

바이오써포트 [GMP 밸류체인 콜라보레이션 서비스] 사업 소개 및 우리의 파트너

바이오써포트는 GMP 발전과 품질에 대한 사명감을 기반으로 대한민국 제약 및 바이오산업의 발전에 작은 힘이나마 일조하고자 2000년 설립된 대한민국 No.1 GMP & Validation 솔루션 컨설팅 기업입니다.

지난 24년간 "Global GMP & Validation Solution Service" 분야에서 쌓아 온 경험과 핵심역량을 기반으로 국내 제약 및 바이오 산업의 지속적인 발전에 도움이 될 수 있도록

"제약바이오 및 GMP 밸류체인 콜라보레이션 서비스(PharmaBio & GMP Value Chain Collaboration Service)"를 파트너와 함께 실현하고 있습니다.

늘 여러분의 벗이자 파트너인 (주)바이오써포트와 함께 하시죠!!!

대표이사 김경민 배상

제약바이오 장비, 시스템, 서비스 등에 대한 견적서, 정보 등을 의뢰하거나 문의사항이 있으신 고객님께서 아래의 이메일로 문의사항이나 의뢰정보를 보내주시면 성심을 다하여 답변을 드리도록 하겠습니다.

gmp@biosupport.co.kr / 담당 : 밸류체인 디커플링 캠퍼스 김지민 상무

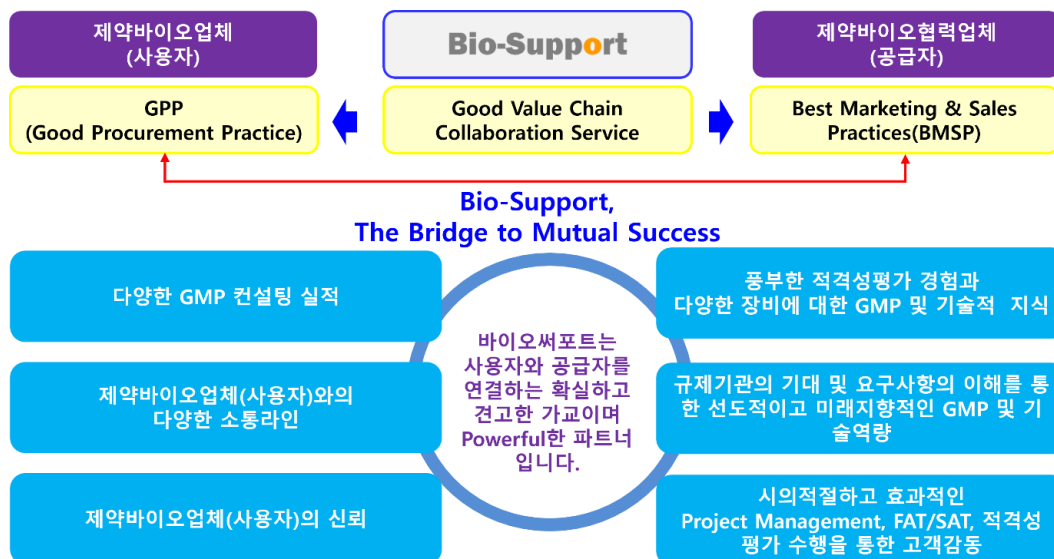
제약바이오 및 GMP 밸류체인 콜라보레이션 서비스
(PharmaBio & GMP Value Chain Collaboration Service) 소개

바이오써포트는 2000년 이래로 제약바이오 분야에서

- 1,200건 이상의 다양한 GMP(개념설계, 품질시스템, 모의실사 및 밸리데이션 등) 컨설팅 실적
- 사용자 임원 및 실무진과 정확하고 실속 있는 다양한 경로의 의사소통 라인
- 성공적인 컨설팅 프로젝트 수행에 따른 사용자의 신뢰 등의 역량을 가진 회사입니다.

상기의 역량을 기반을 공급자와 사용자가 함께하는 Innovative Value Chain Collaboration Service를 실현하여서 공급망의 파트너와 함께 혁신적인 부가가치를 창출합니다.

바이오써포트는 제약바이오 사용자 및 공급자와 함께 혁신적인 밸류체인을 만들어 갑니다.



