Bio-Support Tofflon

Business Engine 03

Integrated Project Strategy

Bio-Support Business Engine
Introduction of GMP Design & Modular Construction Biz

Global Technology × GMP Expertise × Integrated Realization



Our Mission: 우리는 삶의 가치를 높이는 기술과 미래를 실현하는 솔루션으로, 사람과 건강한 삶을 연결한다.
We connect people with healthier lives through technologies that enhance quality of life and solutions that turn the future into reality.

Bio-Support

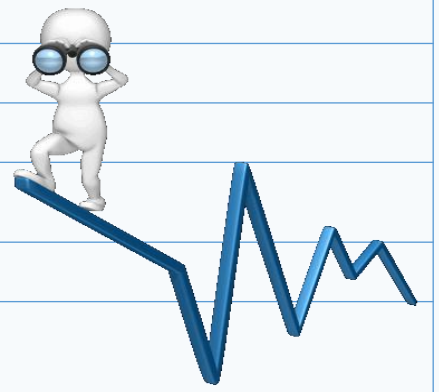
Your Trusted GMP Value Chain Integrator
Leading Value. Connecting with Trust. Realizing the Future.

| Developed by
Kyung-Min Kim, CEO of Bio-Support
| 2026-11-05 | Version: 01

Bio-Support: Company Overview

제약·바이오 고객의 GMP와 글로벌 기술을 연결하는 통합 실행 파트너

ITEM	DECSRIPTION
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 Aug 2026)
Main business	• [GMP & Validation Solution Consulting Biz] • [PharmaBio Value Chain Collaboration Biz] • [GMP Design & Modular Construction Biz] • [PharmaBio Knowledge & Competency Development Biz] • [Global BioTech Gateway Collaboration Biz] • GMP (Good Manufacturing Practices, pharmaceutical manufacturing management and quality control standards) for pharmaceuticals, biopharmaceuticals, ATMP, veterinary drugs, medical devices, and health functional foods
Main Certificates	• 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



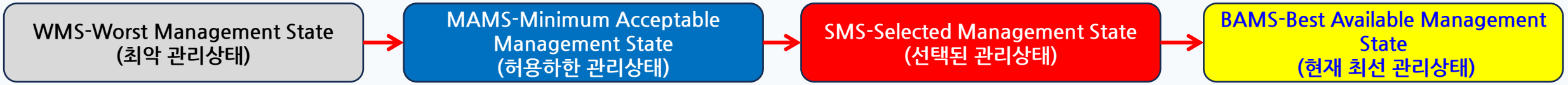
품질선언문
Bio-Support Quality Statement

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



[GMP & Validation Solution Consulting]

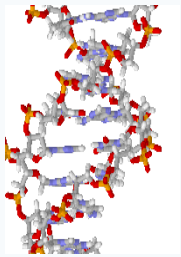


New/Remodeling GMP Facility Consulting(Turnkey Project); [Conceptual Design Execution, VMP, QRM(RA), URS, DQ, IQ, OQ, PQ, CSV, CV, PV and/or PQS Consulting]	
GMP Facility Design Solution (Conceptual Design)	GMP Facility for Oral Solid Dosage Form, Liquids, Ointments, Eye Drops, Injections
	GMP Facility 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



Bio-Support: Company Overview

제약·바이오 고객의 GMP와 글로벌 기술을 연결하는 통합 실행 파트너



한 장으로 보는 바이오써포트

고객사가 GMP 프로젝트를 더 빠르고, 더 안전하게, 더 확실하게 실행하도록 지원합니다.

26년	1,306+	392+	111+	202+
GMP & Validation 컨설팅 역사	총 프로젝트 수행 건수	함께한 고객사	Turnkey 프로젝트 실적	GMP 제조소 설계 프로젝트

Bio-Support의 고객 가치

규정·기술·엔지니어링·운영을 하나의 실행체계로 연결하여 GMP 리스크를 낮추고 프로젝트 성공 가능성을 높입니다.

고객과 함께 만드는 성과

신축·개축 GMP 제조소, PQS, DI, CCS, Qualification/Validation, 글로벌 GMP 대응까지 고객사의 목표 GMP 수준에 맞춰 수행합니다

.

Global Technology × Global GMP Expertise × Integrated Realization

"Bio-Support", The Leader in GMP Solution Consulting, Our Valued 392 Customers!!

Bio-Support × Tofflon
MODU GMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering



[GMP & Validation Solution Consulting Biz]

Bio-Support × Tofflon
MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

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
Yeoju 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]

Bio-Support × Tofflon
MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

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


RPBIO Hwaseong Plant


AppClone
ATMP GMP Facility


Daewoong Pharmaceutical
ATMP GMP Facility


Chungbuk Techno Park
ATMP GMP Facility


Vigencell
ATMP GMP Facility

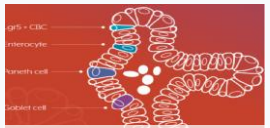

Samjin Pharmaceutical
Osong Factory

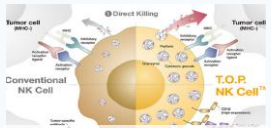

Curocell
ATMP GMP Facility


Pharma Research Bio
Gangneung Plant 2


ExocoBio Exosome Therapeutics
GMP Facility


Antrogen
ATMP GMP Facility


Organoid
ATMP GMP Facility



GICELL
ATMP GMP Facility


Ajou Pharmaceutical
Pyeongtaek Factory


Daewoong Pharmaceutical
Nabota Plant 3


Dongkwang Pharmaceutical
Pyeongtaek Plant


Coatem Chemon
ATMP GMP Facility


Merck
SKOR BioP Plant/ GMP Facility


SK Bioscience
Global R&PD Center/ GMP Facility


Daehan New Pharma
Hyangnam GMP Facility


Myeongin Pharmaceutical
GMP Facility


SK Plasam
Indonesia Plant


Dong-A ST
Cheonan Plant


Dongguk Pharmaceutical
Jincheon Factory


Seoul National University Hospital
ATMP GMP Facility


Optus Pharmaceutical
Osong Plant 2


KyungBo Pharmaceutical
ADC Factory


Korea Otsuka Pharmaceutical
Hyangnam Plant


Cheil Pharmaceutical
Baekam Factory


Korea Vaccine
Ansan Factory


ISU ABXIS
Yongin Factory


National Cancer Center
ATMP GMP Facility

Proposal Message

A customer-facing strategy to realize Global GMP-ready aseptic injectable facility through integrated partners

