

GMP 제조소 신축을 위한 최신 기술인 Modular Construction & Qualification에 대하여

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

Tofflon

회사명: 바이오써포트

날 짜: 2025년 4월 23일

발표자: 김지민 상무/책임엔지니어

전익진 부사장/수석 컨설턴트

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대한민국 No.1 GMP 및 Validation 솔루션 컨설팅 기업

Bio-Support

+

Tofflon

중국 No.1 글로벌 제약바이오 장비 및 솔루션 기업

GMP 제조소 신축을 위한 최신 기술인
Modular Construction & Qualification에 대하여

Introduction of PharmaBio & GMP Value Chain Collaboration Biz of Bio-Support

다양한 GMP 컨설팅 실적

제약바이오기업(사용자)와의
다양한 소통라인

제약바이오업체(사용자)의 신뢰

바이오써포트는
사용자와 공급자를
연결하는 확실하고
견고한 가교이며
Powerful한 파트너
입니다.

풍부한 적격성평가 경험과
다양한 장비에 대한 GMP 및 기술적 지식

규제기관의 기대 및 요구사항의 이해를 통한
선도적이고 미래지향적인 GMP 및 기술역량

시의적절하고 효과적인
Project Management, FAT/SAT, 적격성평가
수행을 통한 고객감동





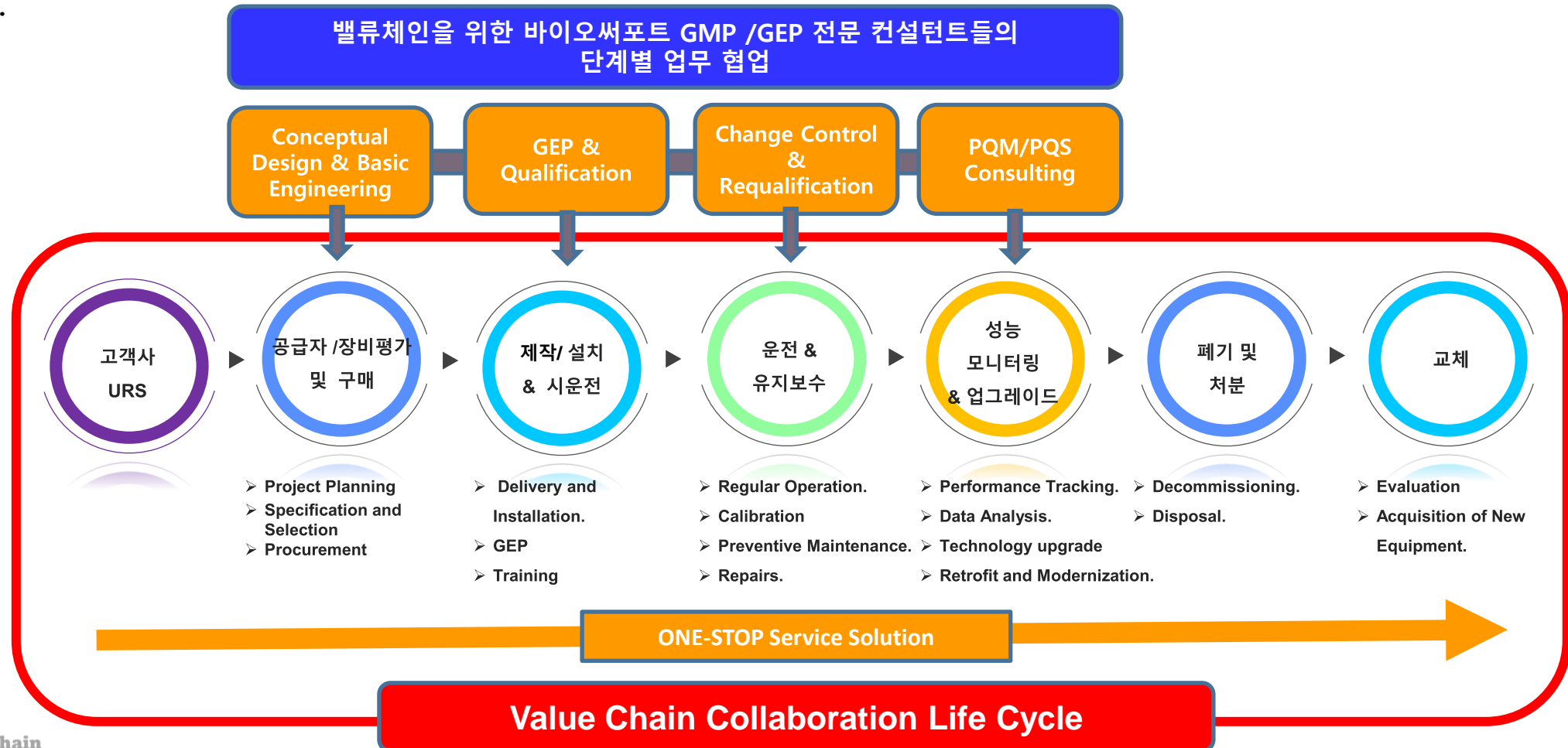
Bio-Support, The Bridge to Mutual Success

우리의 파트너(Our Partner)

Tofflon	<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/ 		
Wonsen	<ul style="list-style-type: none"> OSD Production Line Equipment(Total Solution) OSD Laboratory Equipment / OEB Containment Equipment Digital Smart Factory Solutions 	IVEN	<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
portlogics	<ul style="list-style-type: none"> We will solve the fundamental problems of import and export logistics market / Provides optimized TOMS for every enterprises Trade Order Management System 	SED PHARMA	<ul style="list-style-type: none"> Aseptic Filling Line Equipment(Injections, Eye Drop) OSD Equipment(Tablet, Capsule, Softgel)
Lives International Raising Standards	<ul style="list-style-type: none"> GMP Validator/Data Logger for Thermal Validation 	SPM	<ul style="list-style-type: none"> Aseptic Filling Line Equipment(Injections, Eye Drop) OSD Production Line Equipment + Oral Liquid Filling Line Equipment
华致林 HAGILIN	<ul style="list-style-type: none"> Single Using Bio-Pharma System Single-Use Bioreactor Bags(2D/3D) (Single-Use Storage Bags): Pharmaceutical TPE Tubes / Tyvek Sterilization Bags 	KONZER SAFETY PROTECTION	<ul style="list-style-type: none"> Pharmaceutical GMP Disposal Cleanroom protective products.

Bio-Support's Powerful Value Chain Collaboration Service

소중한 고객님과 파트너님들과 함께 만들어가는 Value Chain Collaboration Life Cycle은 이미 시장에서 인정받는 바이오써포트의 유능한 컨설턴트들과 함께 고객사의 요구사항을 면밀히 분석하고, 최적의 장비를 추천하며, 구매과정에서부터 안정적인 생산 환경 구축 및 유지보수까지 모든 절차를 신속하고 정확하게 수행 할 수 있도록 최선을 다합니다.





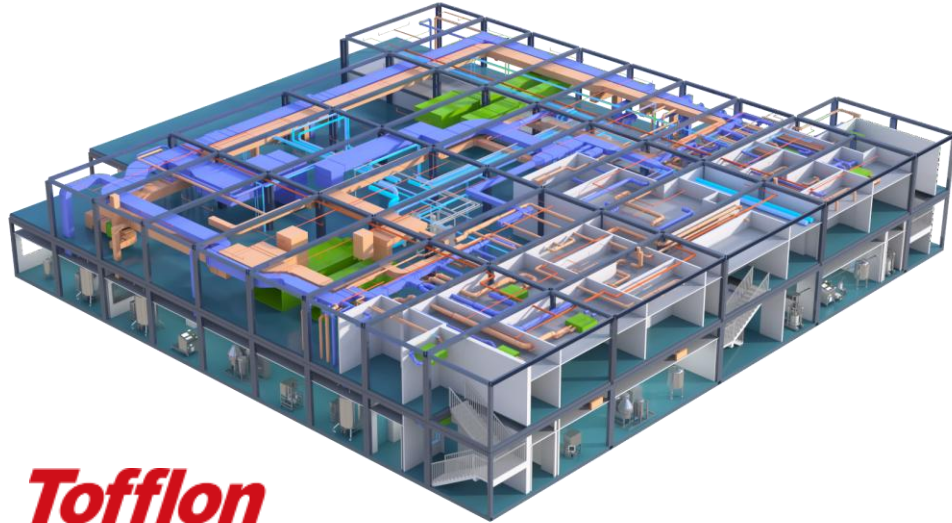


바이오써포트의 강력한 Value chain Partner

- 모듈러 건축(Modular Construction)이란 **건축물의 주요 구조 및 내부 설비를 공장에서 사전 제작 (Pre-fabrication)한 후, 현장에서 조립하는 방식**입니다.
- 전통적인 현장 시공(On-site Construction)과 달리 **공장 내에서 70~90%까지 제작 후, 현장에서 빠르게 설치하는 공법**으로, **공사 기간 단축, 품질 향상, 비용 절감 등의 효과**가 있습니다.

- ✓ "공장에서 제작 → 현장에서 조립"하는 개념
- ✓ 설계·제작·시공·설비 공사가 동시 진행 가능 → 공기 단축 효과
- ✓ 제약 공장, 병원, 학교, 주택 등 빠른 건설이 필요한 분야에서 활용 증가

오늘날의 모듈러 컨스트럭션은 단순한 "조립식" 개념을 넘어,
"고정밀 디지털 건축 + 스마트 제조 기술"이 결합된 하이브리드 산업으로 발전 중입니다.



Tofflon

80%

Off-site: 80%

10

Turn-key: 10 Month*

5%

Cost predictability:
5%

Modular construction removes the 80% of the delivery of your project from the conditions on your final site. It includes all structural parts, building fixtures, clean room, HVAC, process equipment, utilities, power supply system, auto-control system etc. By Modular construction, we can deliver your project like an equipment.

모듈러 공법의 역사

1. 기원 – 산업혁명 이후(19세기 중 후반)

- 초기 모듈러 건축 개념은 19세기 산업혁명 이후 나타남. 1850년대 영국에서는 **식민지로의 이주를 위한 조립식 주택(Prefab Home)**이 등장.
- 대표적 사례: 영국의 'Manning Portable Cottage' (1837년경) – 호주로 이주한 이들을 위해 선적 가능한 조립식 주택 제작.
- 미국 서부 개척 시대에도 기차로 운송 가능한 패널형 주택이 제작됨.

2. 2차 세계대전 이후 – 대량 생산 개념 도입

- 전쟁 후 전 세계적으로 주택 공급 부족 문제가 심화되면서, **조립식 건축(Prefabricated Construction)**이 활성화 됨.
- 대표 사례: 1940~50년대 미국의 Quonset Huts: 군용 임시 막사를 조립형 으로 생산 / 일본의 프리팩 산업화: 태풍 및 지진 피해를 대비한 가벼운 구조물 중심 발전.
- 이 시기에는 아직 “모듈 단위” 보다는 패널, 조립 부재 중심의 프리팩브 (Pre-Fabrication) 형태였음.

