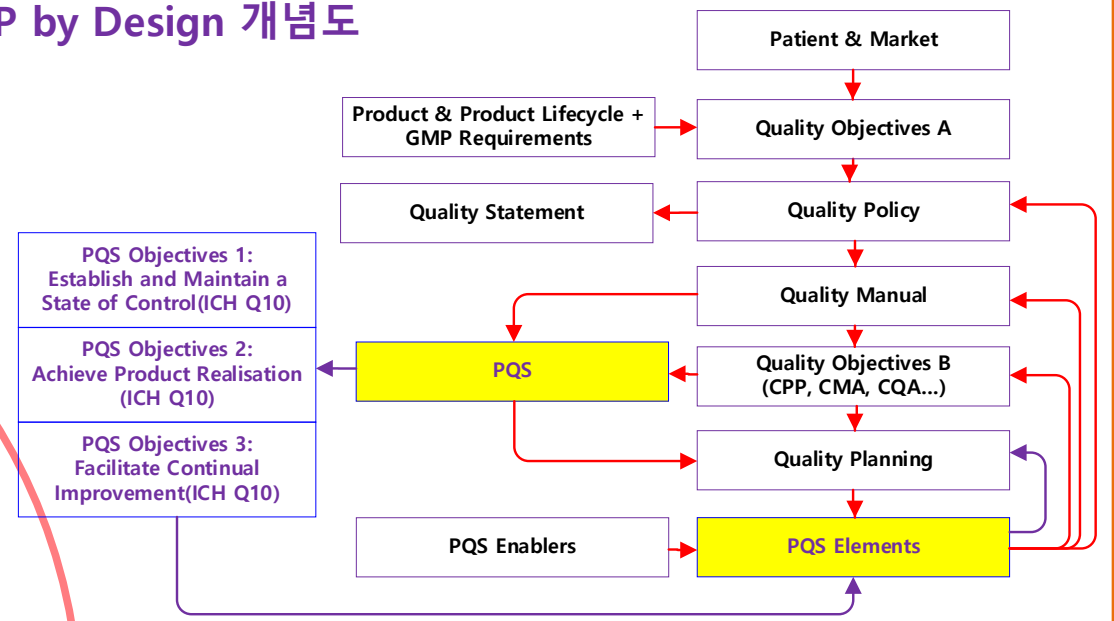
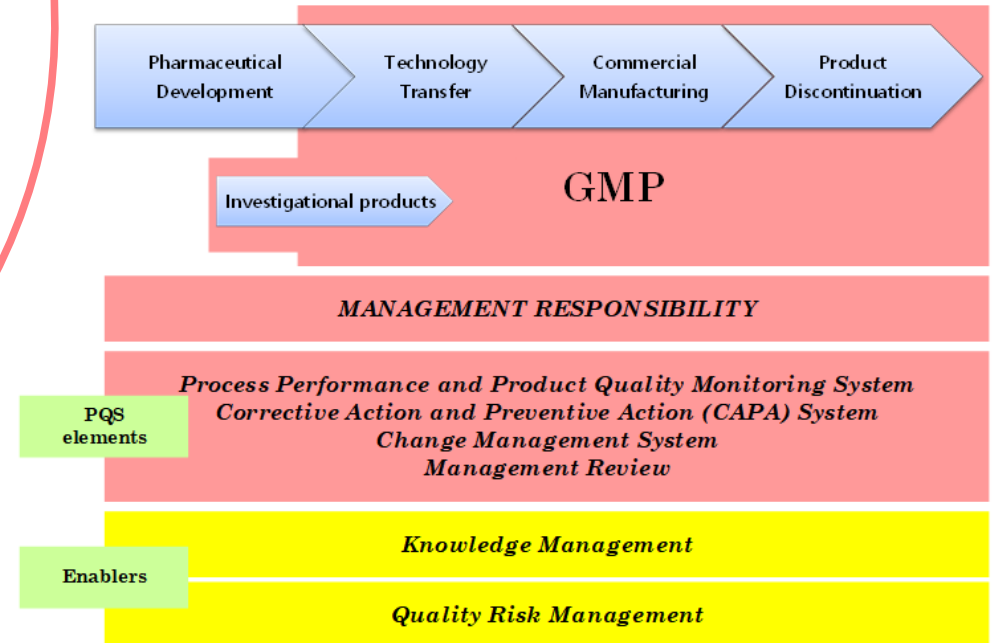


Diagram of ICH Q10 Pharmaceutical Quality System Model



Culture of Quality: An environment where each and every person understands and embraces their responsibility for protecting product quality and patient safety*

Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system

[GMP & Validation Solution Consulting Biz]
Bio-Support's Advanced GMP by Design!!!