Bio-Support × Tofflon
MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

This project is not only a facility construction project.
It is an integrated GMP realization project that connects regulatory strategy, modular construction, aseptic technology, smart factory design, and lifecycle qualification.

Global GMP-Ready	Modular Delivery	Aseptic Excellence	Lifecycle CQV
EU GMP + CGMP + KGMP Compliance ; CCS, QRM and qualification requirements embedded from the concept stage	Tofflon-supplied GMP modular construction with Bio-Support GMP construction management	Tofflon aseptic filling system supported by barrier technology and integrated facility interfaces	Bio-Support qualification strategy from URS and DQ through FAT/SAT, IQ/OQ/PQ and readiness

Recommended positioning

One GMP Strategy · One Integrated Design · Multiple Specialized Partners

Proposal Summary

Global GMP-Ready Modular Aseptic Injectable Manufacturing Facility Realization Project

Bio-Support × Tofflon
MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

Project Goals

- Global GMP Inspection Readiness
- Sterility Assurance by Design
- Faster Delivery through Modular Construction
- Integrated Smart Factory Approach

Integrated Project Strategy

1	2	3	4	5	6
Conceptual Design	Smart Factory Design	Basic & Detailed Design	GMP Modular Construction	Aseptic Filling System	Qualification
By Bio-Support + Tofflon	By Partner of Bio-Support	By Partner of Bio-Support + Supported by Tofflon	Supplied by Tofflon	Supplied by Tofflon	By Bio-Support
			GMP Construction & Interface Management: By Bio-Support		
GMP Compliance	Smart Factory Integration	Integrated Collaboration	Modular Construction	Aseptic Process Excellence	Quality by Design

Bio-Support's Integrated Role

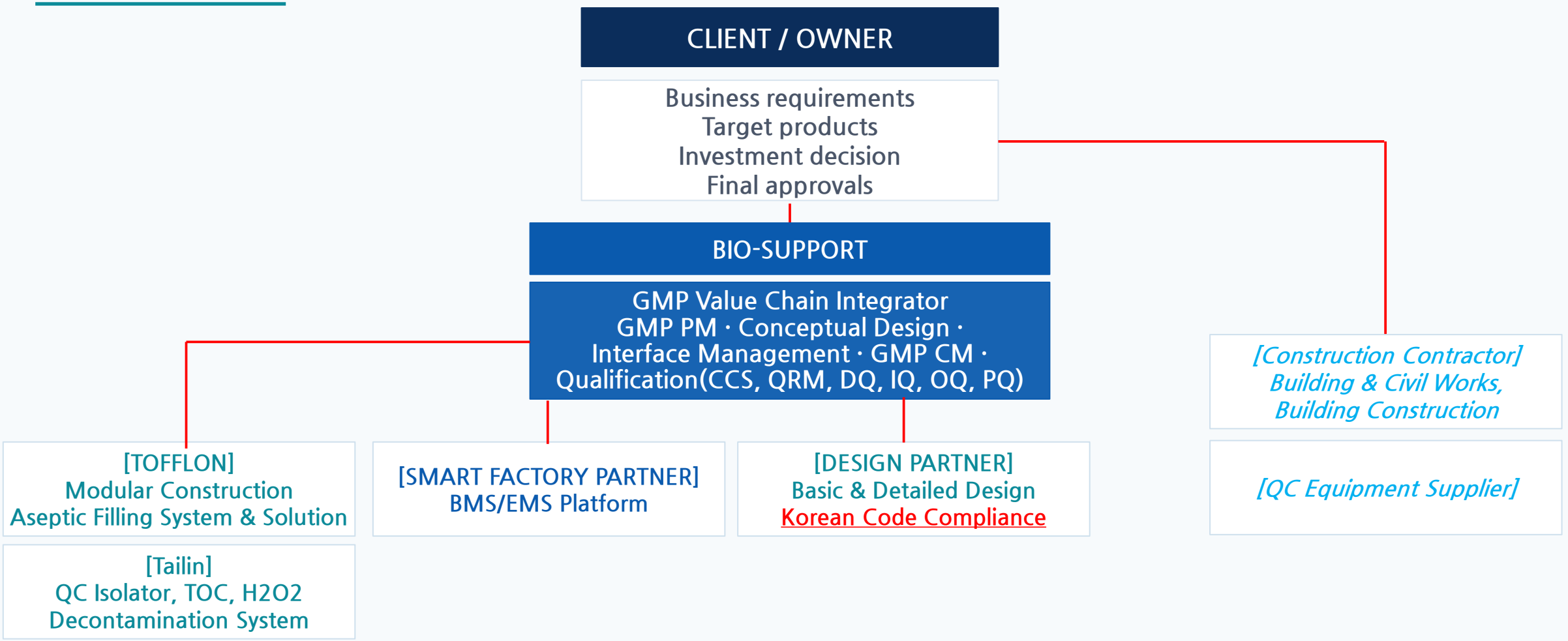
- GMP Value Chain Integrator
- Concept-to-Qualification Coordination
- Interface & GMP Construction Management
- Global GMP & CCS Alignment