3. 1960~70년대 – 현대적 모듈화의 태동

- 스웨덴, 네덜란드, 독일 등에서 패널 → 모듈로 진화
- 건물 전체를 Box 형태의 유닛(Unit)으로 제작하고 현장에서 조립하는 방식 도입
- 대표 사례: Habitat 67 (캐나다, 1967년 몬트리올 엑스포) → 콘크리트 박스를 블록처럼 쌓아 만든 혁신적 모듈러 아파트

4. 1990년대~2000년대 – 공장 제작 + 고정밀 시스템화

- 자동화 생산설비, 정밀 용접/절단 기술, 3D 설계 도구(BIM) 등장
- 미국, 영국, 일본에서 병원, 호텔, 기숙사, 학교 등 반복형 건축물에 본격 적용
- 일본 기업 세키스이 하우스(Sekisui House), 다이와 하우스, 미쓰비시 홈 등 프리팩브 시장 주도

5. 2010년대~현재 – 첨단 모듈러 & 디지털 전환

- 모듈러 건축 + 스마트 공장 + 자동화 시스템 융합
- 제약, 병원, 데이터센터, 스마트 주택 등 고정밀 산업 시설에 적용 확대
- 최근에는 모듈러 바이오 플랜트, 모듈러 백신 공장, 모듈러 병동 등 GMP 수준의 건물도 가능
- 세계적 사례: Broad Group (중국): 57층 건물을 19일 만에 조립 / Tofflon (중국): 제약 GMP 모듈러 제조소를 사전 제작 후 납품

모듈러 공법과 일반 건축 비교 (비용&기간)

Man-Power
Cost
Comparison

항목	일반 건축 방식	모듈러 건축 방식
전체 공사비 대비 인건비 비중	30~40%	15~20%
현장 인건비 비중	높음(작업 중심)	낮음(조립 중심)
공장 제작 인건비 비중	낮음	현장 대비 인건비 낮음(자동화 보완)
인건비 리스크	기후, 숙련도, 타공정간 작업 간섭 등 영향이 큼	일정화된 작업환경으로 리스크 낮음

Man-Power
Cost by
Work scope

공정 항목	일반 건축(비중)	모듈러 건축(비중)
토목/기초 공사	20~25%	20~25% (거의 동일)
골조/외장 공사	25~30%	10~15% ▼
내부 마감 공사	25~30%	10~15% ▼
설비 및 전기 공사	20~25%	10~15% ▼
기타 현장 지원	5~10%	2~5% ▼

Duration of
Construction
Period

구분	일반 건축(30개월)	모듈러 건축(18개월)	차이
골조 공사 기간	6~8개월	2~3개월	50~60% 단축
마감 및 설비공사	6~9개월	3~5개월	40~50% 단축
시운전 및 검수 기간	2~4개월	2~3개월	20~30% 단축
총 공사기간	24~32개월	12~18개월	30~50% 단축

- ◆ 모듈러 방식에서 ****프리패(Pre-fab, 사전 제작)****을 적용하면 **공장에서 미리 제작한 부품(골조, 벽체, 배관 등)을 현장에서 조립하는 방식**이기 때문에, 일반 건축 방식 대비 **품질 관리 측면에서 여러 가지 강점이 있음.**
- ◆ 프리패를 적용한 모듈러 방식은 품질 관리가 용이하며, 특히 제약 공장 같은 고품질 기준이 필요한 건축물에 적합함.
- ◆ 결과적으로 설치에서 발생할 수 있는 일탈관리(Deviation) Control이 용이 함.

항목	프리패 적용 시 장점
정밀한 품질 관리	공장 제작으로 오차 최소화 ($\pm 1 \sim 2\text{mm}$ 수준)
일관된 생산 품질	동일한 환경에서 제작 → 품질 균일성 확보
불량률 감소	자동화 공정 적용 → 인적 오류 최소화
환경 영향 최소화	기후, 현장 변수 없음 → 균일한 시공 품질
현장 작업 감소	배관, 전기, 설비 사전 조립 → 현장 오류 감소
GMP 등 규정 준수 용이	제약 공장 기준(GMP) 맞춰 표준화된 제작 가능

Schedule Comparison

Fast-track - Time is money

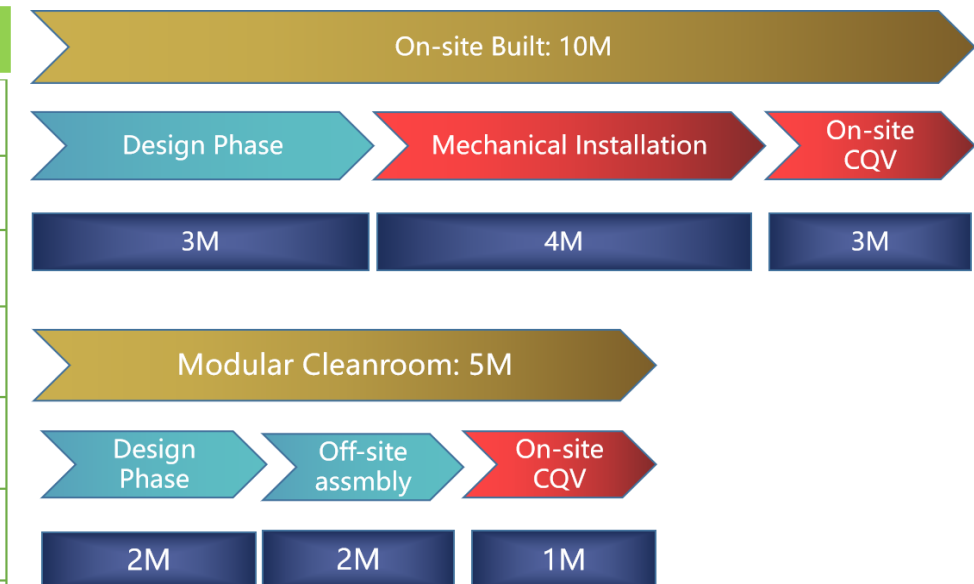
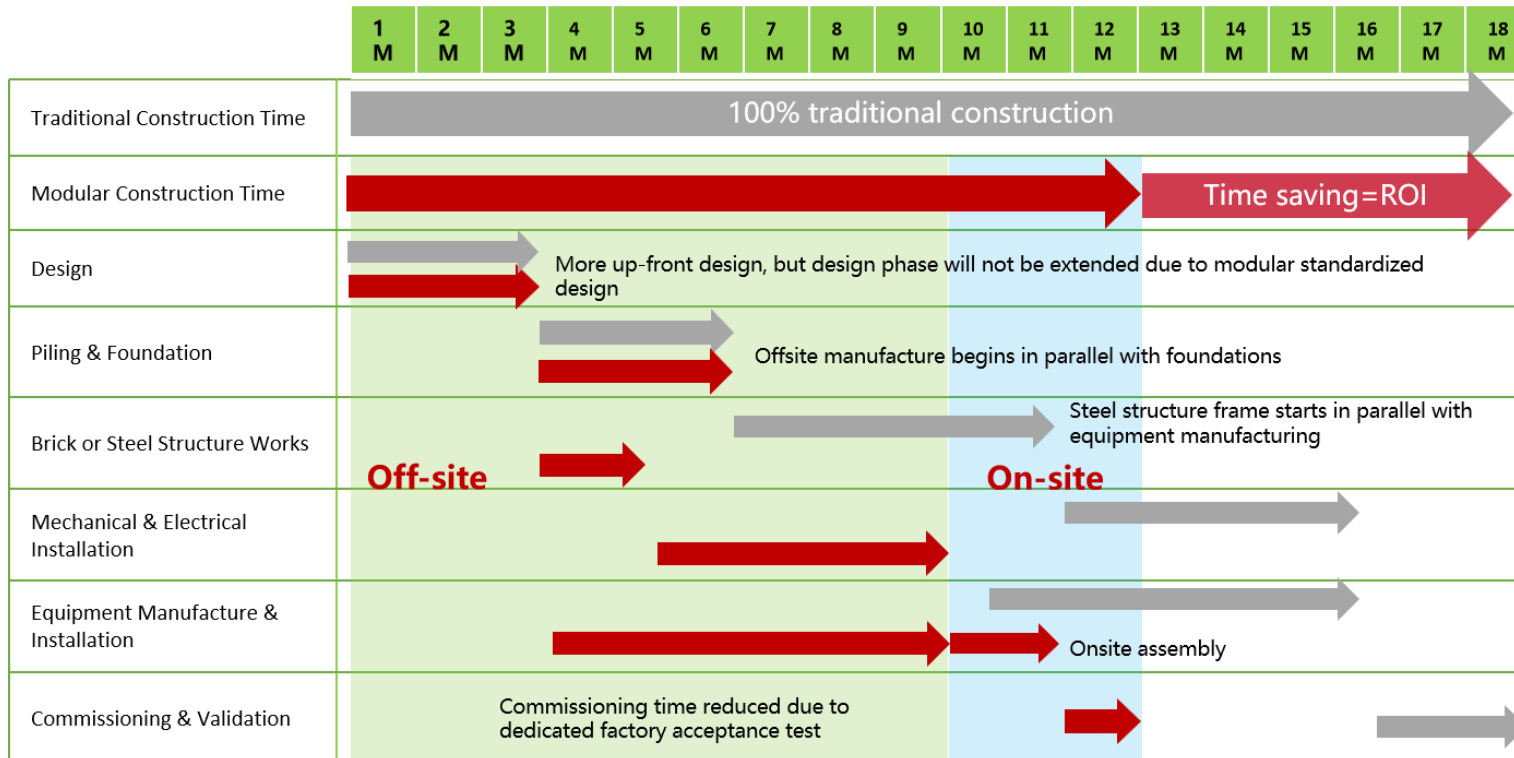
Moving construction offsite and into a controlled factory environment reduces programme times by **up to 50 percent**.