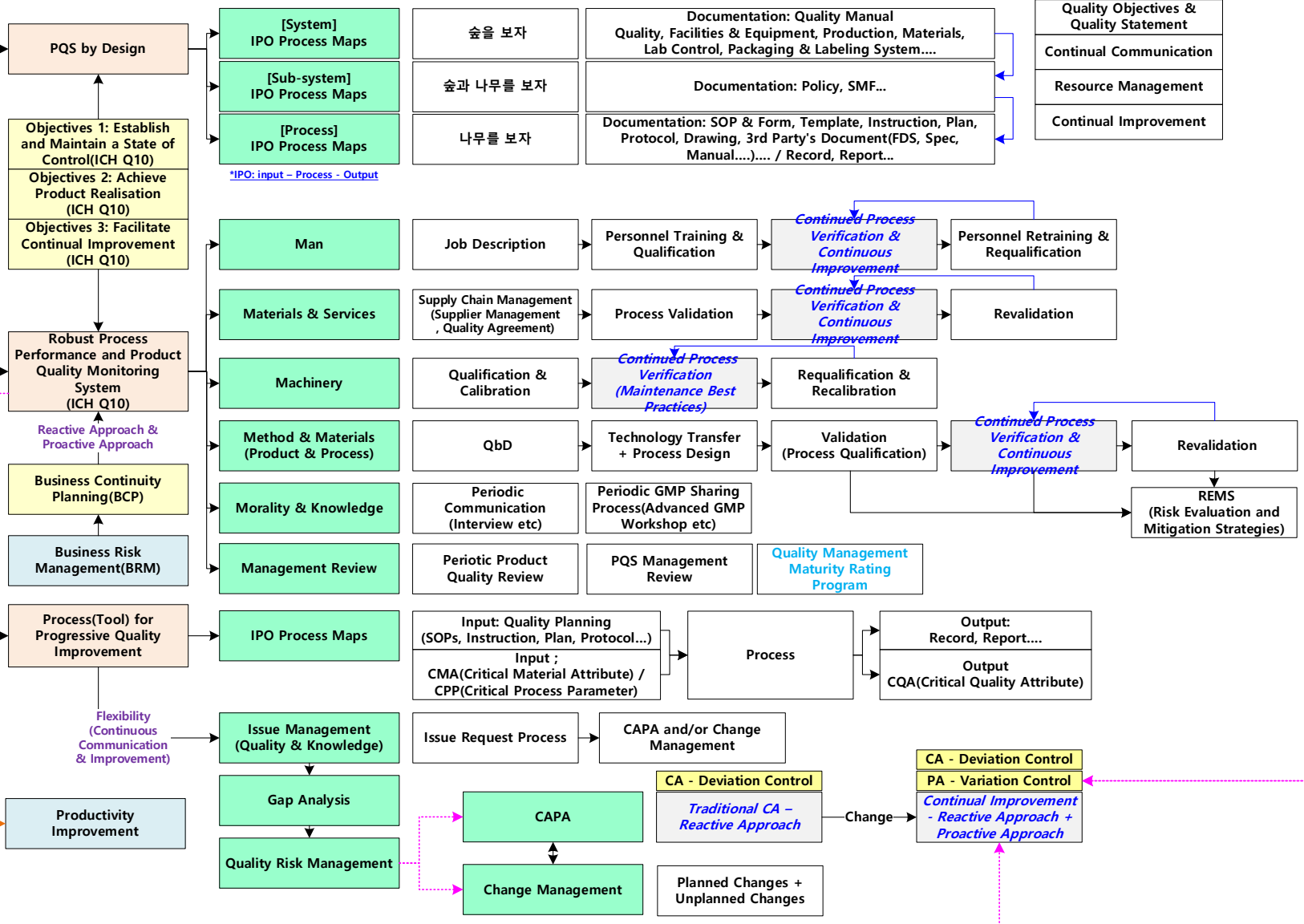
GMP by Design + Data Integrity + Justification

Lifecycle / Risk / Science / System based Approach

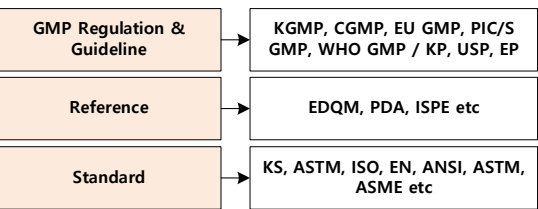
Management Responsibilities (ICH Q10)

Leadership

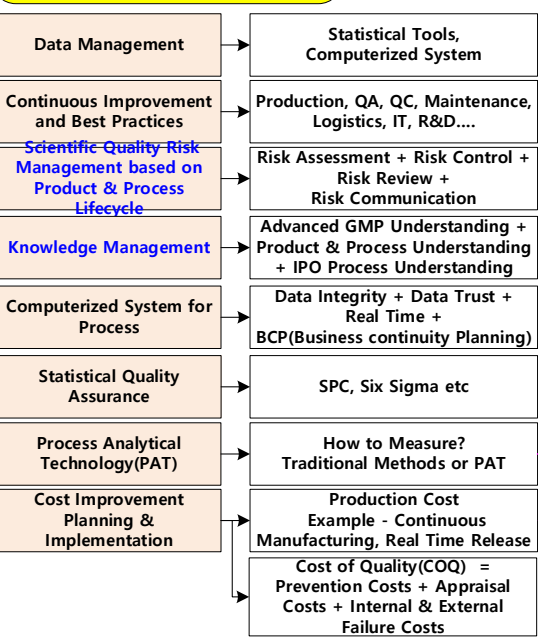
Top Management, Senior Management & HR Management