Key Delivery Concept

Global Technology × GMP Expertise × Integrated Realization

Proposed Integrated Delivery Model

Bio-Support as the GMP Value Chain Integrator connecting Tofflon and specialized partners



Integrated realization of an Global GMP-ready modular aseptic injectable manufacturing facility

Regulatory & GMP Design Basis = EU GMP + CGMP + KGMP

Bio-Support × Tofflon MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

Global GMP readiness is designed into the facility, not checked only after construction

EU GMP Annex 1 + US FDA Sterile Drug Products Guidance*	Sterile manufacturing, CCS, QRM, premises, equipment, utilities, monitoring
EU GMP Annex 15 + US FDA Validation Guidance	Lifecycle qualification and validation planning, protocols, reports and release between stages
EU GMP Annex 11 + US FDA 21 CFR Part 11	Computerised system lifecycle, data integrity, access, audit trail and electronic records
ICH Q9(R1) / Q10	Risk management, knowledge management, PQS and state of control
Inspection Readiness	Traceable design basis, turnover documentation, CQV evidence and operational readiness

Design implication: every major design decision must be mapped to product risk, contamination control, system criticality, data integrity and qualification evidence.

*U.S. FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice
*U.S. FDA Compliance Program Guidance Manual (CPGM) 7356.002A — Sterile Drug Process Inspections

Target Facility Concept

A modular aseptic injectable manufacturing facility designed around sterility assurance



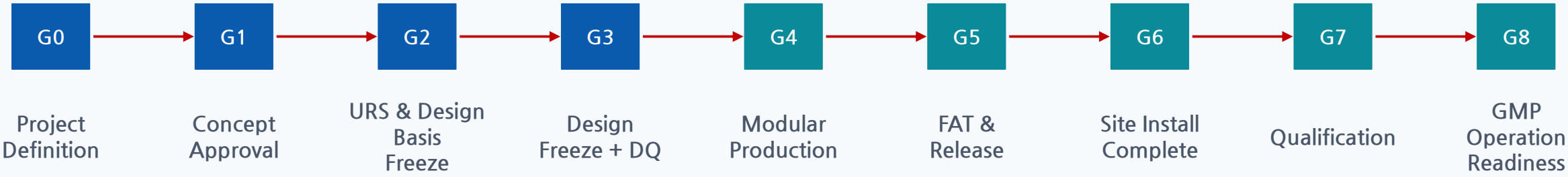
Component Preparation — Compounding — Sterile Filtration — Aseptic Filling + Isolator — Capping & Inspection — 2nd Packaging

Facility	Barrier	Utility	Digital
Cleanroom, pressure cascade, HVAC, personnel/material flow	Isolator/RABS strategy, Grade A protection, intervention reduction	WFI, clean steam, process gas, HVAC and environmental monitoring	EMS/BMS *Out of Scope: MES/eBR, LIMS, eQMS and data platform interfaces*

Design focus: protect the critical zone, minimize open processing, reduce human intervention, and make critical data traceable.

Project Stage-Gate Roadmap

Each gate controls business, design, GMP, modular, equipment and qualification readiness



Early Gates

Confirm product, target market, regulatory basis, concept and CCS

Design Gates

Freeze GMP layout, smart factory architecture, modular interfaces and equipment data

Execution Gates

Release module/equipment manufacturing, FAT, shipment and site installation

Readiness Gates

Complete SAT, IQ/OQ/PQ, GMP readiness and inspection preparation

Package 1 | Conceptual Design

By Bio-Support + Tofflon

Purpose

Define the GMP manufacturing concept before engineering detail begins
: product, process, regulatory basis, CCS, facility, equipment and modularization strategy.

Input	Key Work	Tofflon Support	Output
Product profile, target market, batch size, container, lyophilization, capacity and business requirement	Process concept, block layout, cleanroom concept, utility concept, CCS concept and modular strategy	Modular boundary, equipment data, utility/load requirements, isolator/filling system interface	Conceptual Design Basis, GMP block layout, process flow, CCS concept, equipment list basis

