BIO-SUPPORT × TOFFLON

Introduction of Tofflon Blow-Fill-Seal(BFS) System For the Pharma Industry

For Korean PharmaBio Customers

Tofflon Technology × Bio-Support GMP Expertise
From Product Supply to GMP-Ready Implementation

Bio-Support, Your Trusted GMP Value Chain Integrator
Leading Value. Connecting with Trust. Realizing the Future.



2026-11-06 · Ver 00
Proposed by: Bio-Support

gmp@biosupport.co.kr

Bio-Support
Tofflon

Bio-Support: Company Overview

제약·바이오 고객의 GMP와 글로벌 기술을 연결하는 통합 실행 파트너

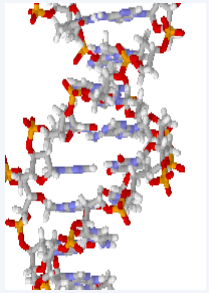
ITEM	DECSRIPTION
Name	Bio-Support Co,. Ltd
Founded	Apr. 19, 2000
CEO	Kim Kyung-min
Address	65, Dongpyeon-ro 13beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
Employee	61 Persons(GMP Consultant 50, GEP Engineer 2)(as of Aug 2026)
Main business	• [GMP & Validation Solution Consulting Biz] • [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



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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

[GMP & Validation Solution Consulting]

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

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[GMP & Validation Solution Consulting Biz]

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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)

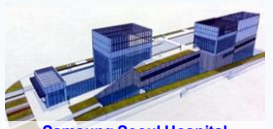

Sama Pharmaceutical
Wonju Plant


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]

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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

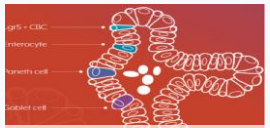

Samjin Pharmaceutical
Osong Factory

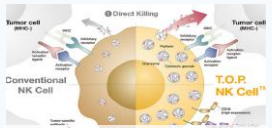

Curocell
ATMP GMP Facility


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

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Bio-Support PharmaBio Value Chain Collaboration Biz

단순 제품 공급이 아니라 고객의 GMP 과제와 글로벌 파트너 기술을 실제 적용 솔루션으로 구현



Bio-Support 수행 역할

- GMP Requirement Review
- Application & Product Selection
- URS / Technical Specification Review
- Design & Interface Review
- Qualification Review or Execution
- Training & Lifecycle Support

고객 기대효과

- 제품 도입 목적과 GMP 요구사항 정렬
- 초기 단계에서 Spec·Interface·Validation 리스크 확인
- 공급자 기술자료와 고객 SOP·Validation 체계 연결
- 도입 후 운영·점검·Lifecycle Support 가능

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Partner Solution for PharmaBio GMP

Tofflon Technology

- Large-scale drug project
- Vaccine project
- High toxicity, activity and sensitization project
- Suspension product project
- Blood product project
- Monoclonal antibody project
- Low temperature project
- Inert gas protection project
- Liposome project
- Microsphere project
- Easy crystallizing product project
- Adhesive product project

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Bio-Support GMP Expertise

- GMP Requirement Review
- URS / Specification
- Design & Interface Review
- Qualification / Validation
- Training & Lifecycle Support

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Customer Value

- Better CCS
- Faster Implementation
- Stronger GMP Evidence
- Lifecycle Support

바이오써포트는 Tofflon의 전략적 파트너이면서 한국 공식 대리점으로서
국내 GMP 환경에 적합한 제품 도입과 Qualification을 지원합니다

Bio-Support
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Technology from TOFFLON. GMP Expertise from Bio-Support. One Integrated Solution for PharmaBio.