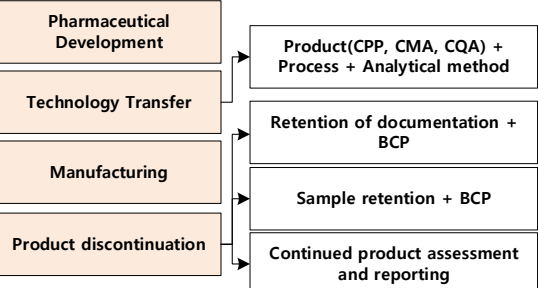
Analysis & Implementation of Advanced GMP Guideline



Enablers of Advanced GMP (ICH Q10)



Product Lifecycle (ICH Q10)



[GMP & Validation Solution Consulting Biz]

“Bio-Support”, The Leader in GMP Solution Consulting, Our Valued 390 Customers!!

ILDONG

INSTITUT PASTEUR
de Dakar

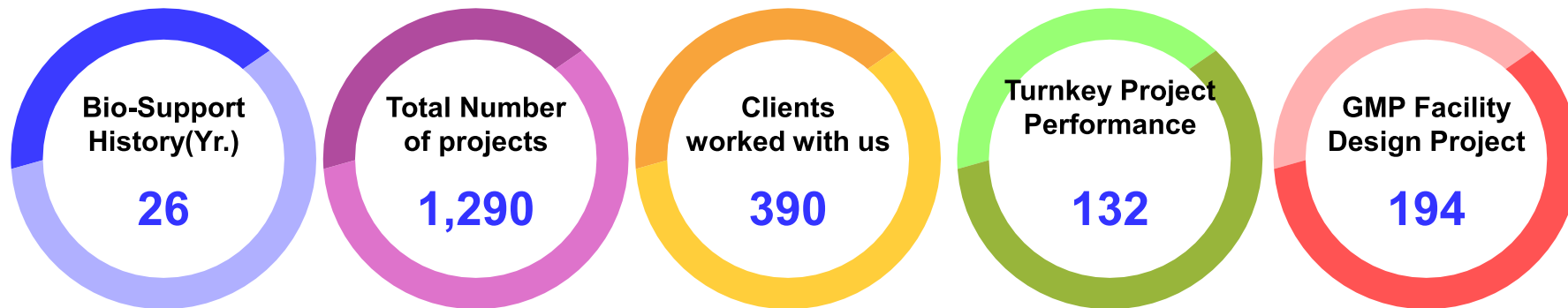


[GMP & Validation Solution Consulting Biz]

We provide integrated, best-in-class GMP consulting solutions, covering Conceptual Design, Qualification & Validation, and Pharmaceutical Quality Systems.

Bio-Support has successfully delivered comprehensive GMP and Validation consulting for new GMP manufacturing facilities, working as one team with a wide range of customers.

**Korea No. 1
GMP & Validation Solution Consulting, Bio-Support**



**Conceptual Design, Qualification & Validation + CSV
PQS, QRM, Data Integrity, CCS, Mock Inspection, Vendor Audit**

[GMP & Validation Solution Consulting Biz]

We provide integrated, best-in-class GMP consulting solutions, covering Conceptual Design, Qualification & Validation, and Pharmaceutical Quality Systems.



**Korean Red Cross
Plasma Fractionation Center**



**Yuyu Pharmaceutical
Jecheon Plant**



**Daejeon High-tech Industry
Promotion Foundation**



**Chuncheon Bio Industry
Promotion Agency**



**Samsung Biologics
Songdo Plant**



**ST Pharm
Banwol Factory 1**



**Unimed Pharmaceutical
Osong Plant**



**Jinyang Pharmaceutical
Wonju Plant**



**Yuyoung Pharmaceutical
Jincheon Factory**



**Samil Pharmaceutical
Ansan Plant**



**Donghwa Pharmaceutical
Chungju Plant**



**NIBEC
Jincheon Factory**



**Boryeong Biopharm
Jincheon Factory**



**Gunil Pharmaceutical
Cheonan Plant**



KGC Wonju Plant



**Myeongin Pharmaceutical
Paltan Factory (Injection)**



**Sama Pharmaceutical
Wonju Plant**



**ST Pharm
Banwol Factory 2**



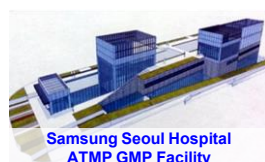
**Ildong Pharmaceutical
Anseong Factory (Sepa Anti-cancer
Drug)**