Decision Gate: Concept Approval

Package 1 | Conceptual Design

By Bio-Support + Tofflon

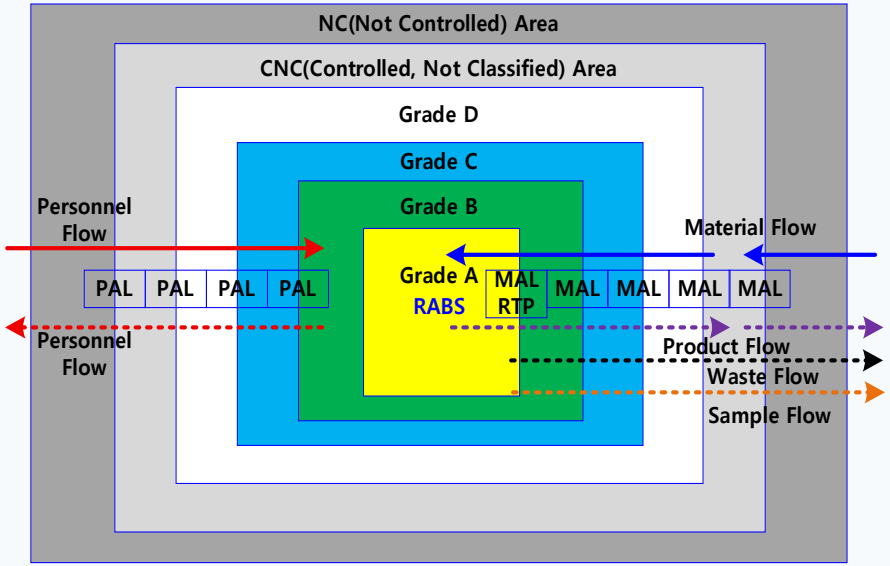
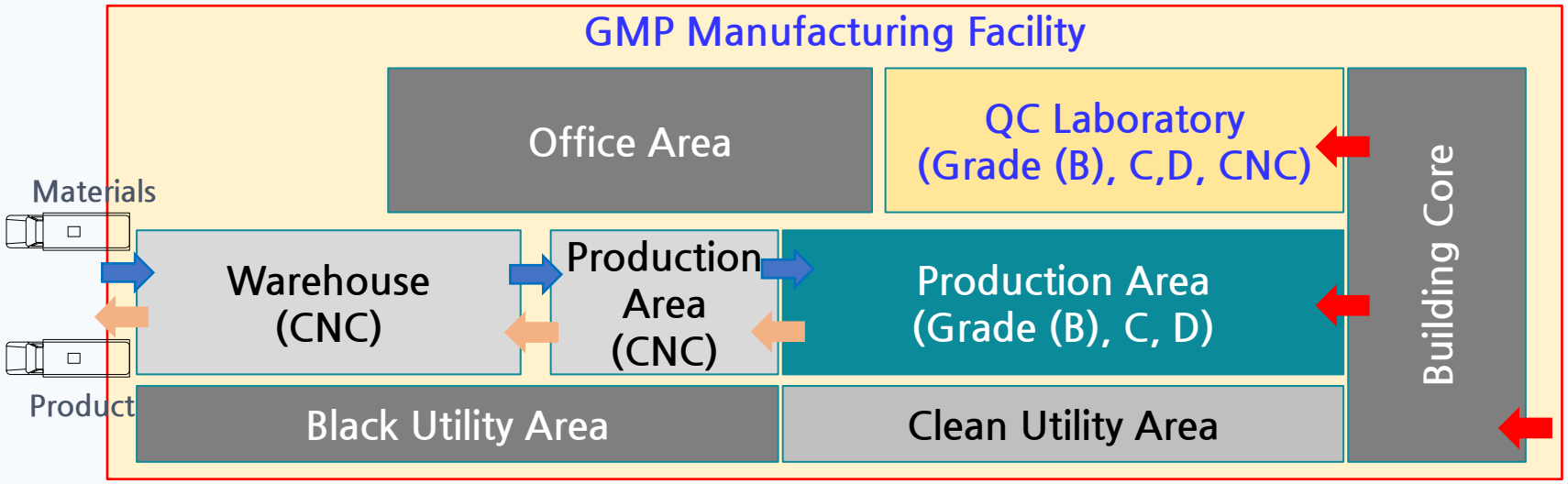


Table 1: Maximum permitted total particle concentration for classification

Grade	Maximum limits for total particle ≥ 0.5 µm/m³		Maximum limits for total particle ≥ 5 µm/m³	
	at rest	in operation	at rest	in operation
A	3 520	3 520	Not specified [a]	Not specified [a]
B	3 520	352 000	Not specified [a]	2 930
C	352 000	3 520 000	2 930	29 300
D	3 520 000	Not predetermined [b]	29 300	Not predetermined [b]



Package 2 | Smart Factory Design

By Partner of Bio-Support, integrated into the facility concept

Enterprise	Manufacturing	Quality	Automation	Control	Field
ERP / planning / finance	*MES · eBR · WMS*	*LIMS · eQMS · EMS*	SCADA · BMS · EMS	PLC · HMI · equipment	Sensors · instruments · actuators

Data at Source	Paperless Target	Connected Quality	Future-ready
Critical data captured directly from equipment and source systems	eBR, eLogbook, electronic review and controlled records	EMS/BMS/LIMS/eQMS linked with batch and asset context	Data platform for digital twin, analytics and selected predictive use cases

Decision Gate: Smart Factory Architecture Freeze

Package 3 | Basic & Detailed Design

By Partner of Bio-Support + Supported by Tofflon



A. Basic Design

GMP layout, HVAC, utility, process, electrical, automation, cleanroom and building interfaces

B. Detailed Design

Construction drawings, room data sheets, P&IDs, hook-ups, interface drawings and procurement details

C. Tofflon Support

Equipment layout, modular interface, utility/load data, installation requirements and FAT requirements

Bio-Support GMP Design Review Focus

- Annex 1 alignment and CCS consistency
- Cleanroom classification and pressure cascade
- Material/personnel/waste flow and airlock strategy
- Maintainability, cleanability and qualification readiness

Decision Gate:
Design Basis Freeze → Design Freeze

Package 4 | GMP Modular Construction

Supplied by Tofflon · GMP Construction Management by Bio-Support

1. Module Engineering Interface data and drawings → 2. Off-site Fabrication Factory-controlled construction → 3. Factory Inspection Quality checks and records → 4. Enhanced FAT Mechanical, utility, automation evidence → 5. Shipment & Installation Transport, lifting, hook-up → 6. SAT / IQ Readiness Turnover package and site verification

Smart GMP Module Concept

Physical	Automation	Digital	Qualification
Cleanroom, HVAC, utility and process interfaces	Instruments, controls, alarms and interlocks	Asset ID, data points and system interfaces	Certificates, inspections, FAT and turnover evidence