Your Partner for Blow-Fill-Seal(BFS) System

Global Technology × Global GMP Expertise

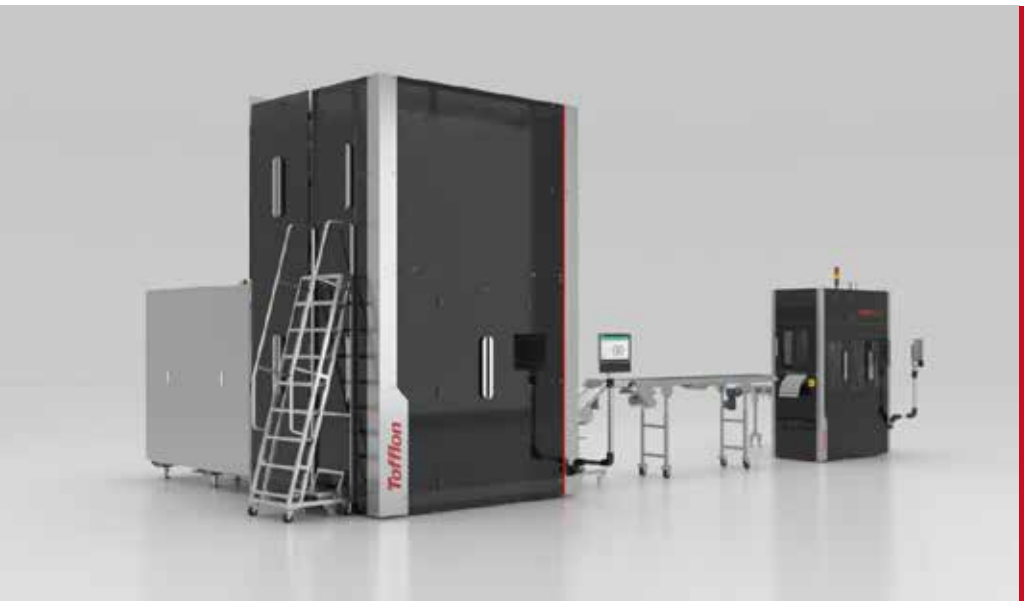
Thank you so much!!!

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

Official Website	YouTube Channel	Bio-Support Role
https://en.tofflon.com/	https://www.youtube.com/@tofflon2954	Korean official distributor, GMP Value Chain Integrator

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

Tofflon



Blow-Fill-Seal (BFS) Systems

Expertise in Biopharmaceutical



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E-mail: info@tofflon.com (sales)
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www.tofflon.com



BFS Technology

Blow-Fill-Seal (BFS) Technology is an advanced aseptic process which automatically delivers a finished plastic package in one continuous operation. Every BFS process begins with the extrusion of pharm grade PE/PP into plastic container within the machine. The container is then instantly molded, filled and sealed in an enclosed system without any external intervention. All the filling process including the dosing system is designed with CIP/-SIP functions. The systems have the advantages of advanced aseptic processing, maximum filling precision, low cross contamination risk and low operating cost. They are ideal for the aseptic filling of liquids which has been widely applied in eye care, injectables, respiratory therapy and other applications

Motivations to Choose BFS Technology for Your Aseptic Filling Processes

- Break-proof, user-friendly containers
- Diverse container shapes and sizes
- Straightforward adaptation to the specific application and adiministration type
- The perfect choice for even sensitive formulations
- Maximum safety thanks to ISO Class 5 conditions
- Approved by international regulatory bodies
- Recognized advanced aseptic processing
- Fully automated processes for blowing, filling and sealing containers in seconds
- Significantly smaller space requirements than conventional filling system
- Excellent process and product reliability
- And much more

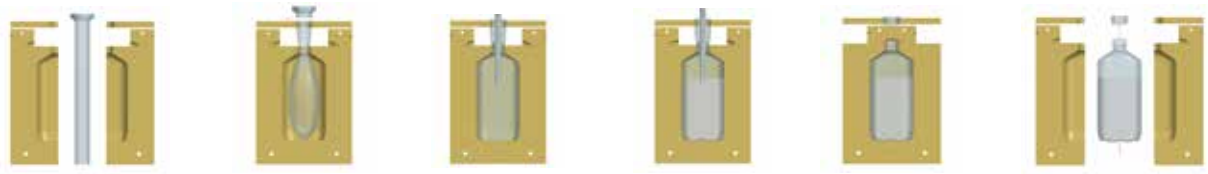
BFS Applications

Small Volume Applications (Range: 0.1ml ~ 20ml): Small volume injectables like plastic ampoules, eye, ear and nose drops, inhalation solutions, anestheric and other cosmetics and food applications.