**Myeongin Pharmaceutical
Paltan Factory (Contents)**



**KCDC
National Stem Cell Regeneration
Center**



**Samsung Seoul Hospital
ATMP GMP Facility**



**BC World Healthcare
Wonju Factory**



**BC World Pharmaceutical
Yeosu Factory**



**Osong Advanced Medical Industry
Promotion Foundation**



DHP Korea Osong Factory



**Hanmi Pharmaceutical
Paltan Plant (OSD)**



**Medipost
ATMP GMP Facility**



**Pharma Research
Gangneung Plant**



**NK Max
ATMP GMP Facility**



**Utilex
ATMP GMP Facility**



**Myeongsang Pharmaceutical
Hyangnam Factory**



**Gangstem Biotech
ATMP GMP Facility**



**SK Chemical
Cheongju Plant (OSD)**



**Hugel
Chuncheon Factory**



**Taejun Pharmaceutical
Yongin Factory**



**YONSUNG Fine Chemicals
Hwaseong Plant**



**Boryeong Pharmaceutical
Budget Factory**



**Myeongin Pharmaceutical
Balan Factory**



**Dasan Pharmaceutical
Asan Plant 2**

[GMP & Validation Solution Consulting Biz]

We provide integrated, best-in-class GMP consulting solutions, covering Conceptual Design, Qualification & Validation, and Pharmaceutical Quality Systems.



[GMP Knowledge Management Service Biz]

Since 2007

한국제약기술교육원
Korea Pharm Tech Education Center

Established in 2007, the *Korea Pharmaceutical Technology Education Center (KPTec)* is a specialized education and training organization dedicated to GMP and Validation excellence.

www.kptec.or.kr /
kptec@biosupport.co.kr

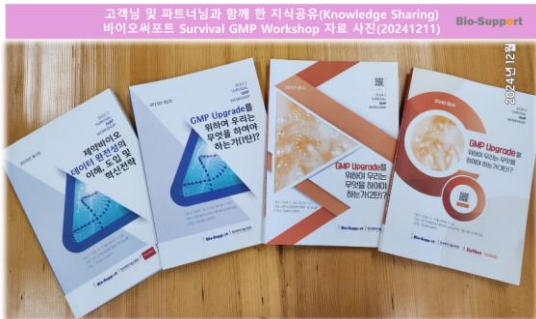
Total number of trainings	442	Number of Website Members	8,000
Total Trainee	13,988	Number of Visitors to the Website	100~200 persons /working day
Total training hours	5,302 hours	Total number of courses	2,270
Total number of companies taking the course	614	Total number of instructors	1,984 persons



Survival GMP Workshop

Knowledge Sharing of Bio-Support

Survival GMP Workshop program to share knowledge with customers



Goal of Bio-Support

As Korea's leading GMP consulting company, Bio-Support is committed to fulfilling its mission and social responsibility in advancing GMP excellence nationwide, while actively promoting meaningful and impactful knowledge sharing!!!



Keyword 1
Future Market & Customer

Keyword 2
Potential & Advanced GMP Technology & Quality

Keyword 3
GMP Value Chain Collaboration(GMP Supply Chain)

**Bio-support has been growing together
with our valued customers and partners since 2000!!!.**

Bio-Support

Introduction of PharmaBio Value Chain Collaboration Biz

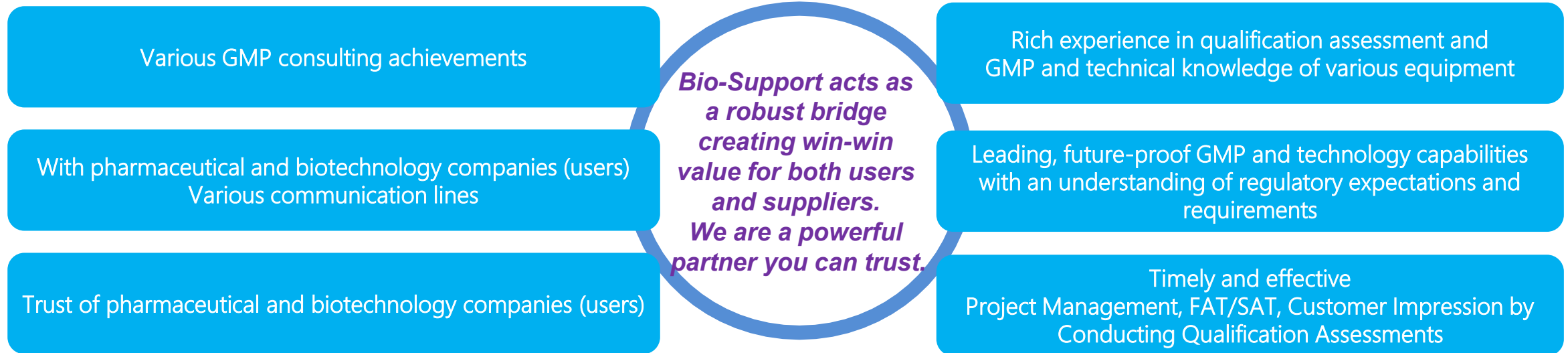
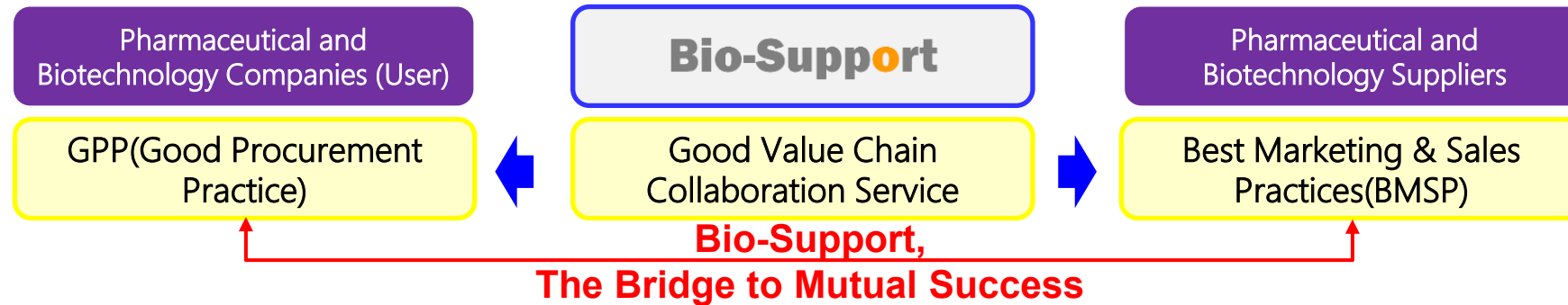
Innovative Value Chain
Collaboration Biz of Bio-Support