Stick-built facility construction: > 18 months

Modular facility construction: < 12 months

On-site fit out works: > 10 months

Modular cleanroom: ~6 months



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

Bio-Support Tofflon



Written by	Bio-Support & Tofflon
Document No.	TBD
Review No.	Draft00-01
Date	2025-04-16

Project Stage	Time Line	GMP / End User/ Consulting(Bio-Support)			Site	Facility Design / 3rd Party		Production Equipment with a long production period / 3rd Party		Site	Engineering for Modular Construction/ Tofflon			Site	Construction / 3ry Party		Site		
		Process	User	Consulting		Job	Description	Job	Description		Process	Engineering	Engineering QA		Job	Description			
Project Planning	3~6 Month	Project Strategy	GMP Facility Site	Supporting		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	On-site	Conceptual Design(CD)	Supporting	Conceptual Design(CD)	Supporting	On-site	Conceptual Design(CD)	Cowork with User	Review	Off & On-site					
	1 Month	VMP	Review & Approval	Execution & Document		Bidding Process & Contract	Supplier's Proposal												
	3~4 Month	URS of Utility System	Review & Approval	Execution & Document		Facility Basic Design (BD)	Execution & Document	URS of Production Equipment Request for Proposal(URS) Bidding Process & Contract	User/Consulting: Documentation User Supplier's Proposal		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)	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)
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			
								Equipment Production at Off-site	Supplier	Off-site				Off-site	Construction Work 1	Site Preparation Work Civil & Foundation Work Architectural Work Warehouse(high Rack) built(if necessary)	On-site		
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					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							
		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 Architectural Finishing Work	On-site		
			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
		1~2 Month	준공허가	Review		-			Commissioning & SAT		Supplier Execution + User/Consulting Review	준공허가	Preparation					Review	준공허가
Commissioning & Qualification	1 Month	Commissioning & SAT	Review & Approval	Review	On-site					On-site	Commissioning & SAT	Execution	Execution & Document	On-site	Commissioning & SAT		On-site		
	2~3 Month	IQ, OQ + CSV	Review & Approval	Execution	On-site			IQ, OQ + CSV	Consulting Execution + User: Review & Approval	On-site	IQ, OQ + CSV	CAPA Execution	Deviation Control	On-site	IQ, OQ + CSV	Deviation Control Supporting	On-site		
Validation	2~4 Month	PQ(Phase 1)			On-site					On-site				On-site					
	6~12 Month	Validation			On-site					On-site				On-site					

Introduction of GMP Facility Modular Construction of **Tofflon**

Tofflon 소개(요약)

역사

30년

제약바이오장비분야에서
30년간의 업력

누적 매출액

5.8조원

2024년도까지
누적 매출액

납품국가

50개국

50개국에 제약바이오
장비 납품 및 설치 실적

고객사

3,000

전세계의 3,000개의
고객사(한국: 25고객사)

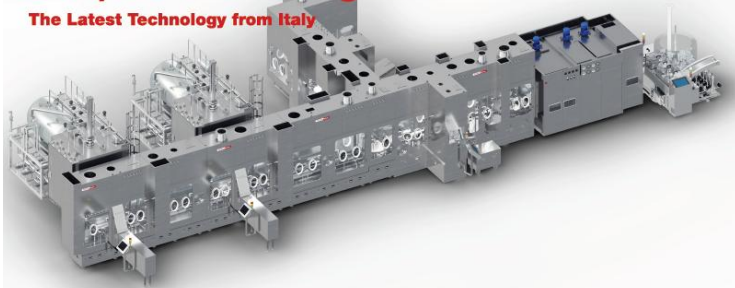
장비 및 시스템

15,000

전세계에 납품된
15,000개의 설비/시스템

Aseptic Vial Filling Line

The Latest Technology from Italy



Tofflon

Your Partner in High-Quality, Innovative
Pharmaceutical & Bio Manufacturing Solutions.

바이오써포트의 파트너사 Tofflon Group 소개

**Tofflon Science and
Technology Group Co.,Ltd.**



China Tofflon

➤ **Global Tofflon**

Equipment Supplier

➤ **Solution Provider**

■■■ Advanced Injectables & Complex Injectables



Compounding



Filling



Lyophilization



Inspection
& Detection



Packaging

■■■ Biotech & Biopharma



Bioreactor



Media/Buffer
Preparation



Purification



Freezing & Thawing



Inactivation

■■■ Cell & Gene Therapy (CGT)



Single Use
Cell Processing



GMP Cell
Processing Station



Expandable Incubator
Storage Matrix



MiniKUFill
Auto Cell Filling System



Auto LN₂
Storage System

Flexible

- 1) Suitable for multipurpose product platform . With closed process equipment and ballroom concept.
- 2) Customized equipment design for modular project, fit into the modular precisely, and avoid site re-assembly.
- 3) Relocatable. easy for dis-assembly and re-assembly.
- 4) Adaptable for scale-up and scale-out, with little interfering for running facilities



Flawless

- 1) High precision 3D model design with BIM and E3D.
- 2) Machining accuracy guaranteed by well trained in-house workers and workshop quality control system.
- 3) High level of FAT, with equipment commissioning in factory.



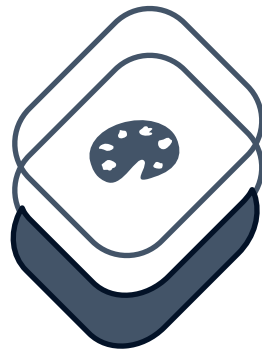
Future Production

- 1) High degree of automation and digitization, integrated SCADA & DCS control system.
- 2) Continuous process concept, with perfusion, continuous inactivation and purification equipment.



Fast-track

- 1) Schedule accelerated to 30-50%.
- 2) Overlapping construction procedure, on-site civil foundation and off-site pre-assembly simultaneously.
- 3) Pre-qualification and validation off-site can reduce on-site qualification and validation time.



Firm

- 1) Firm budget & cost, minimize COs and reworks.
- 2) Value engineering concept, balance initial investment and long-term running cost.
- 3) Firm project management, sole contact point.



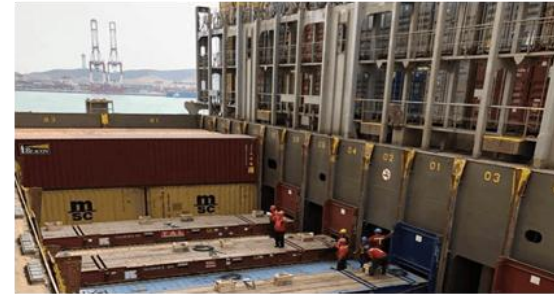
Implementation Procedure



Start

50% time saving

Completion



Feasibility Study

1. Decide modular option
2. Decide process/URS
3. Code, risk, feasibility analysis
4. Proposal comparison
5. Budget & economical analysis

Engineering Design

1. PFD/PID
2. Process calculations
3. 3D Design
4. IFC drawings extract from 3D model
5. Manufacture drawing
6. Government approve

Workshop Assembly

1. Steel Frame manufacture & pre-assembly
2. Clean room & Mechanical Installation
3. Equipment Installation
4. FAT
5. Disassembly for transportation

Transportation

1. Land transportation: Lowboy truck
2. Sea transportation: Bulk carrier
3. Air transportation: as required

Onsite Construction

1. Civil foundation & UG works preparation
2. Module lifting and reassembly
3. Facade and roofing
4. Construction Management

Handover

1. Utilities and clean room commissioning
2. Process equipment commissioning
3. Qualification and verification

Modular Cleanroom design features

Module size:

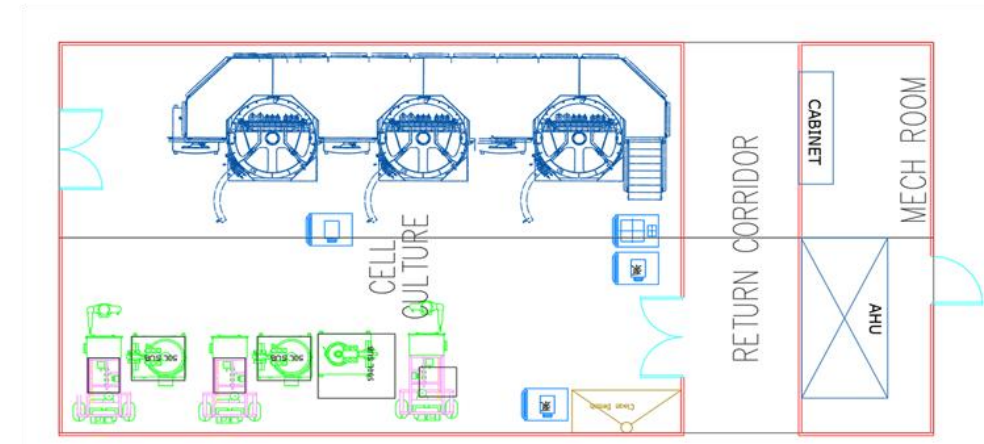
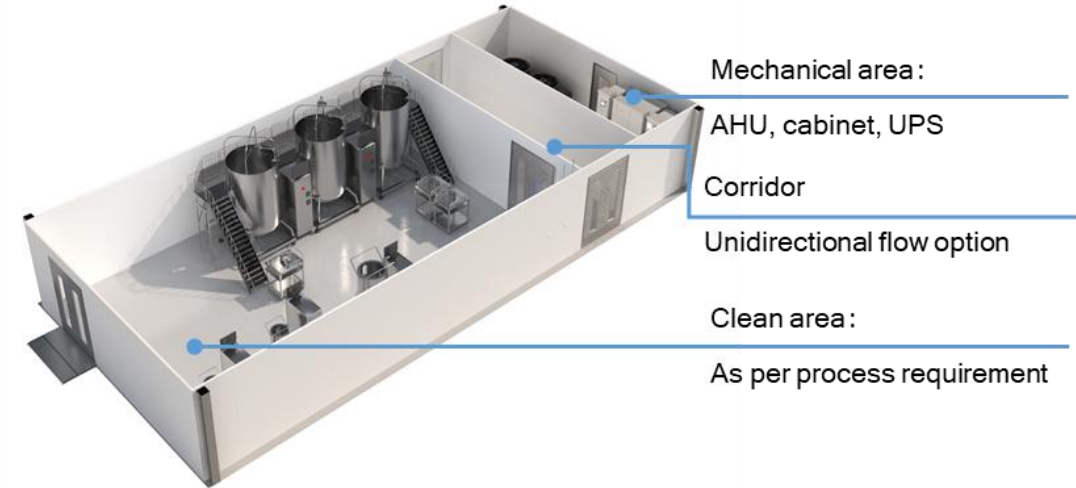
- Standard module: 8.5m*2.6m*4.2m (L*W*H) ;
- Module size can be customized according to projects.