Large Volume Applications (Range: 50ml ~ 1L): Large volume infusion, large volume humidifiers and nebulizers, disinfectants, rinsing solutions, detergent and other applications.



BFS Typical Process



1. Extrusion:

A thermoplastic resin like PE or PP granulate is extruded as a tubular shape called a parison.

2. Parison Cut:

When the parison reaches the proper length, the holding jaw and main mold close. This pinches the bottom of the parison while the top is held in place as the cutting sequence occurs. The mold is then conveyed to a position under the blowing and filling nozzle.

3-4. Blow and Fill:

The blow/fill nozzle is lowered into the parison, forming a seal with the neck of the mold. The nozzles blow sterile, filtered, compressed air or nitrogen into the parison to expand it, and then that air is vented out. The sterile product is placed into the parison through the fill nozzle.

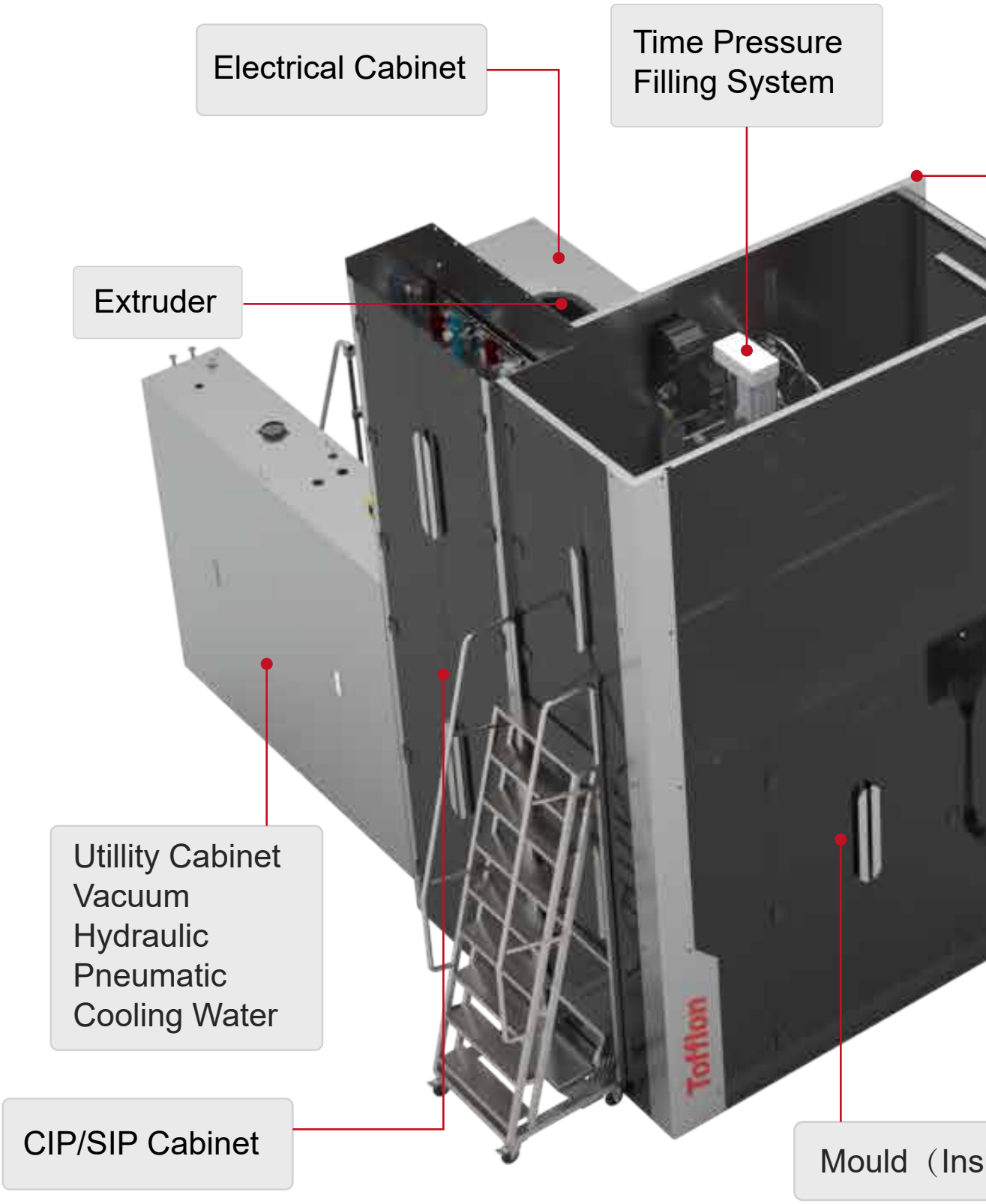
5. Seal:

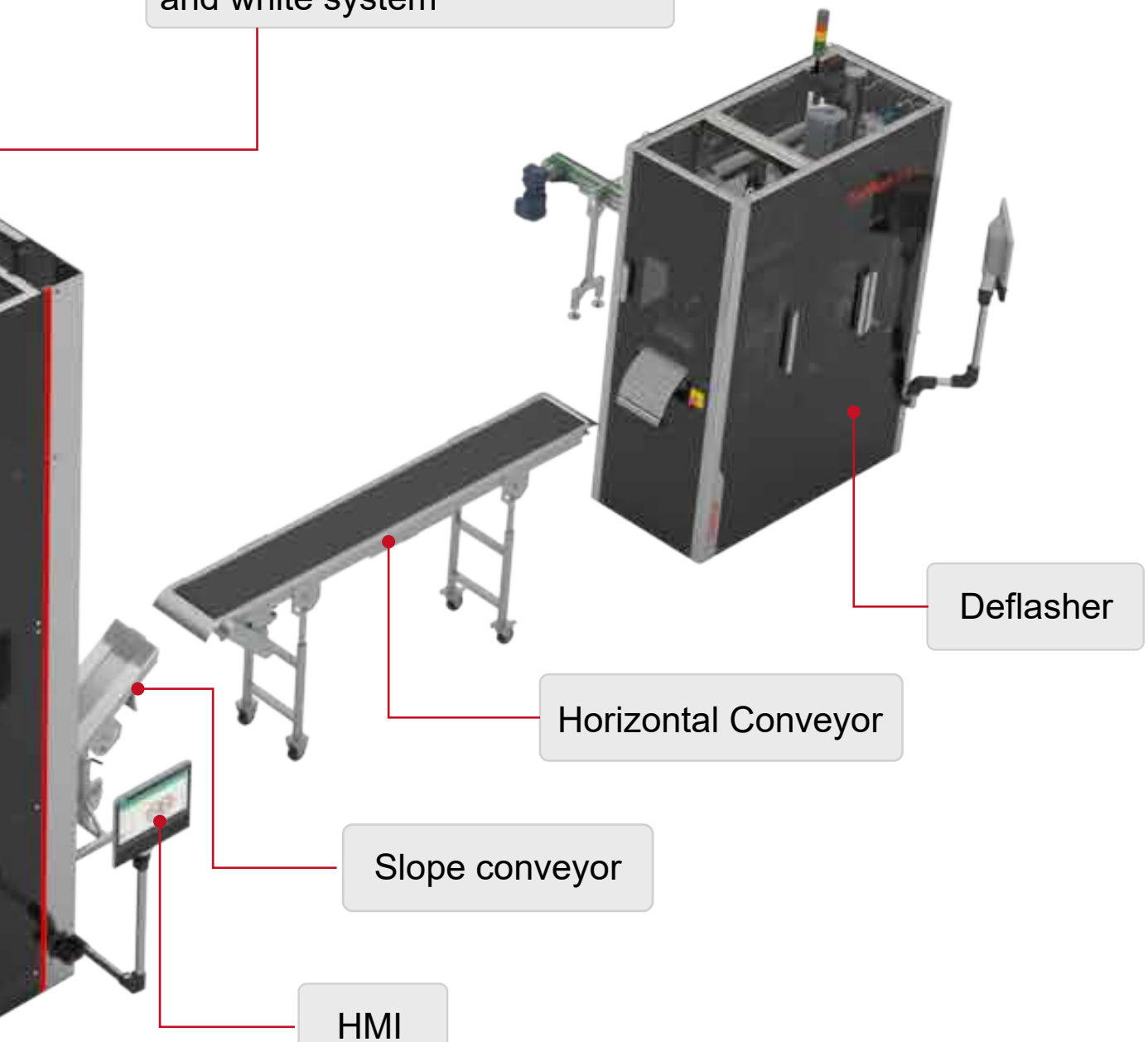
Separate sealing molds close to form the top, which hermetically seals the container.