**바이오써포트의 “제약바이오 및 GMP 밸류체인 콜라보레이션 서비스
(PharmaBio & GMP Value Chain Collaboration Service)”란 무엇인가?**

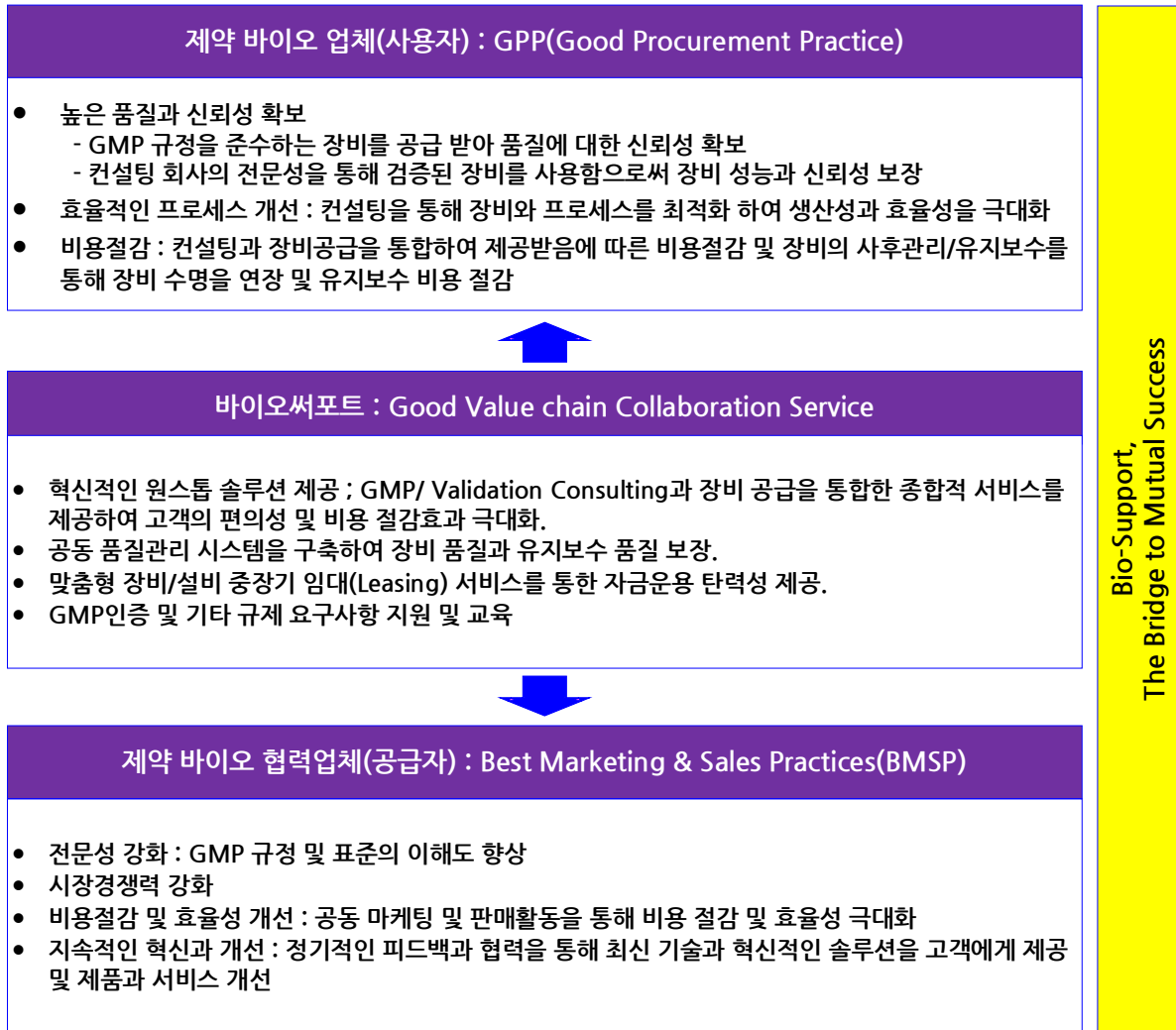
바이오써포트는 파트너와 함께 다음의 “제약바이오 및 GMP 밸류체인 콜라보레이션 서비스(PharmaBio & GMP Value Chain Collaboration Service)”를 제공하고 있습니다.

No	Section	Description(If applicable, 적용시)
1	Project feasibility consulting	● 해당 장비가 설치될 GMP제조소 개념설계, 기본설계 및 상세설계 지원 서비스 (장비 배치도, Utility Requirements 등)
2	Project Management	● 고객 맞춤형 및 디지털 프로젝트 관리서비스(PM +엔지니어 +GMP컨설턴트)
3	Process Development & Design	● 공정개발지원(적용시) 및 공정 설계 서비스
4	USR Development	● 시스템, 장비 및 Computerized System의 Initial URS 개발 서비스
5	Equipment Spec selection and customization	● 공정설계에 따른 고객 맞춤형 장비 규격 결정 서비스 ● GMP(21 CFR Part 11, Data Integrity) Compliance 및 제조공정에 부합하는 Computerized System 디자인 서비스
6	Project engineering design and Manufacturing	● GMP 및 국제적 경쟁력 기반으로 장비 설계 및 제작 ● 장비 규격, 구성품, Computerized System 등의 고객 맞춤형 및 미래지향적인 GMP Compliance 확보 ● 해당 장비 설치 구역의 3D Design 및 동영상 제작 지원 서비스
7	Document Control	● 설계도서, 규격서, 성적서 및 매뉴얼 등의 GMP에 부합하는 디지털 문서관리 서비스
8	Change Control	● 장비 설계, 제작단계 및 초기 밸리데이션 단계에서의 GEP 기반의 설계 변경관리 서비스
9	Delivery	● 고객 니즈에 부합되는 납품일정 관리 서비스
10	Installation and commissioning	● 고객맞춤형 Field Installation 서비스 ● GEP 기반 Commissioning 서비스(FAT/SAT(Optional), 시운전)
11	Validation of the equipment and process (Option)	● GMP 기반 Qualification 및 Computerized System Validation(CSV) 서비스 (VP, URS, DQ, QRM, IQ, OQ, PQ, Deviation Control) ● Contamination Control Strategy(CCS) Consulting ● Data Integrity Consulting ● (Aseptic) Process Validation Consulting
12	Calibration	● 국내외 기준에 따른 교정 서비스
13	Technology transferring & Training for staff	● 고객 니즈 기반의 Technology Transfer & Handover 서비스 ● 효과적이고 지속적인 정보 및 지식 공유 : 장비디자인 및 규격, 운전절차, 세척 절차 그리고 유지보전절차 등에 대한 초기 교육, 반복교육 및 재교육(Off-line / On-line(적용시))
14	Preventive Maintenance	● 고객 맞춤형 사후관리 ● 시의적절하게 고객사와 함께 하는 (예지적) 유지보전 서비스 : 유지보전팀이 한 국에 상주함(Tofflon) ● 원격 디지털 유지보전 서비스(적용시) ● Change Part/Spare Part의 시의적절한 공급 서비스
15	Change Control & Requalification	● 장비 운영 중 발생하는 변경관리 검토 및 재적격성평가 서비스

WHY!!! Innovative Value Chain Collaboration Service 인가?