[PharmaBio Value Chain Collaboration Biz]

Innovative Value Chain Collaboration Service of Bio-Support

Bio-Support leads the creation of an innovative value chain by connecting pharmaceutical and biotechnology suppliers and users in strategic collaboration.

Since 2000, Bio-Support is a company with the capabilities of
 1) various GMP (conceptual design, quality system, validation, etc.) consulting results in the pharmaceutical and biotechnology field,
 2) accurate and practical communication lines with user executives and executives, and
 3) user trust in the implementation of successful consulting projects.
 Based on the above capabilities, we realize the Innovative Value Chain Collaboration Service with suppliers and users to create innovative added value together with partners in the supply chain.



[PharmaBio Value Chain Collaboration Biz]

The services of Bio-Support's value chain business with partners (pharmaceutical and biotechnology partners) are as follows.

No.	Service Category	Description
1	Project Feasibility Consulting	Conceptual design, basic design, and detailed design support for GMP facility (equipment layout, etc.)
2	Project Management	Customized and digital project management services (PM + Engineer + GMP Consultant)
3	Process Development & Design	Option development and process design services
4	URS Development(Optional)	Initial User Requirement Specification (URS) development services
5	Equipment Specification Selection & Customization	Customer-specific equipment specification definition based on process design
6	Project Engineering Design & Manufacturing	GMP-based equipment design & manufacturing, international competitiveness, 3D design and installation video support (Optional)
7	Document Control	GMP-compliant digital document management for design docs, specifications, reports, manuals
8	Change Control (Design Stage)	GEP-based design change management during design, fabrication, and initial validation
9	Delivery Management	Delivery schedule management aligned with customer requirements
10	Installation & Commissioning	Customized installation and GEP-based commissioning services (FAT/SAT optional)
11	Equipment & Process Validation (Optional)	GMP qualification & CSV services (VP, URS, DQ, QRM, IQ, OQ, PQ, Deviation Control)
12	CCS & Data Integrity Consulting(Optional)	CCS, Data Integrity, and (Aseptic) Process Validation consulting
13	Technology Transfer & Training	Technology transfer, handover, and continuous training (online/offline)
14	Change Control & Requalification (Optional)	Change management review and requalification services

[PharmaBio Value Chain Collaboration Biz]









The PharmaBio Value Chain Collaboration Service is provided by Bio-Support in collaboration with the following partners.

Why!!! Should it be a service of Bio-Support?

The Innovative Value Chain Collaboration Service is Bio-Support's signature platform, combining its mission and GMP expertise to unlock collaborative value beyond traditional GPP (Good Procurement Practice).

Through transparency, efficiency, and trust, the service enables seamless procurement and builds long-term partnerships between suppliers and users.

Our Partner

	<ul style="list-style-type: none"> • Aseptic Drug Product(DP + Lyophilization) Production Line Equipment(Total Solution) • Biological Product(DS: USP & DSP)) + DP) Production Line Equipment(Total Solution) • Clean Air Equipment(RABS, Isolator) for Production and QC Sterility Test • GMP Facility Modular Construction https://www.tofflon.com/ 		<ul style="list-style-type: none"> • OSD Production Line Equipment(Total Solution) • OSD Laboratory Equipment • OEB Containment Equipment • Digital Smart Factory Solutions
	<ul style="list-style-type: none"> • Portable and Remote Particle Counter for GMP Cleanroom & Clean Air Equipment • Real-Time Viable Particle Counter • Ventilation Test Instruments https://tsi.com/ 		<ul style="list-style-type: none"> • Aseptic Drug Product(DP + Lyophilization) Production Line Equipment(Total Solution) • Clean Air Equipment(RABS, Isolator) for Production and QC Sterility Test
	<ul style="list-style-type: none"> • GMP Validator/Data Logger for Thermal Validation 		<ul style="list-style-type: none"> • Aseptic Filling Line Equipment / OSD Production Line Equipment
	<ul style="list-style-type: none"> • Single Using Bio-Pharma System (SUS) • Single-Use Bioreactor Bags, (2D/3D) (Single-Use Storage Bags): • Pharmaceutical TPE Tubes • Tyvek Sterilization Bags 		<ul style="list-style-type: none"> • Aseptic Filling Line Equipment / OSD Production Line Equipment