6. Release:

Finally, the mold opens, and the formed, filled, and sealed containers are conveyed out of the machine.

Tofflon BFS Competence and Advantages




Separation board between gray and white system
Deflasher
Horizontal Conveyor
Slope conveyor
HMI

ide)

- As a fast growing BFS technology brand, we offer safe, reliable, affordable and integrated BFS Systems to accelerate BFS technology applications in dynamic global emerging markets.

- + 100 Tofflon BFS machines and systems have been installed in various applications in China market as well as in international markets.

- Strength, Capability and Expertise to meet international regulatory requirements.

- Complete System Capabilities： We have designed and built BFS machine that incorporates with upstream auto solution preparation systems and with downstream leak detection, labelling, cartooning and palletizing machines as complete system solution.

- Our factory acceptance testing (FAT) incorporates a pre-validation documentation package (IQ/OQ) to assist you with preparation of your own on-site commissioning and validation program.

- We use internationally standard components that are readily available in local markets to support you with local spare parts supply. Our BFS systems are backed by Tofflon global service network covering 50 countries and regions around the world to provide local service support and technical support to you.

- Modular design for easy separation of gray and white system zones which not only guarantees sterility assurance of filling zone, but also much reduces space footprint than conventional filling systems to effectively save facility capital cost and operation cost.

- Various in-process control parameters utilizing the latest generation of fully system integrated PLCs control and monitor container weight, fill weight, wall thickness, isolation of visual defects, and other factors, facilitating optimized system function.

- Further options include advanced technologies for suspension products, temperature sensitive products, auto filter integrity test and newly developed solutions for high throughout application and large volume container application.



Tofflon BFS Machine Functions





- Extruder System
- Parison Clamp and Cut-Off Mechanism
- Particle Removal System
- Mold and Its Carriage and Carriage Assembly
- Filling System
- Hydraulic, Pneumatic, Vacuum, Cooling and Lubrication System
- Class A Air Shower
- Transfer System
- Deflasher
- CIP/SIP System
- Control System

Key Designs

Extruder System

All of our machines are compatible with multiple resins with a simple tooling change. The use of an extruder with three zone control of heating and cooling ensures tighter control of extrusion parameters; a critical element for processing of both polypropylene and high density polyethylene resins.

High precision control for extruder temperature through cast aluminum heaters intercooled with water coils on the screw and temperature control module.



The extrusion head is designed with uniform sterile air flushing to guarantee the sterility of inner wall of the parison.

Auto waste grabbing device reduces manual operation before each production.

The extruder adopts servo motor driver with large torque and low speed to achieve higher efficiency and energy saving benefits.

The unique parison exhaust function makes parison wall thickness more uniform.