Innovative Value Chain Collaboration Service는 단순 GPP (Good Procurement Practice)를 벗어나 공급자와 사용자가 협력하여 상호 이익을 극대화할 수 있는 **“바이오써포트의 Mission과 GMP기술이 담긴 혁신적인 서비스”** 입니다.

이를 통해 효율적인 구매 프로세스를 구현하고, 투명성과 신뢰성을 바탕으로 하여서 사용자와 공급자와의 지속적인 파트너십을 지향합니다.



기존의 Agent 기반 사업과 바이오써포트의 “밸류체인 사업”은 무엇이 다른 것인가?

기존의 Agent 기반 사업과 우리의 밸류체인 사업은 무엇이 다른 것인가?

우리의 밸류체인사업은 Customer, Partner, Bio-Support가 함께 Value-up + Power-up 하여서 상호 Win-win할 수 있도록 한다.



- Biz Value-up & Power-up + Biz Keyword Realization ; 시장에 우리는 어떤 가치를 제공할 것인가?
- Partnership & Trust, Difference, Customization, GMP Compliance, Supplier Management, Knowledge & Information Sharing, Digital Process, Customer Satisfaction & Surprise, Supplier Risk Reduction

- Customer Value-up : 우리가 고객에게 어떤 가치를 드릴 수 있는지 고민하고 또 고민하여서 고객의 가치가 향상될 수 있도록 한다.

- Partner Value-up & Power-up : 우리는 파트너의 Agent로서 판매대행뿐만 아니라, 파트너의 가치를 향상시켜서 함께하는 사업을 더욱 더 빛나게 한다.

- GMP Upgrade : 우리의 고객사와 파트너가 미래지향적으로 GMP를 Upgrade할 수 있도록 한다.

- Powerful Networking : 무형적 또는/및 유형적 Give & Take의 개념으로 수 많은 고객사 및 파트너 그리고 자문역 등과 소통하고, 긴밀한 관계를 유지, 발전시킨다.

- Globalization : 우리는 국내 제약바이오사업의 밸류체인을 글로벌하는데 선도자가 된다. 또한, 우리의 파트너를 중국을 시작으로 하여서 유럽, 미국 등으로 확대하며, 고객사도 국내뿐만아니라 점차적으로 글로벌할 수 있도록 한다.

- Digitalization : 본 사업은 아날로그와 디지털 기반의 거대한 그릇을 디자인하고 실현하여서 미래 지향적으로 사업을 추진한다.

우리의 파트너(Our Partner)

바이옴포트는 다음의 파트너와 함께 “제약바이오 및 GMP 밸류체인 콜라보레이션 서비스 (PharmaBio & GMP Value Chain Collaboration Service)”를 제공하고 있습니다.



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
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
Wonsen	<ul style="list-style-type: none"> OSD Production Line Equipment(Total Solution) OSD Laboratory Equipment / OEB Containment Equipment Digital Smart Factory Solutions
SED	<ul style="list-style-type: none"> Aseptic Filling Line Equipment(Injections, Eye Drop) OSD Equipment(Tablet, Capsule, Softgel)
SPM	<ul style="list-style-type: none"> Aseptic Filling Line Equipment(Injections, Eye Drop) OSD Production Line Equipment + Oral Liquid Filling Line Equipment
Lives International	<ul style="list-style-type: none"> GMP Validator/Data Logger for Thermal Validation
华致林 (HAGLIN)	<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
TSI	<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
KONZER	<ul style="list-style-type: none"> Pharmaceutical GMP Disposal Cleanroom protective products. 坤泽尔 KONZER

“제약바이오 및 GMP 밸류체인 콜라보레이션 서비스(PharmaBio & GMP Value Chain Collaboration Service)”를 늘 여러분의 벗이자 파트너인 (주)바이옴포트와 함께 경험해 보시죠!!!

바이옴포트 소개

사훈 : 우리는 창조적이고 도전적으로 꿈을 디자인하고 즐겁게 실현한다. 우리의 꿈은 목표가 아닌 우리의 의무이다.

GMP & Validation Solution Consulting Services.

We know what YOU need in the area of GMP & Validation. We offer a full scope of GMP & Validation Solution Consulting Services.