Package 4 | GMP Modular Construction

"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

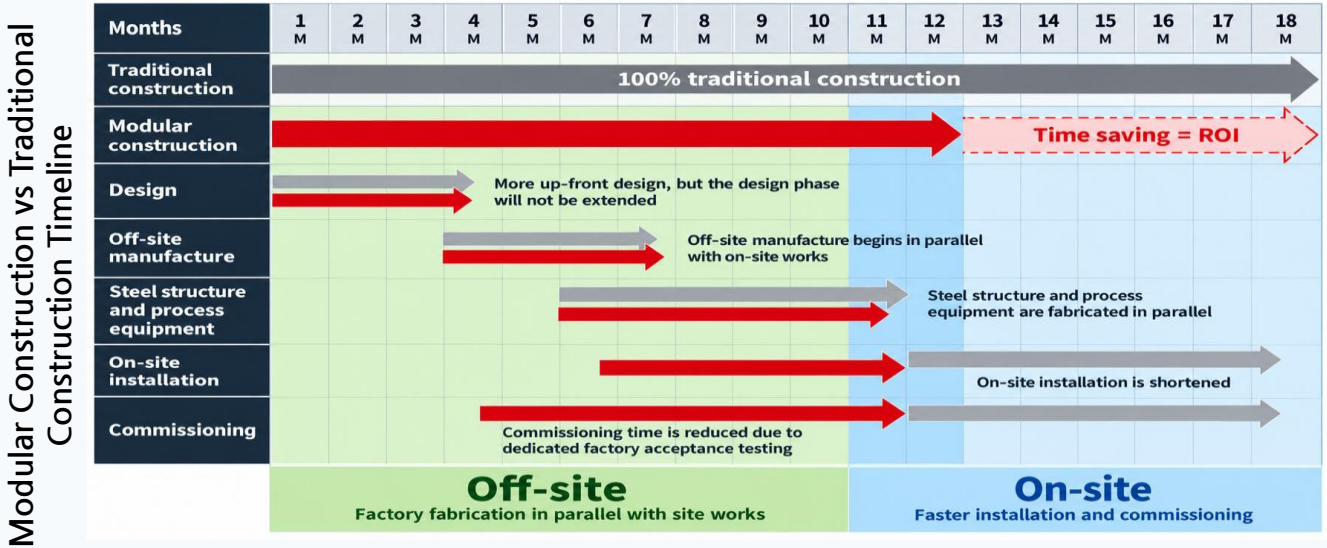
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Tofflon
China's No.1 Global Pharmaceutical & Bio Equipment and Solution Enterprise

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

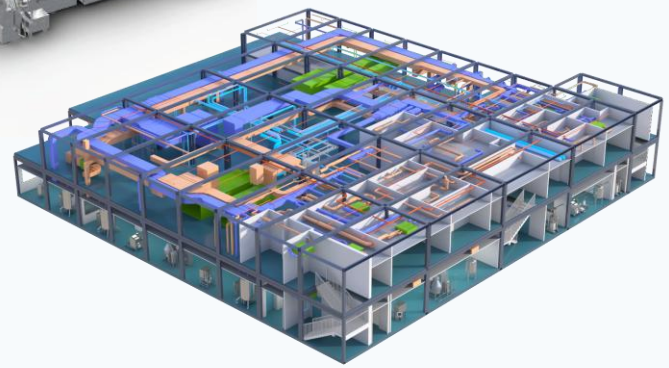
5S+M, the core strategy of GMP manufactory modular construction, is a comprehensive solution that realizes efficiency, safety, quality, sustainability, and customer satisfaction at the same time.

- Save Time → Rapid installation minimizes project completion time
- Save Cost → Standardization and efficient processes optimize investment and operating costs
- Secure Safety → Pre-production and modularization minimize the risk of safety accidents
- Superior Quality → Manufactured in a uniform environment to ensure high quality with GMP level
- Sustain the Environment → Realizing eco-friendly construction by reducing waste, noise, and carbon emissions
- Maintenance → Systematic follow-up management supports stable and long-term operation





Tofflon



Package 4 | GMP Modular Construction

Bio-Support × Tofflon
MODUGMP
Integrated Modular Construction for Global GMP Facility
Compliance-Driven Design, Validation-Assured Engineering

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				Project Strategy	Supporting	Supporting				
			Product & Production Capacity														
			Target GMP	Supporting													
			URS of Conceptual Design	Supporting													
Facility Design	4~5 Month	Conceptual Design(CD)	Review & Approval	Execution & Document		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	URS of Production Equipment	User/Consulting: Documentation		Facility Basic Design(BD)	Execution & Document(Eng. Area)	Review				
		Facility Basic Design (BD)	Review & Approval	Execution & Document				Request for Proposal (URS)	User								
								Bidding Process & Contract	Supplier's Proposal								
	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	Equipment Production at Off-site	Supplier	Off-site	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						Factory Modular Construction Process (Fabrication, and modular assembly)	- HVAC System, Clean Room, Water & Steam system, gas System etc. - BMS - Production Equipment	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)	On-site
		Design Qualification U2(Utility)	Review & Approval	Execution & Document							Design Qualification U2(Utility)	FDS Preparation	FDS Review				
		Off-Site FAT & Pre-delivery Inspection	Review & Approval	Review				Off-Site FAT & Pre-delivery Inspection	Supplier Execution + User/Consulting Review		Off-Site FAT & Pre-delivery Inspection	Execution	Execution & Document				
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	
								Equipment Installation at Site	Supplier(Cowork with Engineering)			Utilities & Production Equipment Installation +Hook Up				Architectural Finishing Work	
		As Built Document + Supplier's Document for Qualification	Review	Review							As Built Document + Supplier's Document for Qualification	Preparation	Review		As Built Document + Supplier's Document for Qualification	Preparation	
	1~2 Month	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		On-site
	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													