[PharmaBio Value Chain Collaboration Biz]

우리의 취급 서비스 및 품목 요약(Our Services & Items Summary)

System for Aseptic Chemical Drug (Turnkey Project)	<ul style="list-style-type: none"> ● Aseptic Drug Product(DP) Production Line Equipment for Injections, Eye Drop & Liquids <ul style="list-style-type: none"> • <i>[Autoclave - H₂O₂ Fumigation System] + [Preparation & Formulation System – Sterilization by filtration] + [Vial Washer – Tunnel Sterilizer – Aseptic Filing Machine – Aseptic Lyophilization Machine(Auto Loading/Unloading System) - Capping Machine] + [C-RABS or Isolator] + [Vial inspection M/C + Leak Tester + Labelling M/C + Packaging Equipment] + [Process Control & Monitoring Computerized System]</i> • <i>Glass Vial, Plastic Vial, Ampoule, Pre-filled Syringe, BFS, Bag, Bottle etc.</i> • <i>PIC/S GMP Annex 1, 21 CFR Part 11 and Data Integrity Compliance</i>
	<ul style="list-style-type: none"> ● Aseptic DS & DP Lyophilization Production Equipment ; cGMP Grade Freeze dryer (Auto Loading/Unloading System)
	<ul style="list-style-type: none"> ● Drug Product Packaging Line Equipment for Injections, Liquids, OSD...
System for Oral Chemical Drug (Turnkey Project)	<ul style="list-style-type: none"> ● Solid Dosage Form Production (Turnkey Project) <ul style="list-style-type: none"> • <i>Tablet Press Machine / Capsule Filling Machine / Softgel Encapsulation Machine / Coating Machine / Dryer / Granulator / Mixer / Pulverizer / Screening Machine / Assistant Machine</i>
	<ul style="list-style-type: none"> ● Oral Liquid Filling Line Equipment
CCS Single Use System(SUS)	<ul style="list-style-type: none"> ● Single-Use Bioreactor Bags, (2D/3D) (Single-Use Storage Bags), Pharmaceutical TPE Tubes, Tyvek Sterilization Bags

[PharmaBio Value Chain Collaboration Biz]

우리의 취급 서비스 및 품목 요약(Our Services & Items Summary)

System for Biological Drug (Turnkey Project)	<ul style="list-style-type: none"> ● Biological Product(Drug Substance, DS) Production Line Equipment <ul style="list-style-type: none"> • <i>USP Production Line Equipment : Cell Culture or Fermentation, Harvest & Clarification ~~~ Stainless Steel & Single Use System</i> • <i>DSP Production Line Equipment : Purification, Diafiltration & Concentration + Bulk Formulation & 1st Packaging + Freezing(Optional)</i> • <i>Process Control & Monitoring Computerized System</i> • <i>PIC/S GMP Annex 1, 21 CFR Part 11 and Data Integrity Compliance</i>
	<ul style="list-style-type: none"> ● Aseptic Biological Product(DP) Production Line Equipment for Injections <ul style="list-style-type: none"> • <i>Glass Vial, Plastic Vial, Pre-filled Syringe, Bag etc.</i>
	<ul style="list-style-type: none"> ● Biological Product(DS & DP) Lyophilization Production Equipment ; cGMP Grade Freeze dryer (Auto Loading/Unloading System)
	<ul style="list-style-type: none"> ● Biological Product Packaging Line Equipment for Injections
	<ul style="list-style-type: none"> ● Cell Therapy & Gene Therapy Production Line Equipment
Equipment	<ul style="list-style-type: none"> ● Clean Air Equipment for Production and QC Sterility Test : C-RABS, Isolator etc. ~~~ PIC/S GMP Annex 1 Compliance
	<ul style="list-style-type: none"> ● Particle Counter for GMP Cleanroom & Clean Air Equipment
	<ul style="list-style-type: none"> ● GMP Validator/Data Logger for Thermal Validation : CGMP Compliance + 21 CFR Part 11 & Data Integrity Compliance
GEP/ Engineering (Turnkey Project)	<ul style="list-style-type: none"> ● Bio Engineering Solution Service : Conceptual, Basic & Detailed Design
	<ul style="list-style-type: none"> ● Innovative Modular Construction for GMP Facility <ul style="list-style-type: none"> • <i>Conceptual Design & URS --- Project Master Planning</i> • <i>Basic & Detailed Design & Technical Specification --- Design Qualification</i> • <i>Off-site Fabrication/FAT & Prequalification(Supplier Site) --- Transportation(From Supplier Site to User Site)</i> • <i>On-site Engineering & Construction(User Site) --- Qualification(IQ & OQ) --- Handover</i> • <i>Maintenance Supporting Service & Requalification Service</i>

GMP Modular Construction Service

"Bio-Support and Tofflon" designs and realizes the latest technology for GMP Modular Construction & Qualification.