Modular including:

- Core equipment, including bioreactor, chromatography, UF, filling, etc.
- Cleanroom: including clean board, floor, windows, doors, etc.;
- HVAC system: including AHU, exhaust fan, ducts, turret, valves, etc.;
- Fire protection: including hydrants, extinguisher, fire alarm, sprinkler, etc.;
- Piping system: including clean utility, black utility, piping, valves, etc.;
- Electrical: including power supply, lightning, socket, etc.;
- Telecommute: including entrance guard, interlock, network, CCTV, etc.;
- Control system : including BMS/EMS etc., SCADA system as option;
- Furnitures: including wardrobe, bench, etc.;

Service scope:

- Engineering, procurement, fabrication, construction turn-key solution;
- Pre-engineering, pre-commissioning, pre-qualification, pre-validation;
- Commissioning, qualification, verification (DQ/IQ/OQ) and training;



Modular Facility Design Feature

Module size:

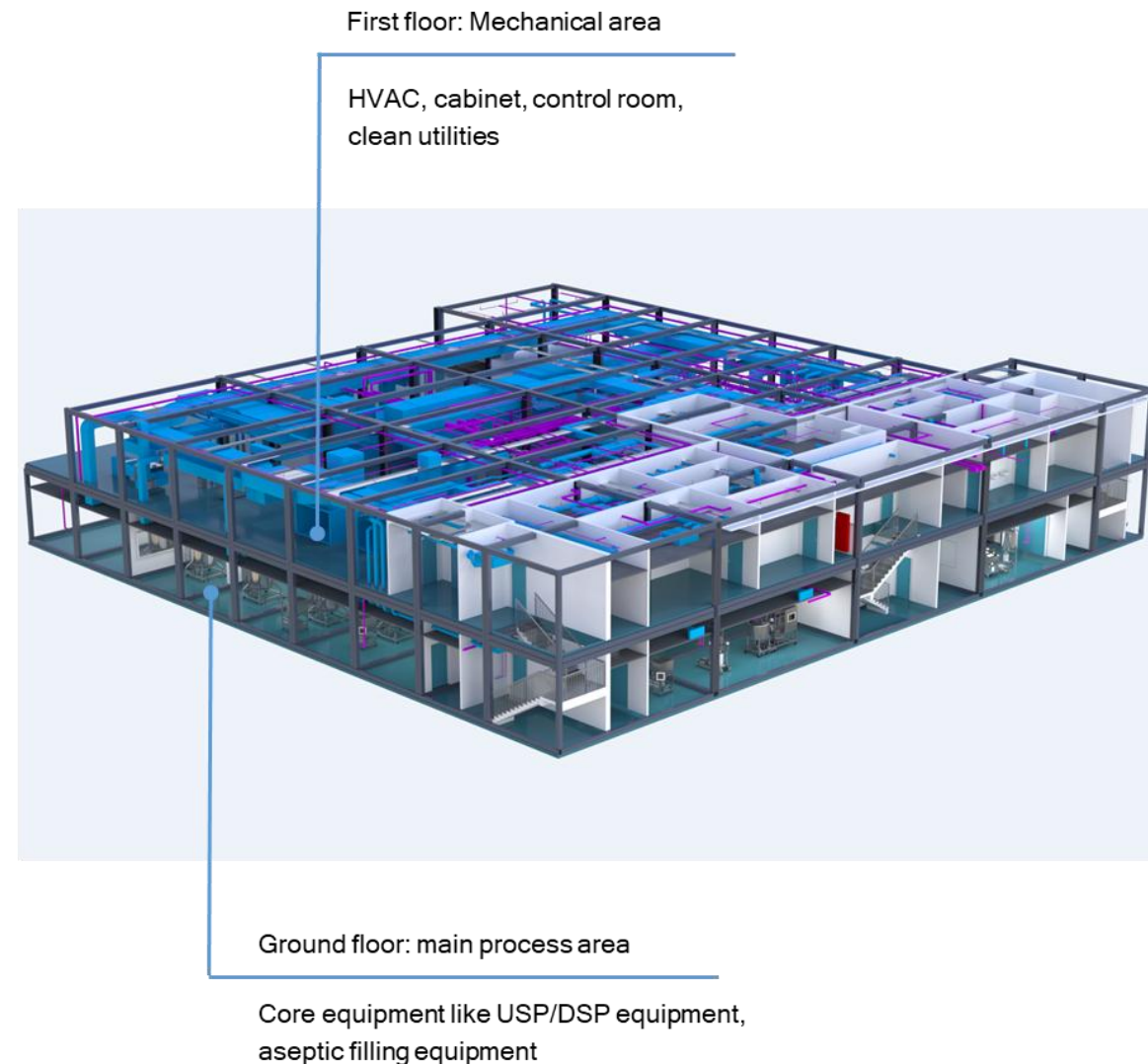
- Standard module size: 13.50m*4.50m*4.50m (L*W*H) ;
- Module size can be customized according to projects.

Modular including:

- Core equipment, including bioreactor, chromatography, UF, filling, etc.
- Steel structure: including beam, column, installation fixtures, etc.;
- Cleanroom: including clean board, floor, windows, doors, etc.;
- HVAC system: including AHU, exhaust fan, ducts, turret, valves, etc.;
- Fire protection: including hydrants, extinguisher, fire alarm, sprinkler, etc.;
- Piping system: including clean utility, black utility, piping, valves, etc.;
- Electrical: including power supply, lightning, socket, etc.;
- Telecommute: including entrance guard, interlock, network, CCTV, etc.;
- Control system : including BMS/EMS etc., SCADA system as option;
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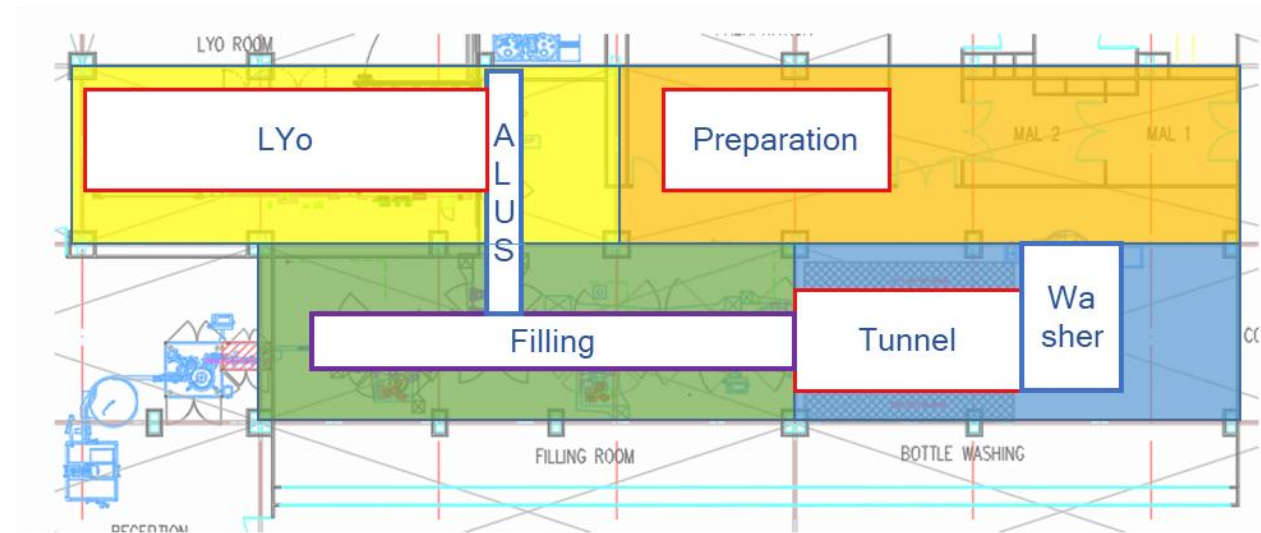
Equipment Integration Strategy

➤ Equipment Customization

- ✓ Reducing connections between modules;
- ✓ Proper design to segregate filling line;
- ✓ Sectional design of tunnel to reduce size;
- ✓ Flexible design of Lyo chamber & condensor to reduce height and weight, making it available to fit in the module;
- ✓ Customized Isolator & BIBO design to reduce height;
- ✓ ALUS pro without pushing system to reduce spaces and increasing flexibility;
- ✓ Customized centralized control system & cabinet;

➤ Layout solutions

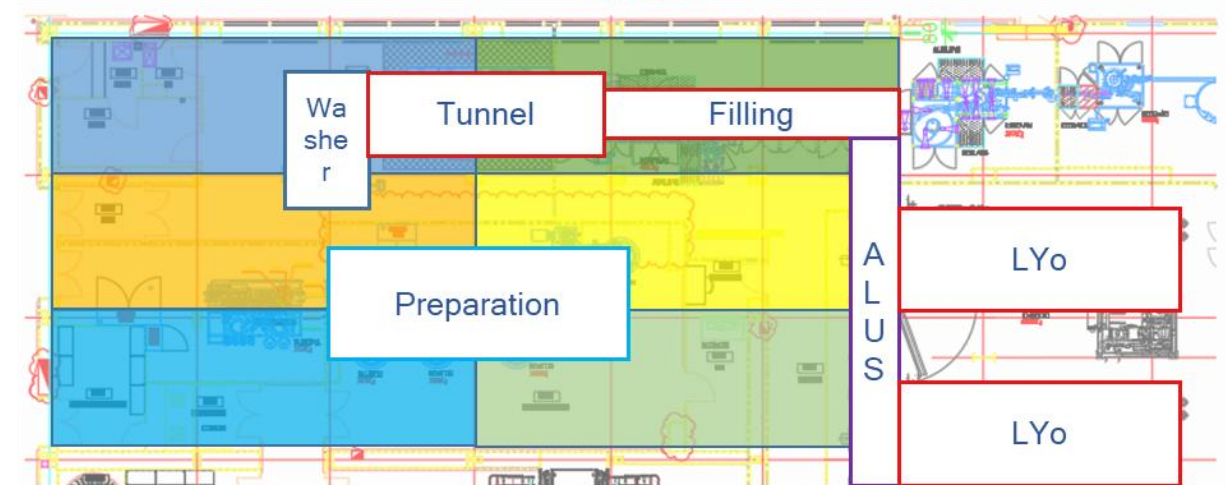
- ✓ Adjustment of modules to allow process layout more reasonable;
- ✓ Customized capper & stopper treatment machine for high-speed filling lines (located on 2nd floor)



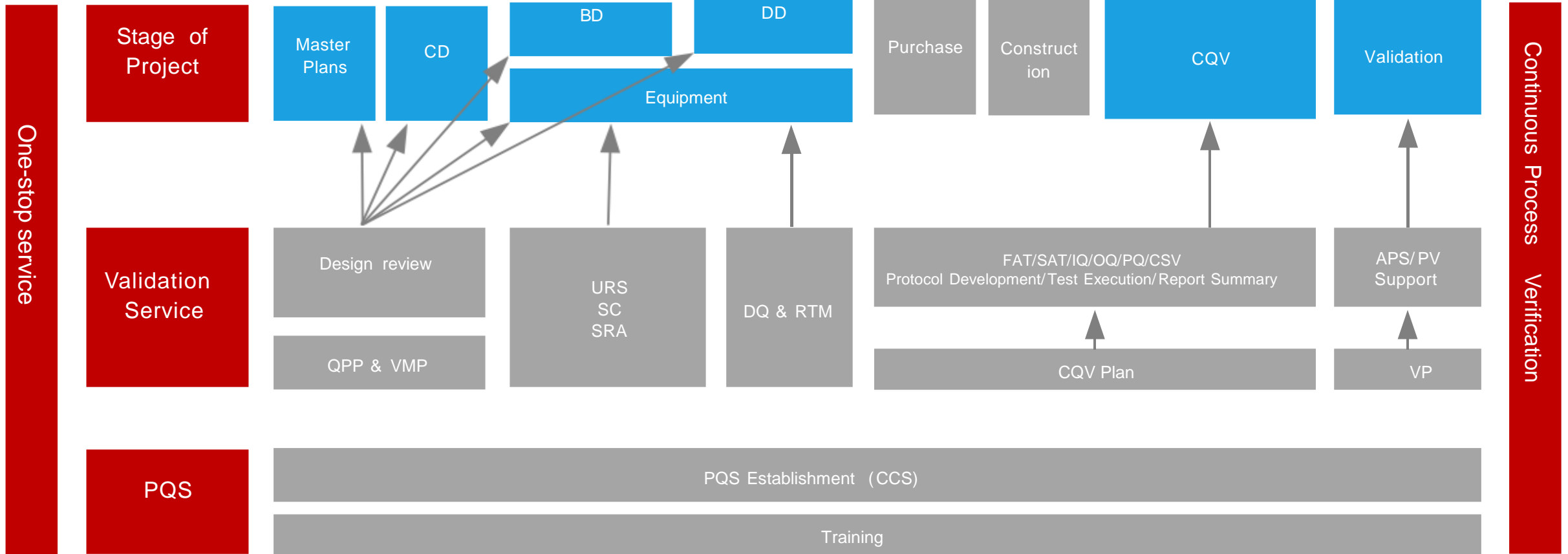
Tofflon Modular (Up)

Vs.