Time-Pressure Filling



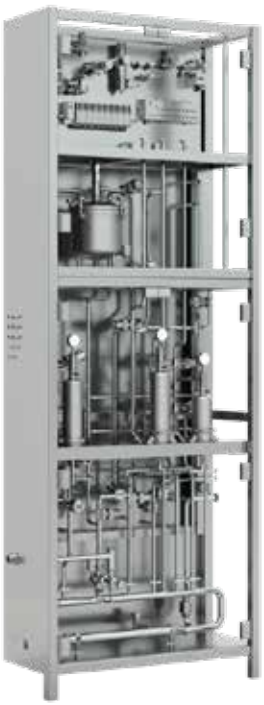
The filling system adopts advanced PID control and algorithmic programming to achieve high filling precision.

The filling nozzle movement is driven by servo motor so that filling nozzle movement can be accurately controlled and any damage to the mold and filling nozzle can be avoided during machine maintenance.

We offer a dedicated airborne particle counter for continuous on-line monitoring of particulate counts in the critical zone, ensuring compliance with FDA and other regulatory authorities who require close monitoring of particle count in the nozzle shroud area (conforming to class 100 standards in dynamic conditions).

Output from the particle counter can be sent directly to the data logger for secure data collection.

CIP/SIP System



- Automatic cleaning and sterilization system (CIP/SIP) with integral data acquisition.
- All the pipes for cleaning and sterilization are in accordance with ASME standard.
- All drainage lines are connected to the central condenser for final drainage. The drainage system has one-way valve to avoid reverse suction. And exhaust steam cooling device is designed to avoid steam impact upon the drainage system.
- We provide an integrated, 21CFR Part 11 compliant, temperature/process data logger to document all temperatures during SIP. Multiple PT-100 sensors or thermocouples are strategically placed throughout the product path to ensure sterility. The sensors can be calibrated in place, using the data logger's built-in capability.

Deflasher



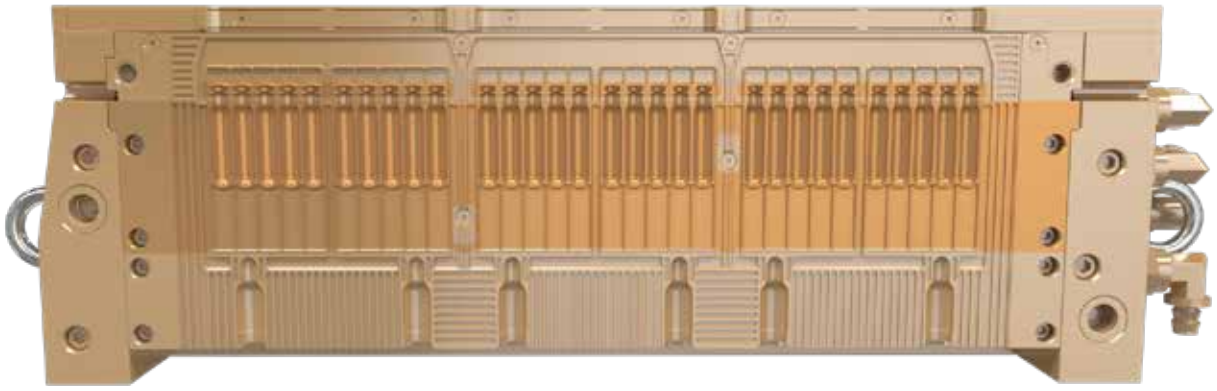
- The special structure desgin of the deflasher can meet different heights of the cut-off mold.
- CUT-OFF Mechanism has its independent hydraulic system to reduce interference towards aseptic area during cut-off process, to reduce hydraulic oil leakage risk towards aseptic area and facilitate later maintenance.
- The special CUT-OFF Mechanism design ensures that the finished products are regularly delivered to the conveyor belt to offer automatic line integration possibility with the downstream process.