Package 4-1 | GMP Construction Management

By Bio-Support: construction control with GMP, CCS and CQV perspective

Construction Management Scope

- Site GMP inspections
- Clean construction controls
- Material and installation verification
- Modular installation review
- Punch and turnover package control
- Design change impact assessment

GMP Impact Review Lens

- GMP impact
- CCS impact
- Qualification impact
- Data integrity impact
- Regulatory/inspection readiness impact
- Operational readiness impact

Bio-Support
GMP CM = Schedule/Construction Quality + GMP/CCS/CQV/Inspection Readiness

Package 4-2 | Project Interface Management

The success of the project depends on controlling scope gaps between packages



Modular ↔ Building

Module boundary, structure, transport, lifting, site hook-up

Modular ↔ Utility

WFI, clean steam, HVAC, process gas, drain and electrical interfaces

Filling ↔ Facility

Footprint, cleanroom classification, flows, clearances and utility loads

Equipment ↔ Automation

I/O, PLC, HMI, SCADA, alarms, recipe and data capture

Smart Factory ↔ GMP

MES/eBR, audit trail, electronic records, validation and data integrity

Design ↔ CQV

URS, risk assessment, DQ, FAT/SAT evidence and turnover package

Bio-Support operates a Project Interface Matrix defining requirement, input, output, responsible party, review party, approval, due date, verification method and qualification impact.

Package 5 | Aseptic Filling System

Tofflon

Supplied by Tofflon and integrated with the modular facility



Vial Washing → Depyrogenation Tunnel → Aseptic Filling + Stoppering → Isolator → Capping → Inspection → 2nd Packaging

Barrier First	Intervention Reduction	First Air Protection	Electronic Data
Critical zone protected through isolator/barrier strategy	Minimize human intervention in Grade A critical operations	Protect product, container and critical surfaces	Capture critical process data and batch context

Key interfaces to be frozen early:
filling ↔ isolator ↔ lyophilizer ↔ HVAC ↔ utility ↔ EMS/BMS ↔ *MES* ↔ qualification.

Package 6 | Qualification Strategy

By Bio-Support using a lifecycle and shift-left CQV strategy



1. QRA
Risk-based criticality
→
2. URS
User and GMP requirements
→
3. DQ
Design verification
→
4. FAT / SAT
Vendor and site evidence
→
5. IQ / OQ
Installation and operation
→
6. PQ / Readiness
Performance and GMP readiness

Shift-left CQV Principle

Move evidence generation and issue detection as early as possible:
design review → vendor review → module factory inspection → enhanced FAT → site SAT/IQ/OQ/PQ

Decision Gate: Qualification Release → GMP Operational Readiness

Package 6 | Qualification - Contamination Control Strategy by Design

CCS becomes the backbone connecting facility, process, operation and monitoring

Facility	Process	Barrier
Layout, pressure cascade, cleanroom classification, airlocks	Closed processing, sterile filtration, hold time, aseptic connections	Isolator strategy, gloves, transfer ports and VHP cycle

People & Materials	Monitoring
Gowning, movement, transfer, disinfection and waste flow	Particle, microbial, pressure, temperature, humidity, alarms and trends

Digital CCS long-term target:
contamination risk → critical control → parameter → sensor/system → alarm → deviation → CAPA → trend/KPI.

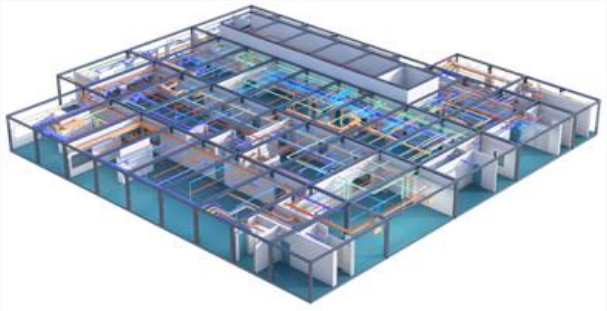
Package 6 | Qualification - Modular FAT · SAT · IQ · OQ Strategy

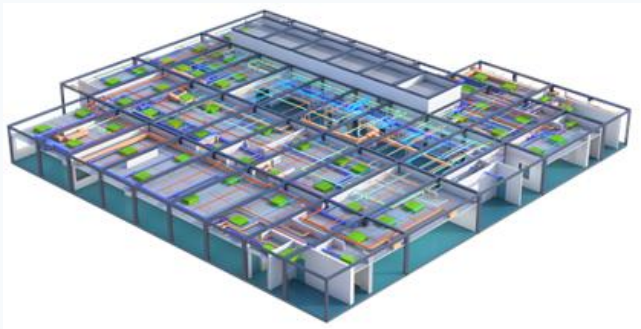
Bio-Support × Tofflon MODUGMP Integrated Modular Construction for Global GMP Facility Compliance-Driven Design, Validation-Assured Engineering

Installation verification: Off-site FAT & Pre-qualification → On-site SAT / IQ

Modular qualification takes a fundamentally different approach from conventional IQ: FAT & Pre-Qualification are performed at the manufacturer's site, minimizing on-site SAT / IQ deviations and dramatically shortening the schedule.