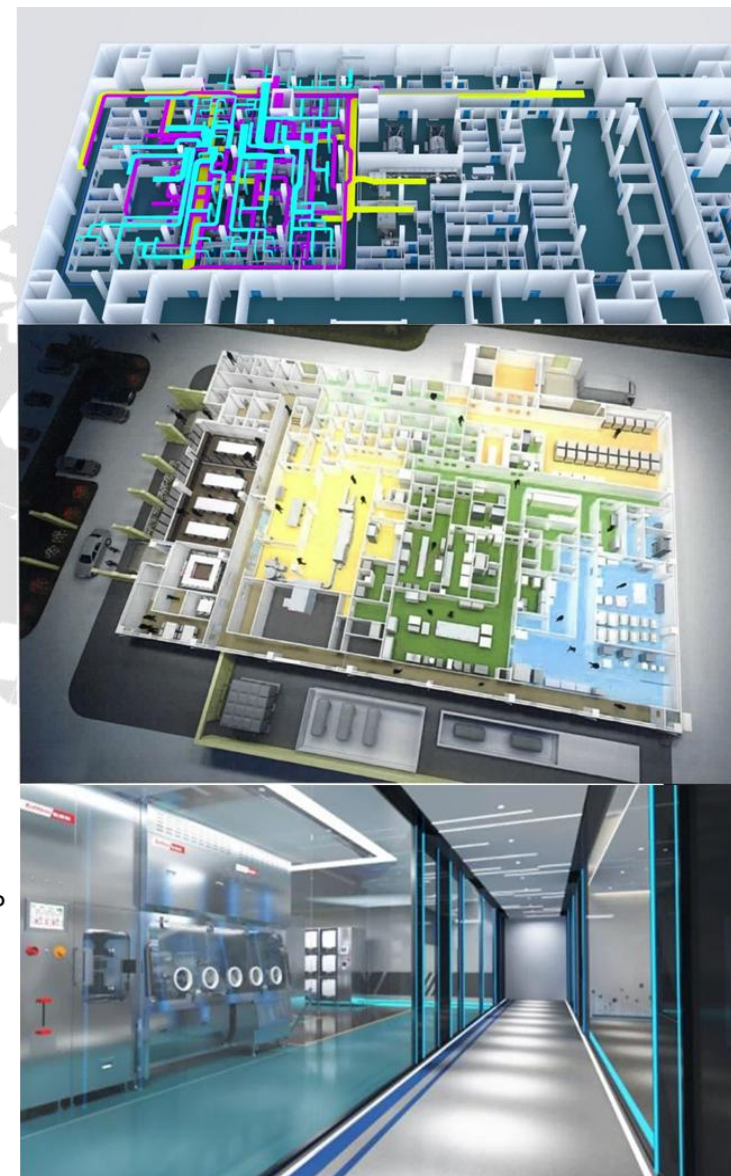
Other Supplier (Down)



CQV(Commissioning, Qualification, and Validation) One-Stop Service



Design Institution



Critical Utility Equipment

Water System

Tofflon cooperates with European AQUANOVA to provide high-end injection water, purified water, pure steam system and distribution system;

Intelligent distribution of water by crests

Automatic maintenance system

Automatic disinfection system



HVAC

The frame adopts high-strength non-cold bridge aluminum profile with a closed cavity structure.

Eliminate all cold bridges. No condensation.

The high-strength aluminum alloy profile is the skeleton and adopts an externally mounted structure.

The wall plate and frame are connected by crimp external fastening, and the inner section of the chassis body has been eliminated for easier cleaning.

Comply with EU clean room air conditioning unit standards .



UAE Vaccine F/F Facility

• Main Equipment:

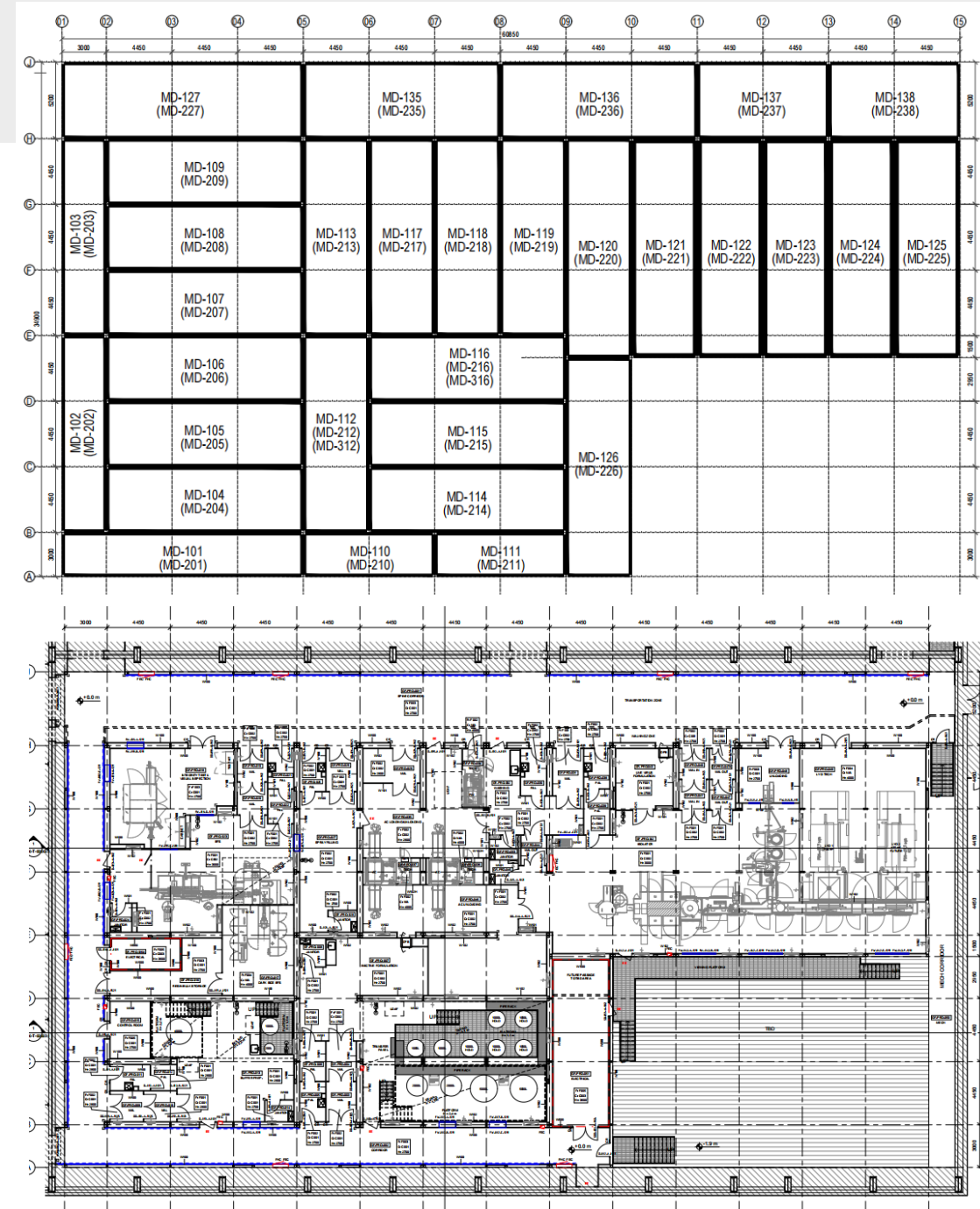
- 300vpm vial liquid/lyo filling line with isolator;
- 1800 uits/hr BFS filling line, 50~500mL;
- Formulation and preparation vessel system (22 tanks in total);
- Clean utility system;

• Facility Information:

- Building footprint: 1800 m²;
- Total area: 3600 m²; 64 module units
- 1st floor area: 1800 m², 30 module units;
- 2nd floor area: 1800 m², 34 module units;

• Project Considerations:

- Core clean area in modular approach; less complex area (eg. secondary packaging, QC lab, animal house) in traditional approach;
- Fast-track delivery: building shell and interior modular facility work in parallel. Whole project delivers in 12 months.