Control System

- Our machine control electronics are based on the proven Siemens PLC platform with Profibus/Profinet and Simatic totally integrated automation. This is an internationally recognized standard that has world-wide local support.
- US FDA 21 CFR Part 11 and cGAMP compliance.
- Access control according to authority levels.
- Audit trail recording user actions and changes to process parameters.
- Query the curve and data table record.
- Query alarm record.
- Database management and maintenance.
- Available with manual or automatic control.



Mold



We have own advanced mold technology in mold design and manufacturing to provide high quality molds and mold maintenance support.

Modular mold components can create a family of container sizes by changing mold inserts to minimize tooling requirements and simply product changeovers. Custom engraving and coding pins provide specific product information such as lot number and expiration date.

The use of special bronze base mold material permits easy machining, excellent heat transfer and long service life.

The mold itself has cooling and vacuum channels which are connected with the cooling and vacuum system of the machine. It can ensure same temperature between the mold and the product.









Manufacturing Capability and Quality Assurance

We have the capabilities to machine different types of complex parts ranging from detailed components on CNC vertical mills, through large heavy duty steel plate or frame machining on our large CNC Horizontal mills, and many other parts on our larger vertical mills.

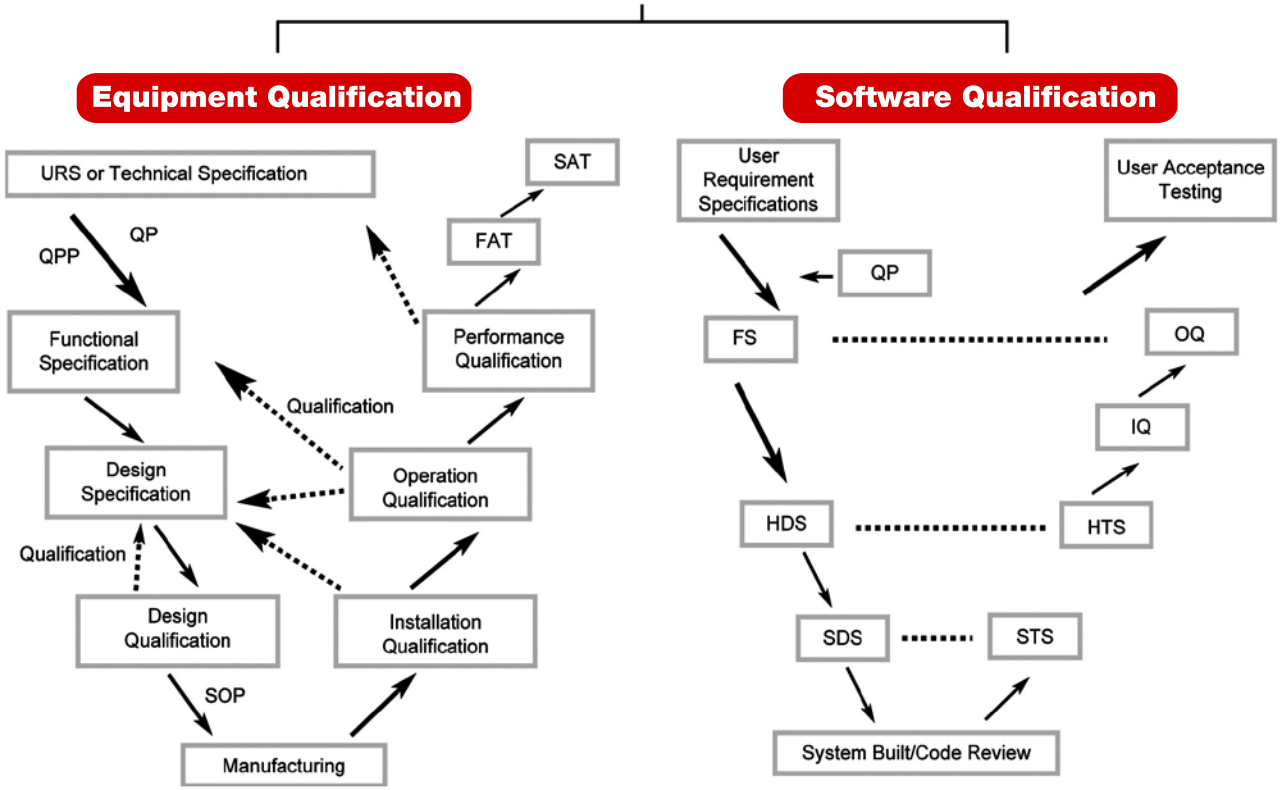
Our mold making capabilities include manufacturing of complex geometries using CNC mold-making vertical mills and horizontal boring mills for mold manufacturing which includes small scale to large scale production molds which are typically used in a pharmaceutical production environment.