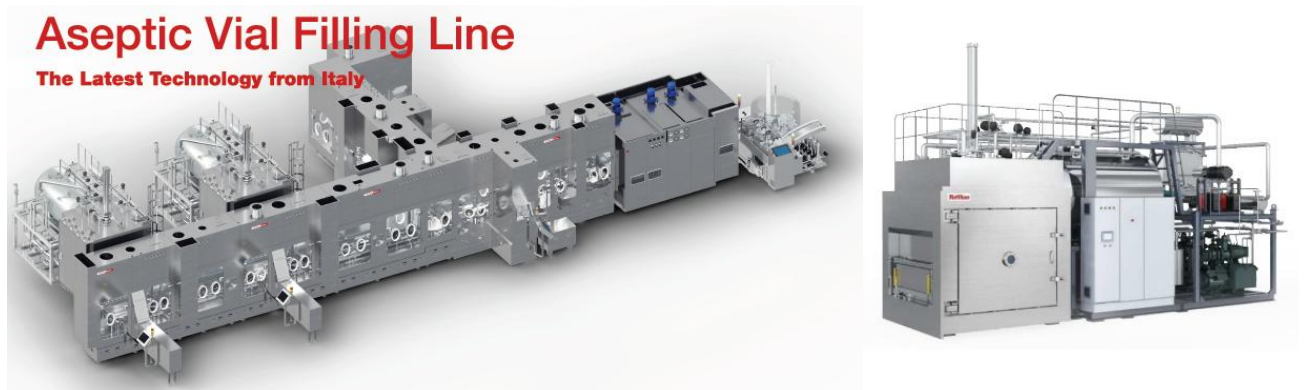


우리의 취급 서비스 및 품목 요약(Our Services & Items Summary)

System for Chemical Drug (Turnkey Project)	<ul style="list-style-type: none"> ● Aseptic Drug Product(DP) Production Line Equipment for Injections, Eye Drop & Liquids ● [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] ● Glass Vial, Plastic Vial, Ampoule, Pre-filled Syringe, BFS, Bag, Bottle etc. ● PIC/S GMP Annex 1, 21 CFR Part 11 and Data Integrity Compliance
	<ul style="list-style-type: none"> ● Aseptic DS & DP Lyophilization Production Equipment ● cGMP Grade 동결건조기(Auto Loading/Unloading System)
	<ul style="list-style-type: none"> ● Drug Product Packaging Line Equipment for Injections, Liquids, OSD...
	<ul style="list-style-type: none"> ● OSD Production Line Equipment : Tablet Press Machine / Capsule Filling Machine / Softgel Encapsulation Machine / Coating Machine / Dryer / Granulator / Mixer / Pulverizer / Screening Machine / Assistant Machine
	<ul style="list-style-type: none"> ● Oral Liquid Filling Line Equipment
System for Biological Drug (Turnkey Project)	<ul style="list-style-type: none"> ● Biological Product(Drug Substance, DS) Production Line Equipment ● USP Production Line Equipment : Cell Culture or Fermentation, Harvest & Clarification ~~~ Stainless Steel & Single Use System ● DSP Production Line Equipment : Purification, Diafiltration & Concentration + Bulk Formulation & 1st Packaging + Freezing(Optional) ● Process Control & Monitoring Computerized System ● PIC/S GMP Annex 1, 21 CFR Part 11 and Data Integrity Compliance
	<ul style="list-style-type: none"> ● Aseptic Biological Product(DP) Production Line Equipment for Injections ● Glass Vial, Plastic Vial, Pre-filled Syringe, Bag etc.
	<ul style="list-style-type: none"> ● Biological Product(DS & DP) Lyophilization Production Equipment ● cGMP Grade 동결건조기(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 Production Line Equipment ● 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"> ● Automatic H₂O₂ Fumigation System / Portable and Remote Particle Counter
	<ul style="list-style-type: none"> ● GMP Validator/Data Logger for Thermal Validation CGMP Compliance + 21 CFR Part 11 Compliance + Data Integrity Compliance
GMP Consumable	<ul style="list-style-type: none"> ● Pharmaceutical GMP Disposal Cleanroom protective products.
	<ul style="list-style-type: none"> ● Single Using Bio-Pharma System
	<ul style="list-style-type: none"> ● Pharmaceutical TPE Tubes / Tyvek Sterilization Bags
GEP/ Engineering (Turnkey Project)	<ul style="list-style-type: none"> ● Innovative Modular Engineering & Construction for New GMP Facility(with Tofflon) ● 새로운 모듈라 형태의 GMP공장 설계 및 시공 서비스 ● Project Master Planning --- Conceptual Design & URS --- Basic & Detailed Design & Technical Specification --- Design Qualification --- Off-site Fabrication/FAT & Prequalification(Supplier Site) --- Transportation(From Supplier Site to User Site) --- On-site Engineering & Construction(User Site) --- Initial Qualification --- Handover --- Maintenance Supporting Service & Requalification Services

Tofflon	Tofflon Science and Technology Group, https://en.tofflon.com/
Injections DP Production (Turnkey Project)	<ul style="list-style-type: none"> • Aseptic Vial Filling Line Equipment and/or Lyophilization System for Injections • Aseptic Ampoule Filling Line Equipment for Injections • Aseptic PFS Filling Line Equipment for Injections • Automatic CIP/SIP System • Engineering Design Supporting / Module Type Engineering of GMP Facility
Lyophilization Process (Turnkey Project)	<ul style="list-style-type: none"> • Aseptic Lyophilization System(inc. Auto Loading/Unloading System) for Sterile DS and DP Production • Lyophilization System for Dietary Supplement • Lyophilization System for R&D and Process Development • Automatic CIP/SIP System
Clean Air Equipment (Turnkey Project)	<ul style="list-style-type: none"> • Isolator & Closed RABS for DS & DS Production • Isolator for QC Sterility Test • Automatic H₂O₂ Fumigation System
DP Packaging Process (Turnkey Project)	<ul style="list-style-type: none"> • Vial, Ampoule & PFS Packaging Line Equipment