Modular E.P.C 사례

Iraq 15kg OSD Facility, OBE4~5

➤ Design Concept:

- ✓ Separate modules set for pedestrian flow, pretreatment, granulation and forming to avoid cross contamination
- ✓ Comply with GMP production requirements, Grade D clean area
- ✓ Integral modular installation of equipment and plant

➤ Equipment:

- ✓ Pretreatment: weighing and sampling isolator
- ✓ Granulation: Wet granulation + Fluid bed dryer and Dry granulation
- ✓ Forming module: Tablet press, Coating machine and Capsule machine

➤ Mechanical Function:

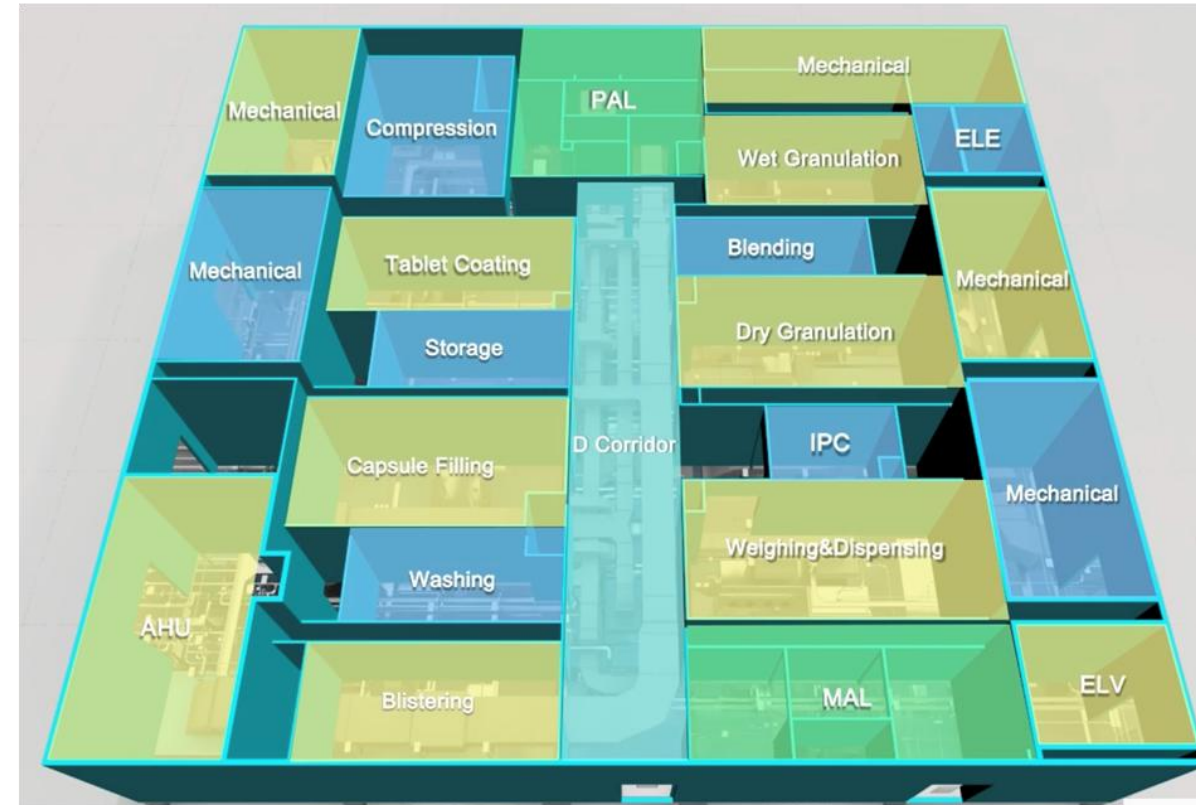
- ✓ Standard: HVAC, power cabinet, control system
- ✓ Optional: PW, chilled water, hotwater, steam, wastewater inactivation

➤ External supply :

- ✓ External power supply, drinking water

➤ Containment Strategy:

- ✓ Key process equipped with isolator;
- ✓ Key process area (weighing, granulation, compression, capsule) equipped with BIBO;
- ✓ Exhaust fan equipped with BIBO.



Modular E.P.C 사례

Mi Bio Factory: Pilot Scale DS Facility

- **Main Equipment:**

- 500L Bioreactor*2, chromatography system, filtration system, clean utilities, buffer and media preparation vessels

- **Facility Information:**

- Building footprint: 538 m²;
- Total area: 839 m²;
- 1st floor area: 538 m², 10 module units;
- 2nd floor area: 301 m², 6 module units;

- **Layout Considerations:**

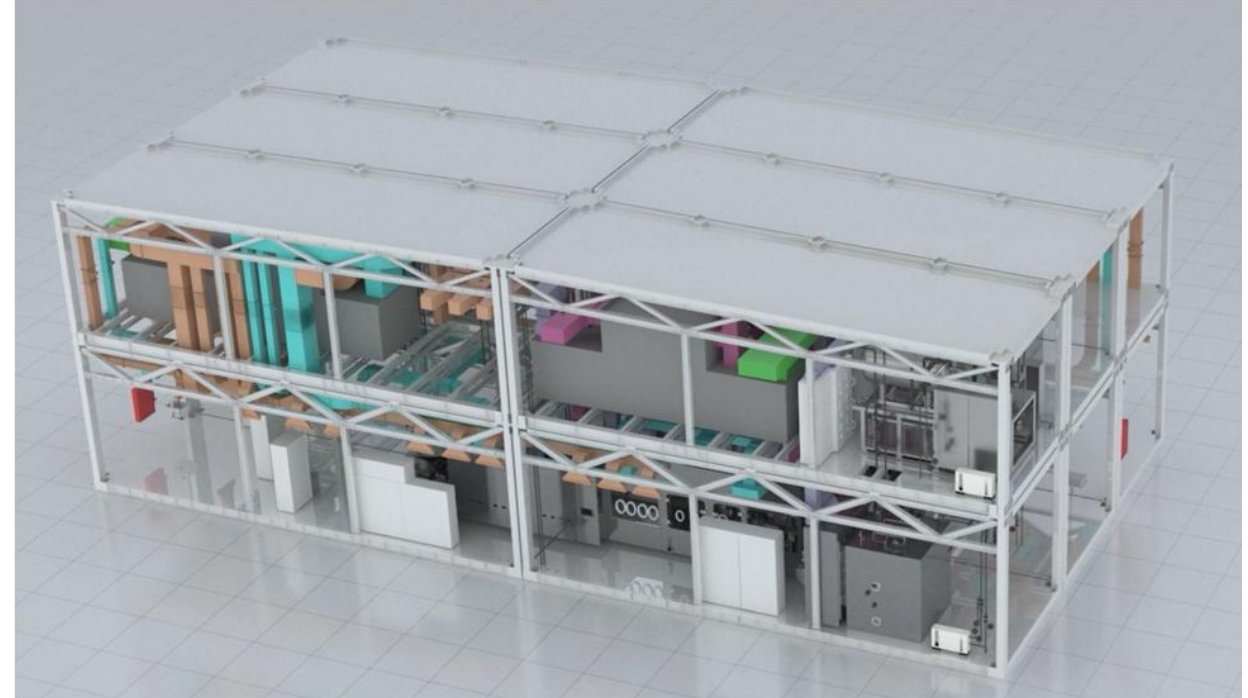
- Ballroom concept: buffer & media preparation ballroom, cell culture & harvest ballroom;
- Less buffer and media traffic;
- Less movement in cell culture and purification area;
- Clean utilities adjacent to the active cell spaces, wastewater directly discharge into inactivation tanks;
- High flexibility;



Modular E.P.C 사례

Flexible DP Facility

- **Main Equipment:**
 - 200 vpm vial filling line, lyo 20, formulation vessels, washing and sterilization machine, clean utilities
- **Facility Information:**
 - Building footprint: 360 m²;
 - Total area: 720 m²;
 - 1st floor area: 360 m², 6 module units;
 - 2nd floor area: 360 m², 6 module units;
- **Layout Considerations:**
 - Design considerations to achieve **REAL** offsite equipment pre-assembly & pre-testing/pre-qualification
 - Equipment segregation & module segregation put in consideration together, to make equipment shipment with modules possible;
 - Customized design of the Lyo machine, to achieve lyo, ALS, filling machine and isolators located in the same module unit.
 - Structure calculation according to the permanent building structure design standard (AISC, DIN, BS, GB etc.)
 - Customized BIBO design to reduce isolator height;
 - Special AHU & duct design for isolators to avoid collision in confined mezzanine spaces;

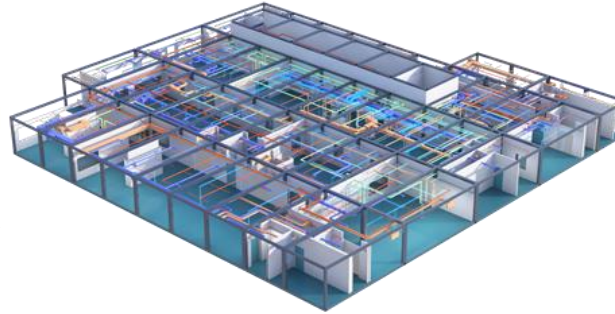


Modular E.P.C 사례

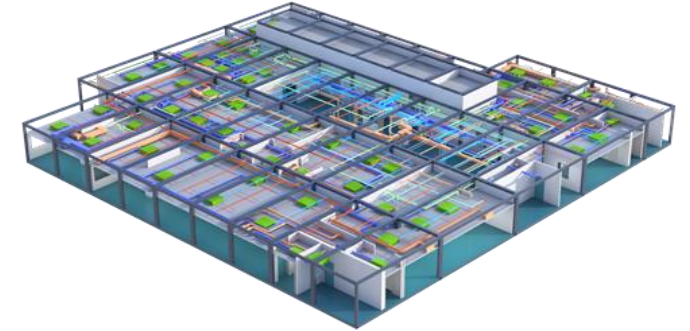
Brief Picture of Modular Delivery (Off Site)



Steel frame fabricate



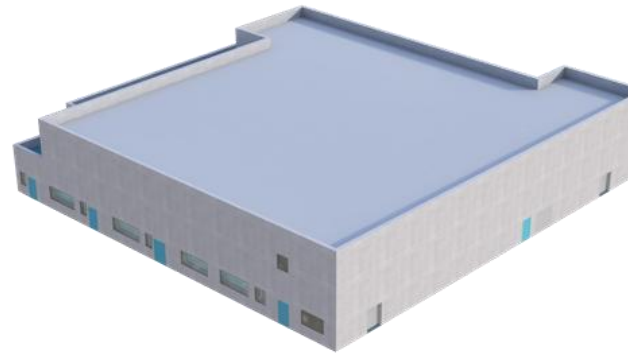
Piping & ducts installation



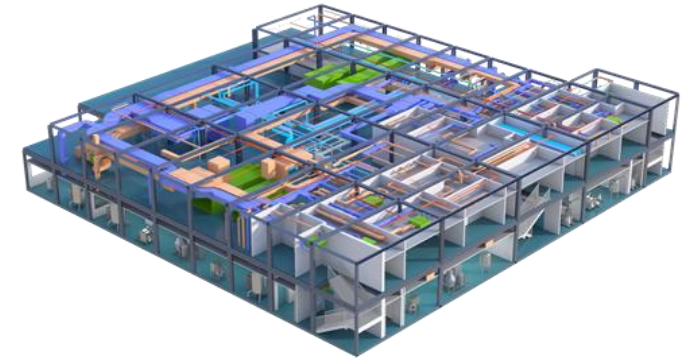
Clean room installation



Packing and shipping



Factory acceptance test



Equipment installation

Brief Picture of Modular Delivery (On Site)

Brief Picture of Modular Delivery (On Site)