Bio-Support

Korea's No.1 GMP and Validation Solution Consulting Company



Tofflon

China's No.1 Global Pharmaceutical & Bio Equipment and Solution Enterprise

"5S + M Strategy" of Modular Construction for GMP Facility

5S+M, the core strategy of GMP manufactory modular construction, is a comprehensive solution that realizes efficiency, safety, quality, sustainability, and customer satisfaction at the same time.

Save Time → Rapid installation minimizes project completion time

Superior Quality → Manufactured in a uniform environment to ensure high quality with GMP level

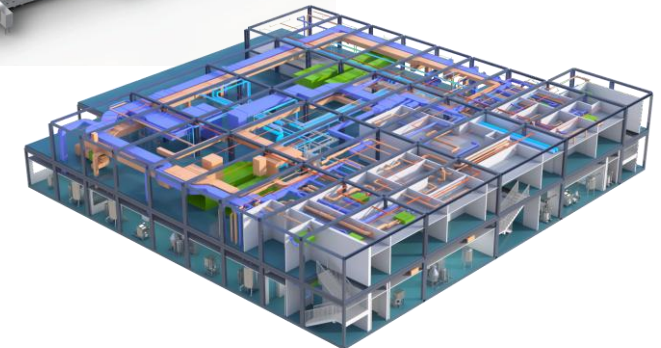
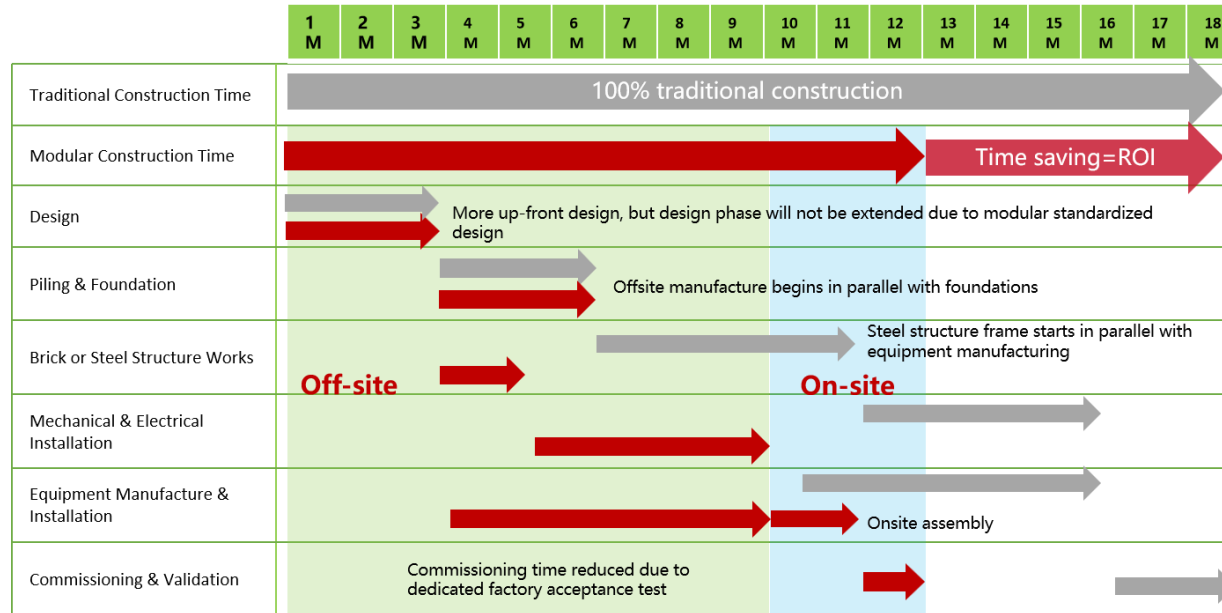
Save Cost → Standardization and efficient processes optimize investment and operating costs

Sustain the Environment → Realizing eco-friendly construction by reducing waste, noise, and carbon emissions

Secure Safety → Pre-production and modularization minimize the risk of safety accidents

Maintenance → Systematic follow-up management supports stable and long-term operation

Modular Construction vs Traditional Construction Timeline



**Concept of Modular Construction & Engineering Process for New GMP Facility
(Tofflon + Bio-Support)**

Bio-Support Tofflon

Written by	Bio-Support & Tofflon
Document No.	BS-MC-S-A001
Revision No.	01
Date	2026-02-02