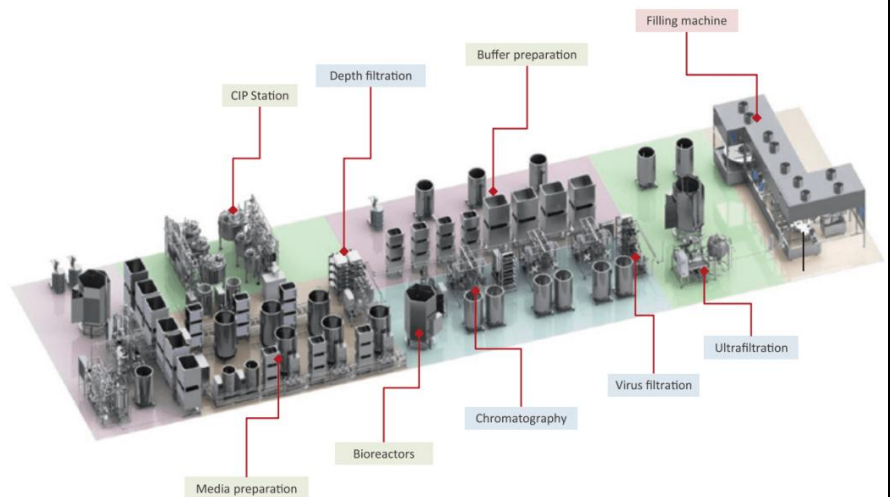
Tofflon 소개(요약)



<p>Tofflon</p>	<p>Tofflon Science and Technology Group, https://en.tofflon.com/</p>
<p>Biological Product Production (Turnkey Project)</p>	<ul style="list-style-type: none"> • Bio Engineering Solution • USP + DSP Equipment for Cell Culture Production • USP + DSP Equipment for Microbial Fermentation Production • Stainless Steel & Single Use System for DS of Biological Product • <i>Monoclonal Antibody, Insulin(E.coli), Inactivated Vaccine, DNA Vaccine, Adenovirus Vaccine, mRNA Vaccine, Recombinant Protein Vaccine, Probiotics, Live Biotherapeutic Product(LBP) etc.</i>
<p>Cell Therapy Production</p>	<ul style="list-style-type: none"> • Cell Therapy Production Equipment
<p>Gene Therapy Production</p>	<ul style="list-style-type: none"> • Gene Therapy Production Equipment



SS. Fermenter 2000L

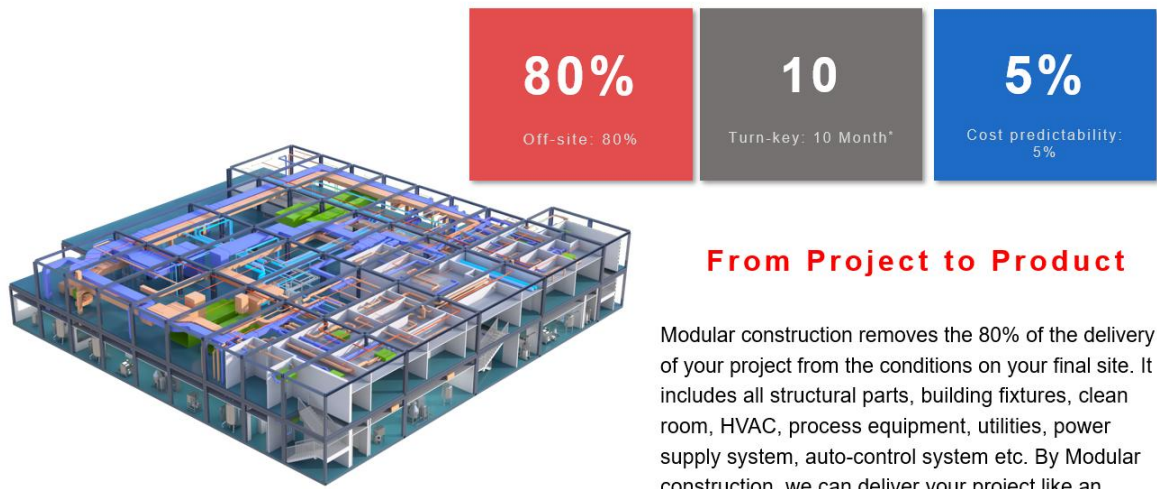


Tofflon	Tofflon Science and Technology Group https://en.tofflon.com/
GEP/Engineering (Turnkey Project)	<ul style="list-style-type: none"> • Engineering Design Supporting • Innovative Modular Engineering & Construction for GMP Facility

Modular Engineering & Construction for GMP Facility

What is Modular

Tofflon



From Project to Product

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.

*Take 4*2000L McAb as example.