Civil foundation



Module lifting



Hook-up



CQV



Roof & Facades

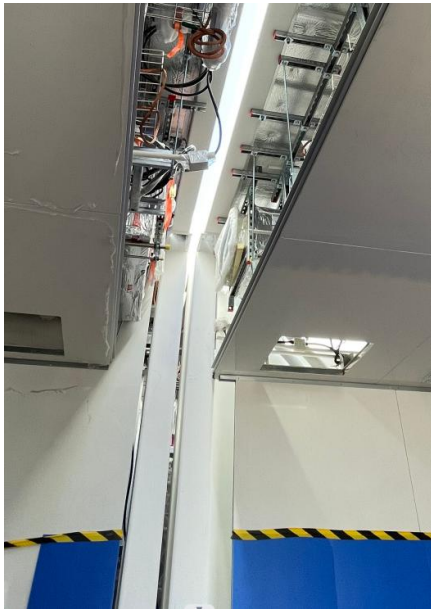
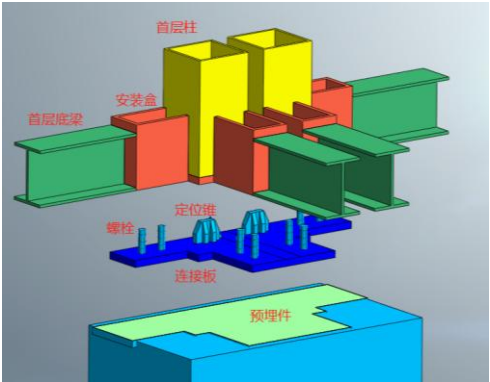
Structure
connection

Floor
connection

Cleanboard
connection

Duct & pipe
connection

Cable
connection





UAE Rabdan Holding Veterinary Vaccine Modular Facility

Vaccine Modular Facility - EU GMP



Project Introduction

Location: Abu Dhabi, UAE

Scope: Modular facility

Area: 4,000m²



Equipment Supply Scope: Compounding system (22 vessels), CIP/SIP, water system

Engineering Supply Scope: DD, Modular facility, equipment installation, cleanroom, MEP, CQV, BMS/EMS, PCS

Kelix Morocco DP & OSD Project

Biosimilar filling - EU GMP

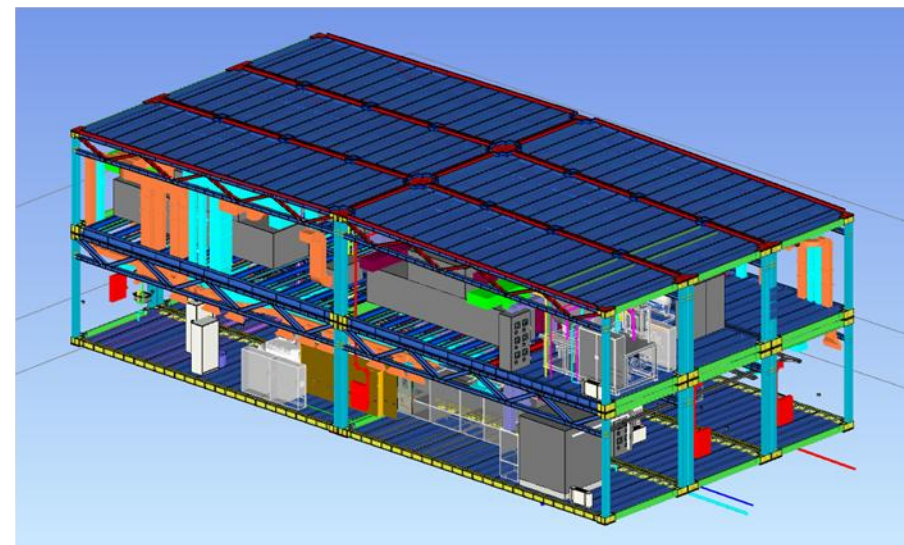
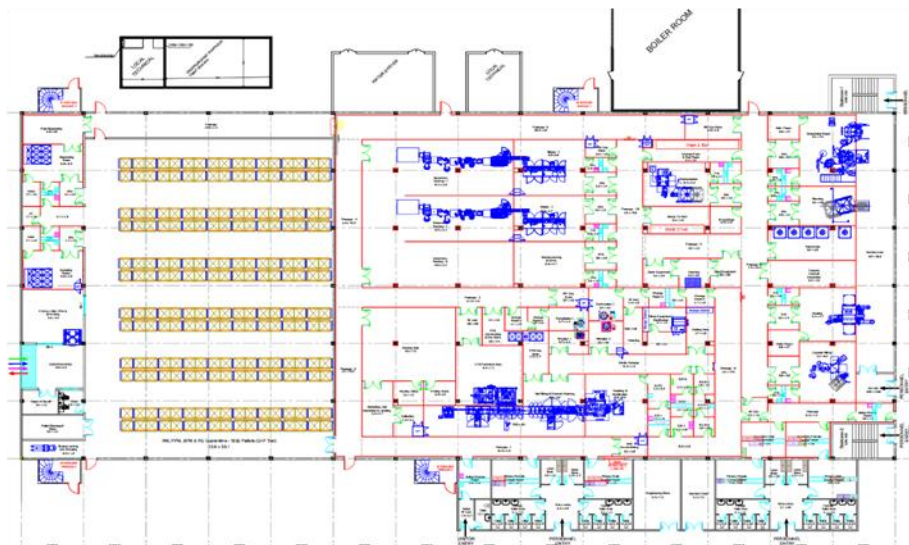
 **KELIX** *bio*

Project Introduction

Location: Rabat,
Morocco

Scope: EPC+M

Area: 3,000m²



Equipment Supply Scope: PFS filling, Bulk vial filling, inspection, packaging, 300kg OSD, Pulverizer, wet granular, fluid bed, tablets, capsule

Engineering Supply Scope: CD/BD/DD, Procurement, equipment installation, cleanroom fit-out, MEP installation, CQV, BMS/EMS, SCADA

Iraq Sama High Potent OSD Modular Facility

OSD Modular Facility - EU GMP



Project Introduction
Location: Bashra, Iraq
Scope: Modular facility
Area: 800m²



Equipment Supply Scope: Fluid bed, roller compactor, capsule, tablet press, coating, blistering machine

Engineering Supply Scope: CD/BD/DD, Modular facility, equipment installation, cleanroom, MEP, CQV, BMS/EMS

ADC drug EPC Project

ADC Drugs-GMP



Project Introduction
Location: Liaoning
Scope: EPC+M
Area: 24,000m²
Duration: 300 Days



Equipment Supply Scope: Washer, tunnel, filling, Lyo, ALUS, inspection, leakage detection, secondary packaging, CU
Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES

Yunnan Walvax HPV Project



HPV Project-WHO PQ

Project Introduction
Location: Yuxi, Yunnan
Scope: EPC+M
Area: 15,000m²



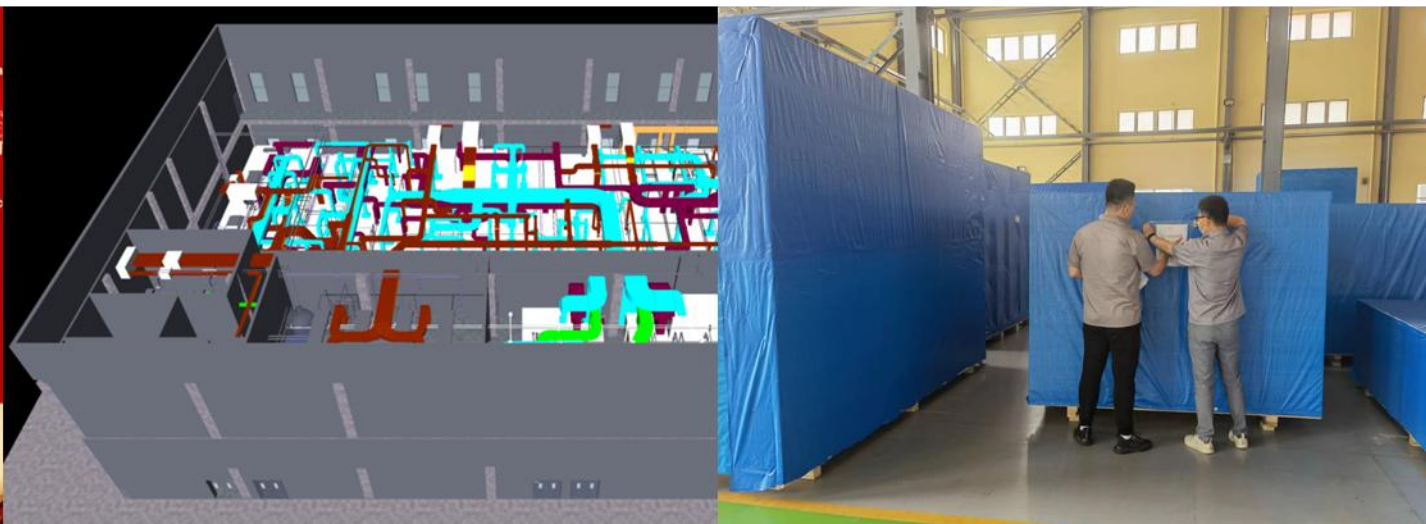
Equipment Supply Scope: Bioreactor, buffer & media preparation, purification, CIP

Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom, MEP, CQV, MES

Covid-19 Vaccine Project in Uzbekistan

Cov-19 Vaccine - EU GMP compliant

Project Introduction:
Location: Uzbekistan
Scope: EPC+M
Area: 2,200m²



Equipment Supply Scope: CES, Single use bioreactor, UF/DF, autoclave, purification, PFS filling, Rabs

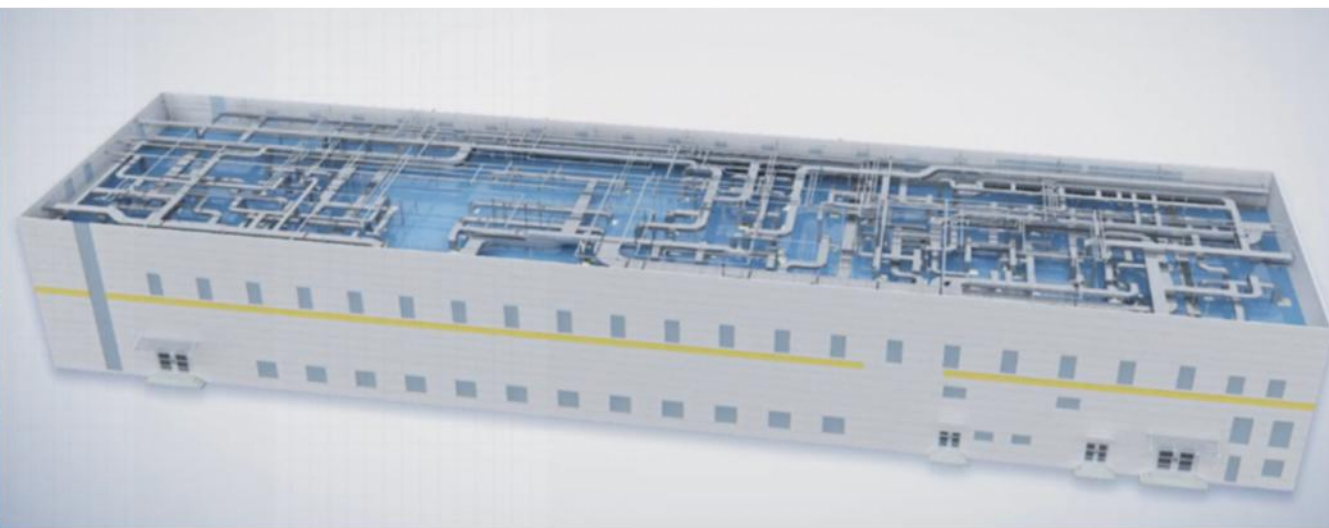
Engineering Supply Scope: Design management, procurement, equipment installation, cleanroom fit-out, MEP installation, CQV, BMS/EMS