Project Stage	Time Line	GMP / End User/ GMP Modular CM & Consulting(Bio-Support)			Site	Facility Design(건축설계사) / 3rd Party		Production Equipment with a long production period / 3rd Party		Site	Engineering for Modular Construction/ Tofflon			Site	Construction / 3ry Party		Site				
		Process	User	GMP CM & Consulting Party		Job	Description	Job	Description		Process	Engineering	Engineering QA		Job	Description					
Project Planning	3~6 Month	Project Strategy	GMP Facility Site	Supporting	On-site	Project Strategy	Supporting			On-site	Project Strategy	Supporting	Supporting								
			Product & Production Capacity	Supporting																	
			Target GMP URS of Conceptual Design	Supporting																	
Facility Design	4~5 Month	Conceptual Design(CD)	Review & Approval	Execution & Document	On-site	Conceptual Design(CD)	Supporting	Conceptual Design(CD)	Supporting	On-site	Conceptual Design(CD)	Cowork with User	Review	Off & On-site							
	1 Month	Site VMP +Utility QMP	Review & Approval	Execution & Document		Bidding Process & Contract	Supplier's Proposal														
	3~4 Month	URS of Utility System & BMS	Review & Approval	Execution & Document		Facility Basic Design (BD)	Execution & Document	Request for Proposal (URS) Bidding Process & Contract	Supplier's Proposal		URS of Production Equipment	User/Consulting: Documentation	On-site					Facility Basic Design(BD)	Execution & Document(Eng. Area)	Review	
		Facility Basic Design (BD)	Review & Approval	Execution & Document																	
	3 Month	Facility Detailed Design(DD)	Review	Review		Facility Detailed Design(DD) + 인허가	Execution & Document	Design Qualification	User/Consulting: Documentation		Facility Detailed Design(DD)	Execution & Document(Eng. Area)	Review								
1 Month	Design Qualification U1(DD -Utility)	Review & Approval	Execution & Document	Design Qualification U1(DD -Utility)	DD Revision			Design Qualification U1(DD -Utility)	DD Revision(Eng. Area)	Review											
C&E Bidding Process & Contract	1~2 Month	Request for Proposal (URS + Detailed Design)	Prep., Review & Approval	Review		Request for Proposal (URS + Detailed Design)	Prep. and Review				Proposal, Bidding Process & Contract	Execution & Document	Review		Proposal, Bidding Process & Contract	Execution & Document					
Construction & Engineering 1	6 Month (Eng: 5~6M / Construction Work 1: 4~6 M)	Off-Site GMP/GEP Supervision & Inspection	Factory Modular Construction Process User Supervision	Consulting or Supervision	Off-site			Equipment Production at Off-site	Supplier	Off-site	Factory Modular Construction Process (Fabrication, and modular assembly)	- HVAC System, Clean Room, Water & Steam system, gas System etc.	Factory Modular Construction Process QA Supervision: Material Inspection, Assembly Inspection, Pre-Commissioning	Off-site	Construction Work 1	Site Preparation Work Civil & Foundation Work Architectural Work Warehouse(high Rack) built(if necessary)					
			Design Qualification U2(Utility)	Review & Approval								Execution & Document	Off-Site FAT & Pre-delivery Inspection					Supplier Execution + User/Consulting Review	Off-Site FAT & Pre-delivery Inspection	Execution	Execution & Document
			Off-Site FAT & Pre-delivery Inspection	Review & Approval								Review									
Shipping	1 Month	Modular Shipping	Supervision	Supervision			Equipment Shipping	Supplier		Modular Shipping	Shipping Planning & Execution	Supervision & Document									
Construction & Engineering 2	2~4 Month	Modular Installation	Supervision	Supervision	On-site			Equipment Incoming at Site	Supplier	On-site	Modular Installation	Modular Structure	Field Quality Inspection Work	On-site	Construction Work 2	Modular Installation Cowork Architectural Finishing Work					
			As Built Document + Supplier's Document for Qualification	Review				Review	Equipment Installation at Site		Supplier(Cowork with Engineering)	As Built Document + Supplier's Document for Qualification	Preparation					Review			
	준공허가	Review	-	Commissioning & SAT				Supplier Execution + User/Consulting Review	준공허가		Preparation	Review	준공허가					Preparation & Execution			
Commissioning & Qualification	1 Month	Commissioning & SAT/TAB	Review & Approval	Review	On-site			IQ, OQ + CSV	Consulting Execution + User: Review & Approval	On-site	Commissioning & SAT/TAB	Execution	Execution & Document	On-site	Commissioning & SAT/TAB						
	2~3 Month	IQ, OQ + CSV	Review & Approval	Execution				IQ, OQ + CSV	CAPA Execution		Deviation Control	IQ, OQ + CSV	Deviation Control Supporting								
Validation	2~4 Month	PQ(Phase 1)	Review & Approval	Execution	On-site					On-site				On-site							
	6~12 Month	Validation	Execution	Consulting																	

GMP Justice
Advanced Quality Culture

Innovative Value Chain
Collaboration Biz of Bio-Support

Thank you so much!!!

**Bio-support has been growing together
with our valued customers and partners since 2000!!!.**

Bio-Support

CONTACT US

- website : www.biosupport.co.kr
- E-mail : gmp@biosupport.co.kr