No.	Test Item	Off-site (FAT) Manufacturer	On-site (SAT/IQ) User Site	Remarks
1	IQ Prerequisite Verification	●	●	
2	Documentation Verification	●		Completed Off-Site
3	Manual Content Verification	●		Completed Off-Site
4	Calibration Verification	●		Completed Off-Site
5	Material of Construction Verification	●		Completed Off-Site
6	Mechanical Installation Verification	●(80%)	●(20%)	Site Hook-Up Check
7	Electrical Installation Verification	●(80%)	●(20%)	Site Hook-Up Check
8	Maintainability Verification	●(90%)	●(10%)	
9	Installation Environment & Safety Check		●	
10	Duct Leak Test Result Verification	●	●	Depending on Installation Options
11	HEPA Filter Integrity Verification	●	●	Depending on Installation Options
12	Cleanroom Installation Verification	●(90%)	●(20%)	
13	Contamination Source Leak Verification		●(100%)	
14	Others			



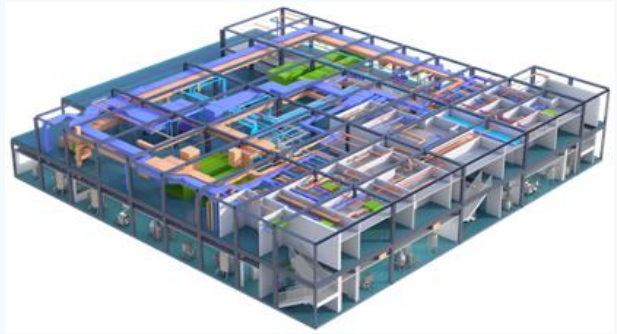


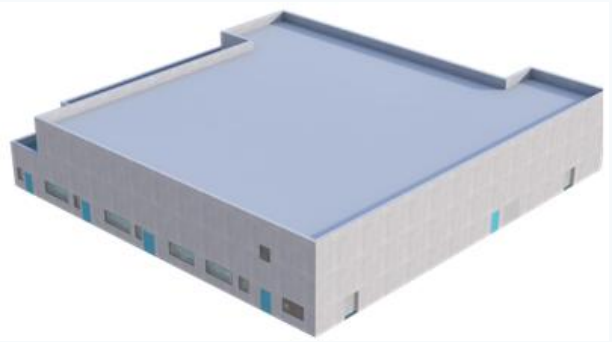
Package 6 | Qualification - Modular FAT · SAT · IQ · OQ Strategy

Operational verification: Off-site FAT & pre-qualification → On-site SAT / OQ

FAT & Pre-qualification at the manufacturer's site cover most key operational tests; on-site SAT / OQ then focuses on verifying those results and a limited set of critical tests significantly reducing both risk and schedule.

No.	Test Item	Off-site (FAT) Manufacturer	On-site (SAT/OQ) User Site	Remarks
1	TAB (Test, Adjust & Balance) Verification	●	●	
2	Control Panel Function Test	●		Completed Off-Site
3	Warning, Alarm & Emergency Function Test	●		Completed Off-Site
4	System Operation Visual Inspection	●		Completed Off-Site
5	AHU Main Airflow Volume Test	●		Completed Off-Site
6	Cleanroom Airflow Volume Test	●(90%)	●(10%)	Verified after Hook-Up
7	Cleanroom Air Change Rate Test	●(90%)	●(10%)	Verified after Hook-Up
8	Room Differential Pressure Test	●(90%)	●(10%)	
9	Cleanliness Classification Test		●	
10	Temperature & Humidity Test		●	
11	Cleanliness Recovery Test		●	Depending on Installation Options
12	Cleanroom Noise Level Test	●		Depending on Installation Options
13	Cleanroom Lighting Intensity Test	●		
14	Door Interlock Test	●		
15	Airflow Pattern Visualization Test	●		





Package 6 | Qualification - Advanced Qualification Strategy

Annex 1 Airflow visualization · Risk-based temperature mapping

Annex 1 airflow requirements and risk-based temperature mapping are **reviewed and fully embedded into your project**, while our in-house equipment fleet **keeps your schedule on track.**

First Air Airflow Pattern Test

Definition Air that passes through the HEPA filter and reaches the product or contact surface first, without obstruction by equipment or operators

Purpose Eliminate turbulence and stagnant air to block contaminant ingress into sterile product at the source

Conventional (Room-centric)	First Air (Product-centric)
Macroscopic check of unidirectional airflow across the entire Grade A zone → Blind spots above the product cannot be identified	Detailed check for airflow disruption or turbulence just before the product and contact surfaces → Mandatory under Annex 1

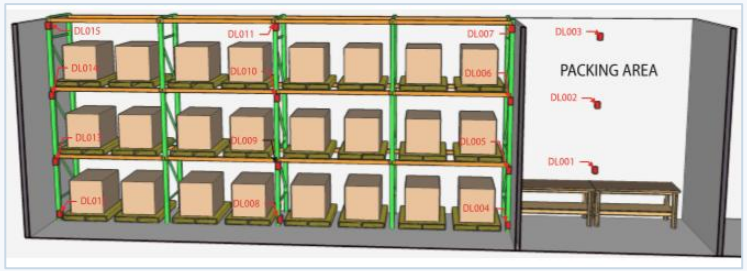
Field Practice Verify arm **shadowing** when handling fallen vials → revise SOPs and operator movement per the **no cross-over** principle

Risk-Based Temperature Mapping

500+

In-house thermal mapping loggers

Large-scale simultaneous measurement to meet your schedule and needs



Source: WHO TRS 961

Sensor Quantity & Location No regulation defines sensor quantity (partly in ISPE GPG) → **determined by risk assessment, prioritizing worst-case locations**

Key Factors Room structure & size / rack design & loading pattern / supply, return & exhaust vents / doors, external walls & heat sources / material & personnel flow / seasonal ambient temperature

Approach **3D mapping** of the entire storage space + measurement focused on product storage locations for justified sensor placement

Package 6 | Qualification - CCS & Risk-Based EM Strategy

Environmental Monitoring program integrated into the CCS · Risk-based sampling point selection → Grid-by-Grid Assessment

Bio-Support × Tofflon MODUGMP Integrated Modular Construction for Global GMP Facility Compliance-Driven Design, Validation-Assured Engineering

We establish a **CCS-integrated EM program** with **QRM-based sampling point selection**, reflecting MFDS, EU / PIC/S GMP Annex 1 and PDA TR13.