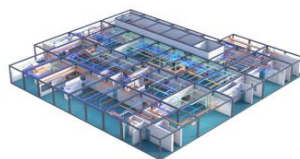
Brief Picture of Modular Delivery

Tofflon

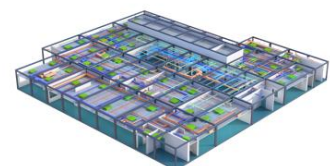
Off-site



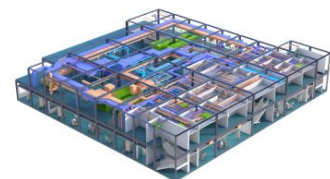
Steel frame fabricate



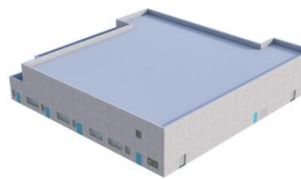
Piping & ducts installation



Clean room installation



Equipment installation



Factory acceptance test

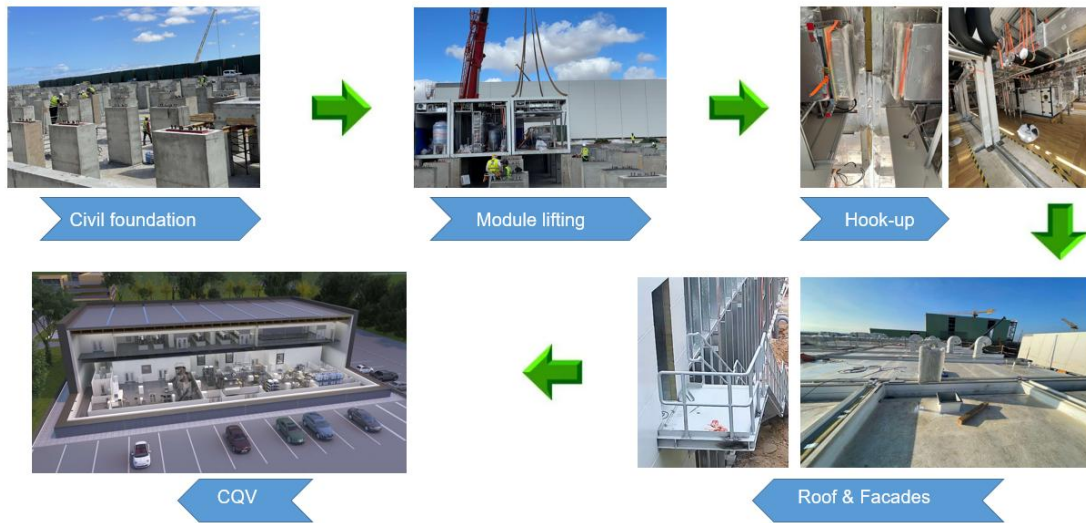


Packing and shipping

Brief Picture of Modular Delivery

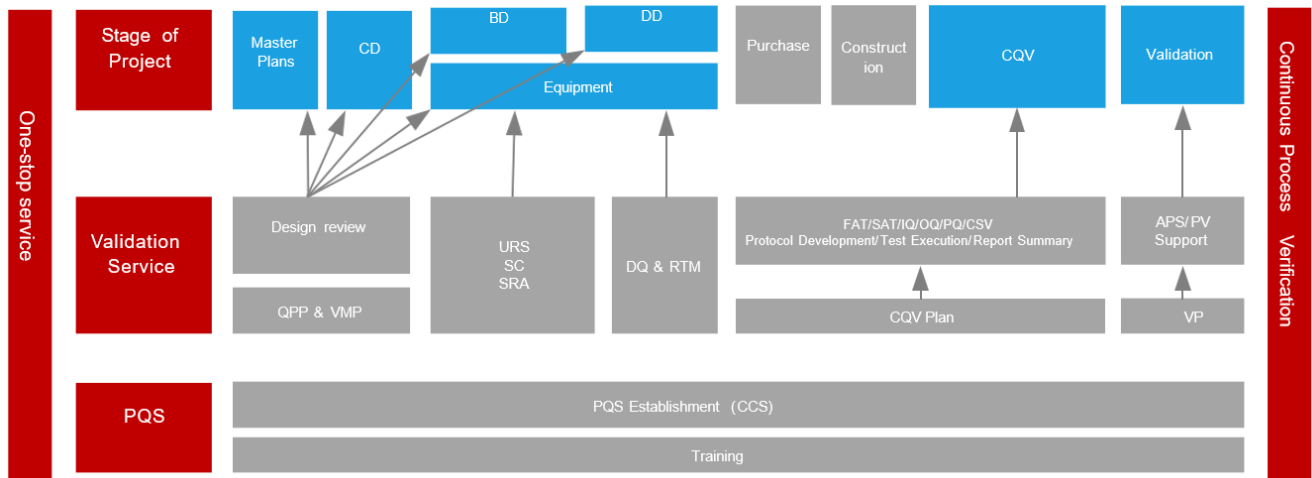
Tofflon

On-site



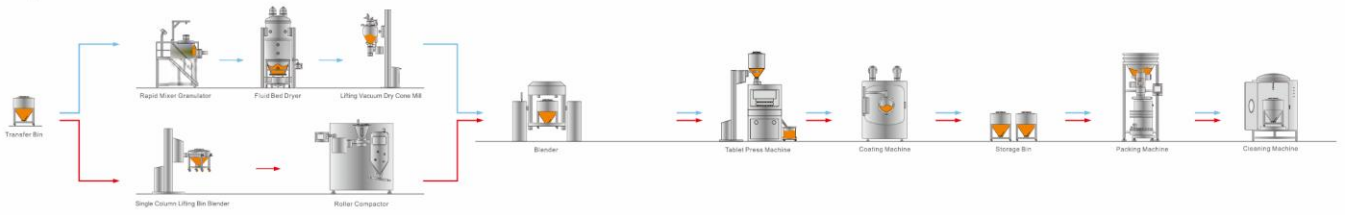
CQV Services

Tofflon

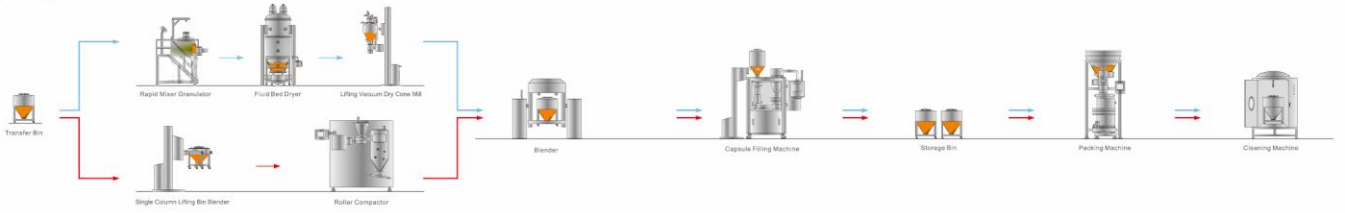


	<p align="center">Yichun Wonsen Intelligent Equipment Co., Ltd. http://www.wonsen.net/</p>
<p>Solid Dosage Form intelligent solution Production</p>	<ul style="list-style-type: none"> ● OSD Production Line Equipment(Total Solution) ● High Speed Tablet Press Machine / Capsule Filling Machine / Fluid Bed Granulator / Coating Machine / Roller Compactor / High Shear Wet Type Mixing Granulator / Automatic IBC Washing Machine

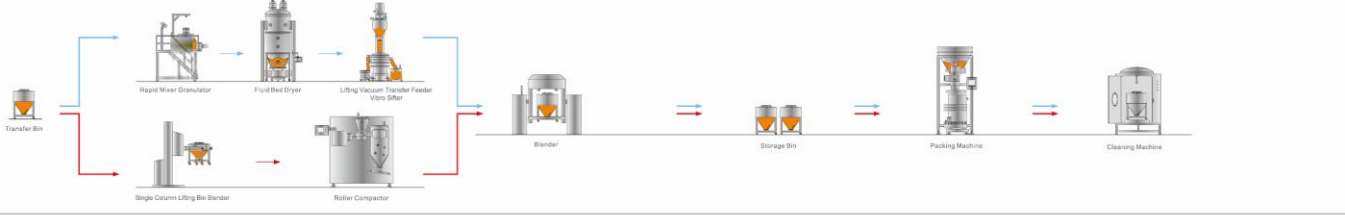
Tablet production line



Capsule production line



Granule production line



Granulation Line



Granulation Line



Dry granulation Series




Auto Lifting Bin Blender Series




Square Cone Bin Blender Series



Coating Series

	<p>Shanghai IVEN Pharmatech Engineering Co., Ltd. https://www.iven-pharma.com/</p>
<p>Injections and Liquid DP Production (Turnkey Project)</p>	<ul style="list-style-type: none"> • Peritoneal Dialysis Solution production line Equipment for Injections • Automatic PP bottle IV solution production line Equipment for Injections • Non-PVC soft bag production line Equipment for Injections • Vial liquid filling production line Equipment for Injections • Ampoule filling production line Equipment for Injections • Cartridge filling production line (Carpule filling production line Equipment for Injections) • BFS (Blow-Fill-Seal) Solutions for Intravenous (IV) and Ampoule Products • Glass Bottle IV Solution Production Line • 30ml Glass Bottle Syrup Filling and Capping Machine for Pharmaceutical • LVP Automatic Light Inspection Machine (PP bottle)