Boya Blood Product Project

Blood Product



Project Introduction:
Location: Jiangxi
Scope: EPC+M
Area: 12,000m²



Equipment Supply Scope: N/A

Engineering Supply Scope: Design management, procurement, DP equipment, cleanroom, MEP, CQV, MES

Lonza New DP Line Project

CMO DP Project- China GMP, EU GMP



Project Introduction
Location: Guangzhou
Scope: EPC+M
Area: 3,000m²
Duration: 240 Days



Equipment Supply Scope: Compounding, filling line, capping, inspection, labeling, packaging, CIP

Engineering Supply Scope: Procurement, equipment installation, cleanroom, MEP, CQV, MES



Approach to Qualification for GMP Facility Modular Construction

대한민국 No.1
GMP & Validation 솔루션 컨설팅, 바이오써포트



Conceptual Design(개념설계), Qualification & Validation + CSV
PQS, QRM, QbD, Data Integrity, CCS, Mock Inspection, Vendor Audit(국내 및 해외)





***Specification Design, **Verification, ***Acceptance Release,
****Operation & Continuous Improvement**

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

Bio-Support Tofflon



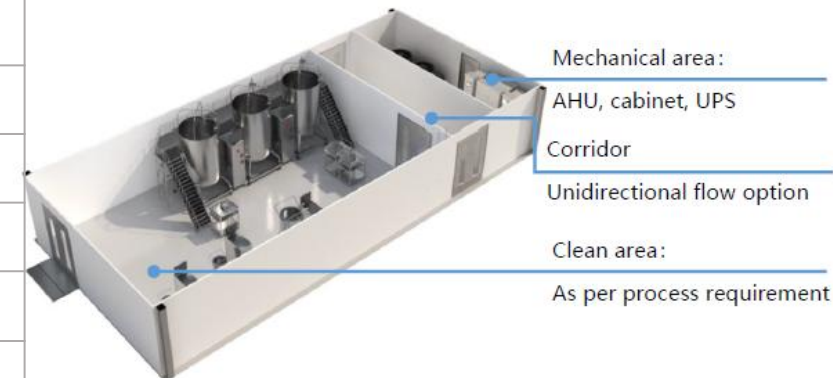
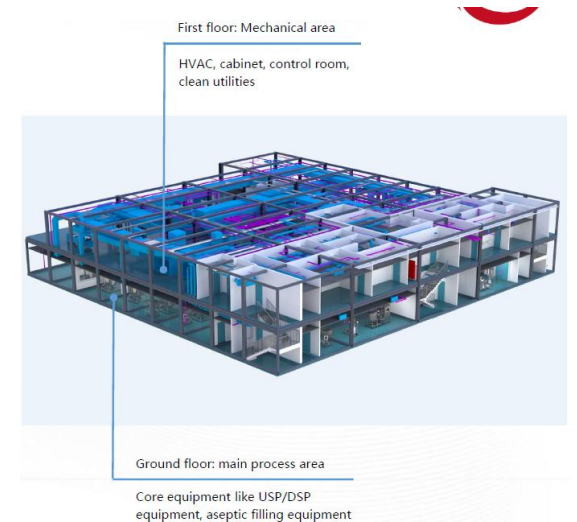
Written by	Bio-Support & Tofflon
Document No.	TBD
Review No.	Draft00-01
Date	2025-04-16

Project Stage	Time Line	GMP / End User/ Consulting(Bio-Support)			Site	Facility Design / 3rd Party		Production Equipment with a long production period / 3rd Party		Site	Engineering for Modular Construction/ Tofflon			Site	Construction / 3ry Party		Site	
		Process	User	Consulting		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	On-site	Conceptual Design(CD)	Supporting	Conceptual Design(CD)	Supporting	On-site	Conceptual Design(CD)	Cowork with User	Review	Off & On-site				
	1 Month	VMP	Review & Approval	Execution & Document		Bidding Process & Contract	Supplier's Proposal											
	3~4 Month	URS of Utility System	Review & Approval	Execution & Document		Facility Basic Design (BD)	Execution & Document	URS of Production Equipment Request for Proposal(URS)	User/Consulting: Documentation		Facility Basic Design(BD)	Execution & Document(Eng. Area)	Review					
		Facility Basic Design(BD)	Review & Approval	Execution & Document				Bidding Process & Contract	Supplier's Proposal									
	3 Month	Facility Detailed Design(DD)	Review	Review		Facility Detailed Design(DD)	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		
								Equipment Production at Off-site	Supplier	Off-site				Off-site	Construction Work 1	Site Preparation Work Civil & Foundation Work Architectural Work Warehouse(high Rack) built(if necessary)	On-site	
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					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						
		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	On-site	
			As Built Document + Supplier's Document for Qualification	Review		Review			Equipment Installation at Site			Supplier(Cowork with Engineering)	Utilities & Production Equipment Installation +Hook Up					
											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	Review & Approval	Review	On-site					On-site	Commissioning & SAT	Execution	Execution & Document	On-site	Commissioning & SAT		On-site	
	2~3 Month	IQ, OQ + CSV	Review & Approval	Execution	On-site			IQ, OQ + CSV	Consulting Execution + User: Review & Approval	On-site	IQ, OQ + CSV	CAPA Execution	Deviation Control	On-site	IQ, OQ + CSV	Deviation Control Supporting	On-site	
Validation	2~4 Month	PQ(Phase 1)			On-site					On-site				On-site				
	6~12 Month	Validation			On-site					On-site				On-site				

설치적격성평가(Installation Qualification)

Modular Construction의 설치적격성평가는 기존의 설치적격성평가와는 전혀 다른 방식으로 접근합니다. 제조사 현장에서 FAT & Prequalification를 실시하여 IQ에서 발생하는 일탈을 최소화 하여 기간을 혁신적으로 단축시킵니다.

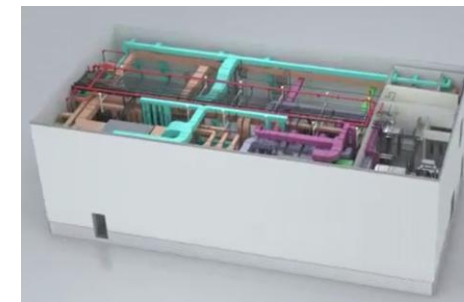
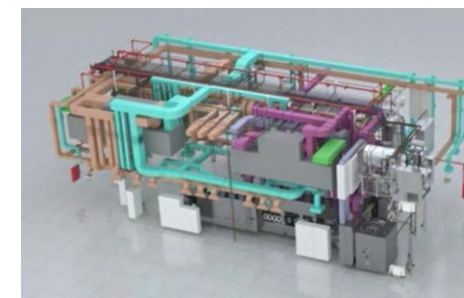
No.	평가항목	Off Site (제조사 현장)	On Site (사용자 현장)	비고
1	설치적격성평가 준비 상태 확인 시험	●	●	
2	문서 적격성 확인시험	●		현장 설치전 완료
3	매뉴얼 내용의 적격성 확인 시험	●		현장 설치전 완료
4	교정 확인 시험	●		현장 설치전 완료
5	재질 확인 시험	●		현장 설치전 완료
6	기계적 설치상태 확인 시험	●(80%)	●(20%)	현장 Hook Up 및 기타 상태 확인
7	전기적 설치상태 확인 시험	●(80%)	●(20%)	현장 Hook Up 및 기타 상태 확인
8	유지보전 측면 확인시험	●(90%)	●(10%)	
9	설치 환경 및 안전 측면 확인 시험		●	
10	덕트 누기 시험 결과 확인 시험	●	●	설치 옵션에 따름
11	HEPA Filter 완전성 확인 시험	●	●	설치 옵션에 따름
12	클린룸 설치상태 확인 시험	●(90%)	●(10%)	
13	오염원 누기 확인 시험		●(100%)	
14	기타			



운전적격성평가(Operational Qualification)

제조사 현장에서 **FAT & Prequalification**를 통해 운전적격성평가의 주요 항목을 대부분 평가하고 사용자의 현장에서는 기실시한 항목에 대한 Verification과 일부 주요 항목에 대해서만 평가함으로써 위험과 시간을 현격하게 줄입니다.

No.	평가항목	Off Site (제조사 현장)	On Site (사용자 현장)	비고
1	TAB 확인시험	●	●	
2	제어판 기능 확인 시험	●		현장 설치전 완료
3	경고, 알람 및 비상 기능 확인 시험	●		현장 설치전 완료
4	시스템 가동상태 육안 확인 시험	●		현장 설치전 완료
5	공기조화기 메인 풍량 확인 시험	●		현장 설치전 완료
6	청정실 풍량 확인 시험	●(90%)	●(10%)	현장 Hook Up 후 Verification 확인
7	청정실 환기횟수 확인 시험	●(90%)	●(10%)	현장 Hook Up 후 Verification 확인
8	청정실 간 차압 확인 시험	●(90%)	●(10%)	
9	청정도 확인 시험		●	
10	온습도 확인 시험		●	
11	청정도 회복 기능 확인 시험		●	설치 옵션에 따름
12	청정실 소음 확인	●		설치 옵션에 따름
13	청정실 조도 확인	●		
14	Door Interlock 확인	●		
15	청정실 기류패턴 확인 시험	●		



대한민국 No.1
GMP & Validation 솔루션 컨설팅, 바이오써포트

저희 바이오써포트가 오는 4월 22일(화)부터 4월 25일(금)까지 진행되는 COPHEX 2025에 참가하오니 저희 부스를 방문해 주시면 “소정의 선물과 본 세미나 자료”를 드리도록 하겠습니다.

많은 관심과 방문 부탁드립니다.

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제20회 국제제약·바이오·화장품기술전
COPHEX 2025
2025.04.22(화) ~ 2025.04.25(금)



Bio-Support가 COPHEX 2025에 참가합니다.

부스번호 : 5D808

킨텍스 제 1전시장

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.

Thank you so much!!!

소중한 고객님 및 파트너님과 함께 성장하는 바이오써포트입니다.

Bio-Support

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