Risk-Based Sampling Point Selection

✓ CCS-Centered EM Program | ✓ QRM-Based Sampling Plan | ✓ EM Data Integrity

Key Factors for Sampling Point Selection

- **Area & equipment layout** of the zone / cleanroom
- All elements with **contamination & cross-contamination** risk
- **Process characteristics** (procedures, intervention level, etc.)
- **Aseptic processing** areas (exposed containers, closures, intermediates)
- Areas where **interventions** occur
- Process **frequency** (daily / intermittent)
- Layout of **supply & return air vents**
- Areas with suspected **stagnation or turbulence** in airflow pattern results
- **Material flow** (exposed intermediates, materials & products)
- **Personnel flow** (key work areas, high activity, main routes)
- **Temperature** weak points (heat, moisture, etc.)
- **Weak areas** in prior monitoring (qualification) results
- Areas **difficult to clean**
- Around equipment **doors & gloves**
- Around cleanroom **entrance doors**
- **Geometric** location considerations
- Other locations

Principle Apply **quality risk-based environmental monitoring** as emphasized in revised Annex 1

Grid Assessment Model Grid-by-Grid Assessment

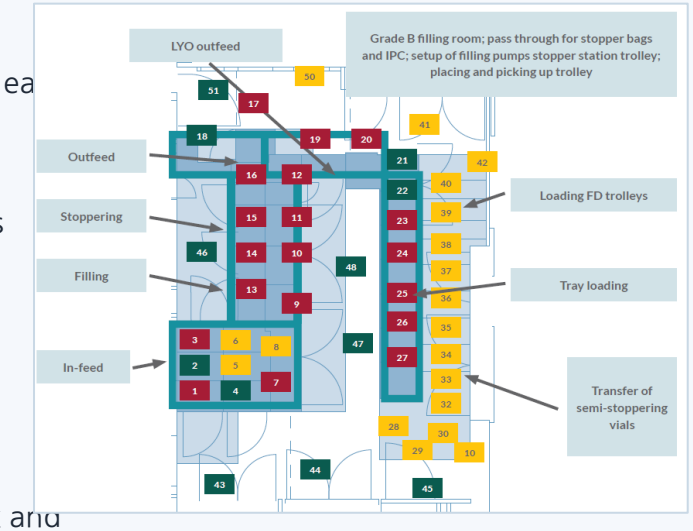
A scientific risk-assessment method that divides the manufacturing area into uniform grids and **quantitatively evaluates contamination likelihood per grid**

Step 1 Grid Division
Divide the layout into 2D/3D grids, ea
with a unique ID

Step 2 Functional Sections
Group grids with similar operations (washing, tunnel exit, filling)

Step 3 Factor Assessment
Rate each grid on key risk factors (Low / Medium / High) and score

Step 4 Scoring & Heat Map
Multiply factor scores into total risk and map it as a heat map



Source: BioPhorum

Outcome Identify the most vulnerable **hot spots** → scientific basis for EM sampling locations and frequency

Preliminary Responsibility Matrix

Final responsibility to be adjusted based on contract structure and scope freeze

Workstream	Client	Bio-Support	Tofflon	Smart Factory Partner	Design Partner
GMP Regulatory Strategy	A	R	S	S	S
Conceptual Design	A	R	R	C/S	C/S
CCS Concept	A	R/C	S	S	S
Smart Factory Design	*A*	*TBD*	*TBD*	*R*	*TBD*
Basic & Detailed Design	A	C/Review	S	C/S	R
GMP Modular Supply	A	CM/C	R	C	C/S
Aseptic Filling System	A	C/Review	R	C	C
Qualification	A	R	S	S	S

A = Approval · R = Responsible · C = Consulted · S = Support · I = Integration

Major Deliverables

A practical output set for customer decision-making and execution control



01 Project Charter & Design Basis	02 Conceptual Design Package	03 GMP Block Layout & Process Flow
04 CCS Concept & QRM Basis	*05 Smart Factory Master Architecture*	06 Basic & Detailed Design Review Report
07 Modular Interface Matrix	08 Equipment & Utility Interface Matrix	09 FAT/SAT Strategy
10 CQV Master Plan & Qualification Matrix	11 GMP Construction Management Plan	*12 GMP Readiness Assessment*

Deliverables are designed to support customer investment decisions, vendor alignment, design freeze, construction control, CQV execution and inspection readiness.

Why Bio-Support × Tofflon

Global technology combined with local GMP expertise and integrated realization



TOFFLON Global Technology	BIO-SUPPORT GMP Expertise	PARTNERS Specialized Execution
GMP modular construction, aseptic filling, isolator integration, lyophilization and pharmaceutical process technology	Global GMP requirement interpretation, CCS/QRM, GMP design review, GMP CM, qualification and inspection readiness	Smart factory architecture, basic/detailed engineering, domestic code compliance and system integration

Bio-Support's positioning

GMP Value Chain Integrator:
connecting customer business goals and Global GMP requirements with engineering, modular construction, aseptic equipment, smart factory and qualification.

BIO-SUPPORT x Tofflon

GMP Design & Modular Construction Biz

Compliance-Driven Design. Validation-Assured Engineering.
One GMP Strategy · One Integrated Design · Multiple Specialized Partners
moduGMP - Integrated Modular Construction & Process Equipment Solutions
for Glonbal GMP Facilities

Thank you so much!!!



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

CONTACT US : 바이오써포트 담당임원 김지민 상무 / www.biosupport.co.kr / gmpkjm@biosupport.co.kr