<p>Biological Product Production (Turnkey Project)</p>	<ul style="list-style-type: none"> • USP + DSP Equipment for Cell Culture Production • USP + DSP Equipment for Microbial Fermentation Production • Stainless Steel & Single Use System for DS of Biological Product • Monoclonal Antibody, Insulin(E.coli), Inactivated Vaccine, DNA Vaccine, Adenovirus Vaccine, mRNA Vaccine, Recombinant Protein Vaccine etc.
<p>Solid Dosage Form Production</p>	<ul style="list-style-type: none"> • High Speed Tablet Press Machine / Capsule Filling Machine / Fluid Bed Granulator / Coating Machine / Roller Compactor / High Shear Wet Type Mixing Granulator / Automatic IBC Washing Machine


	<p>Hangzhou Shengde Machinery Co., Ltd. (SED Pharma) https://sedpharma.com/</p>
<p>Solid Dosage Form Production</p>	<ul style="list-style-type: none"> • Tablet Press Machine / Capsule Filling Machine / Softgel Encapsulation Machine
<p>Injections & Eye Drop DP Production</p>	<ul style="list-style-type: none"> • Aseptic PFS Filling Line Equipment for injections • Aseptic Ampoule Filling Line Equipment for injections • Aseptic Liquid Filling Line Equipment for Eye Drop



SED Certifications

SED Pharma has been approved with all international regulatory certifications like ISO9001, CE, BV, etc.



	Shanghai Pharmaceutical Machinery Co., Ltd (SPM) https://www.spm.so/
Solid Dosage Form Production (Turnkey Project)	<ul style="list-style-type: none"> • Tablet Press Machine / Capsule Filling Machine / Softgel Encapsulation Machine / Coating Machine / Dryer / Granulator / Mixer / Pulverizer / Screening Machine / Assistant Machine
Injections & Eye Drop DP Production	<ul style="list-style-type: none"> • Aseptic Vial Filling Line Equipment for injections • Aseptic Ampoule Filling Line Equipment for injections • Aseptic Liquid Filling Line Equipment for Eye Drop
Oral Liquid Production (Turnkey Project)	<ul style="list-style-type: none"> • Oral Liquid Filling Line Equipment

Aseptic Blow-Fill-Seal System For Plastic Container Parenteral(LVP)

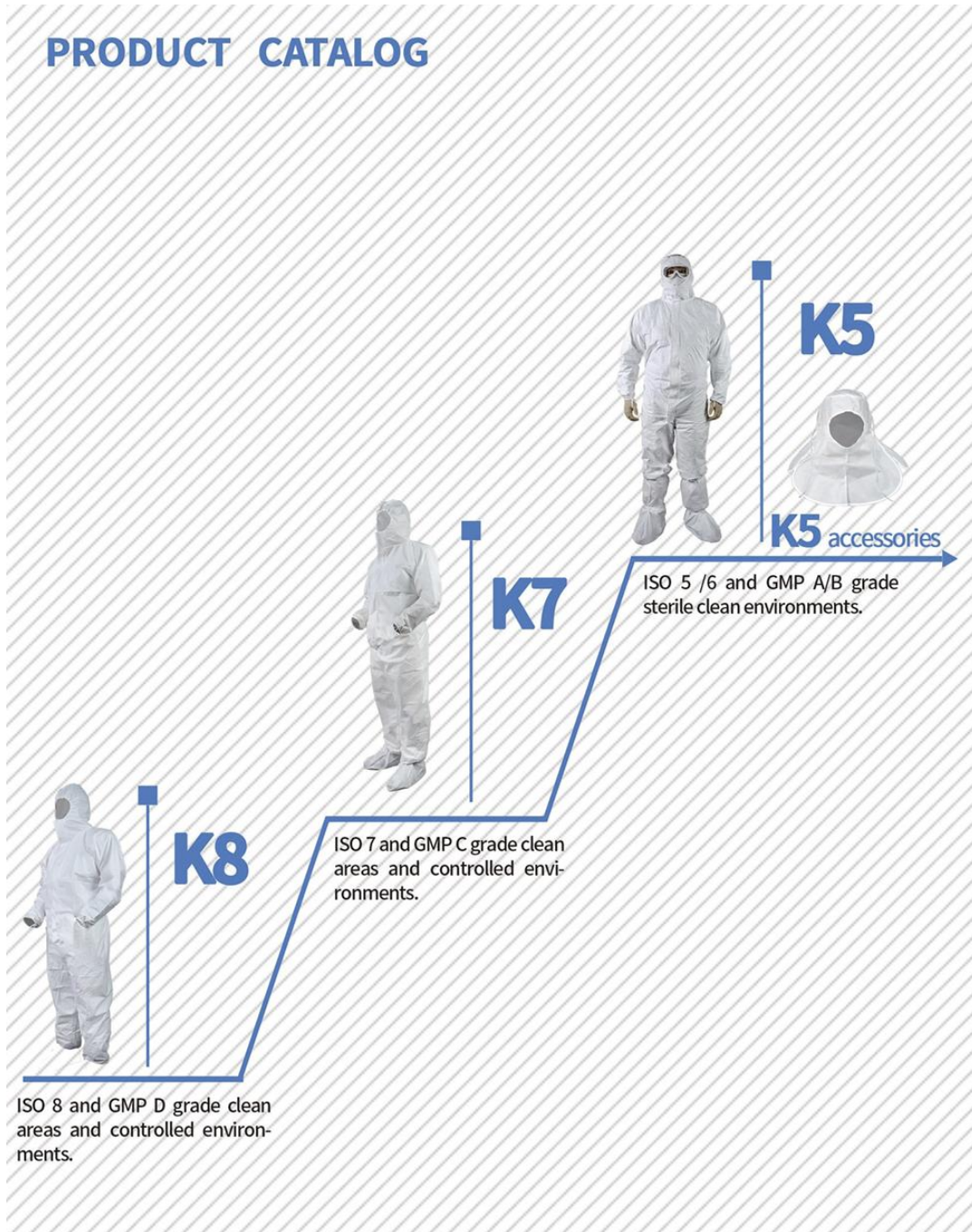



	Lives International(USA) https://lives-international.com/
GMP Validator for Thermal Validation	<ul style="list-style-type: none"> • CGMP Compliance + 21 CFR Part 11 Compliance + Data Integrity Compliance • Standard Data Loggers • Real Time Wireless Data Loggers(실시간 무선 데이터 로거) • Real Time Wire Data Loggers(유선 밸리데이터 로거)

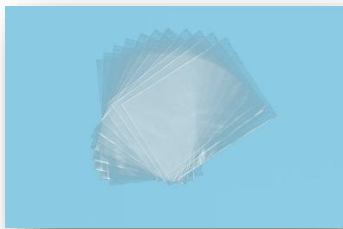


	<p>Weifang KONZER Safety Protective Equipment Co., Ltd. https://www.konzerppe.com/ </p>
<p>GMP Disposal Cleanroom Clothing</p>	<ul style="list-style-type: none"> Pharmaceutical GMP Disposal Cleanroom protective products(무균복, 무진복 등).

PRODUCT CATALOG



	<p>Shandong Hagilin Pharmaceutical Technology Co., Ltd. https://www.asepticprotection.com/</p>
<p>pharmaceutical package bags and bio-pharmaceutical single-use customized system</p>	<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



“제약바이오 및 GMP 밸류체인 콜라보레이션 서비스
(PharmaBio & GMP Value Chain Collaboration Service)”를
늘 여러분의 벗이자 파트너인 (주)바이오써포트와 함께 경험해 보시죠!!!

소통라인 : gmp@biosupport.co.kr /
담당 : 바이오써포트 밸류체인 디커플링 캠퍼스 김지민 상무

Thank you so much!!!

소중한 고객님 및 파트너님과 함께 성장하는 바이오써포트입니다.

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