We adopt scientific instruments to guarantee in-process quality control during the manufacturing life cycle.





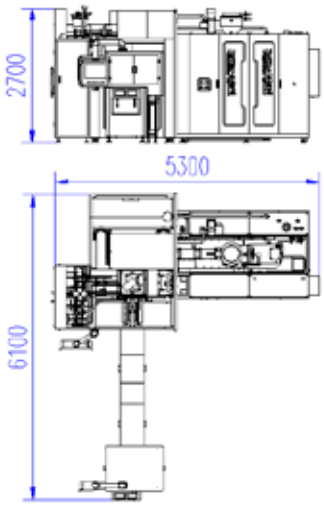
cGMP Documentation and Qualification



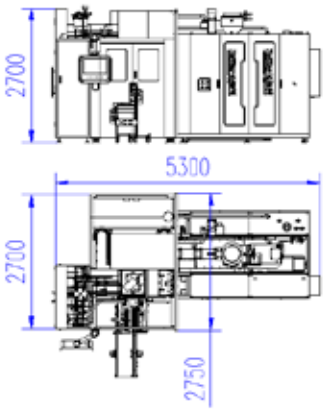
Technical Specification

Model	Mold Number	Cavities Number	Filling Range	Mechanical Output (Containers/Hour)
BFS-310	1	30	0-3ml	9000
BFS-410	1	40	0-3ml	12000
BFS-415	1	20	5-50ml	4000-6000
BFS-320	2	30	0-3ml	18000
BFS-420	2	40	0-3ml	24000
BFS-425	2	20	5-20ml	12000
BFS-510	1	30	0-20ml	6000-13500
BFS-511	1	15-35	10-20ml	7500-16000
BFS-512	2	15-35	1-10ml	15000-32000
BFS-514	14	15	10-20ml	15000
BFS-515	15	15-25	1-10ml	15500-25000
BFS-520	20	25-30	0.2-1ml	30000-44000
BFS-611	1	6	500-1000ml	1000-1300
BFS-811	1	8	100-500ml	1700-1900
BFS-621	2	6	500-1000ml	1600-2000
BFS-821	2	8	100-500ml	2700-3100

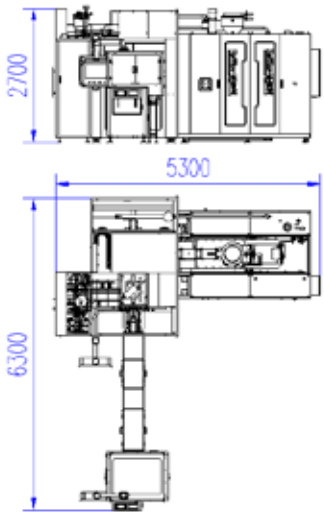
Typical Layouts



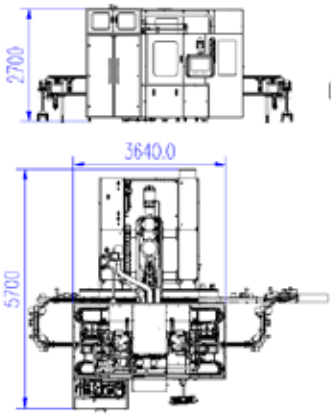
BFS-310/415
(External Cutting)



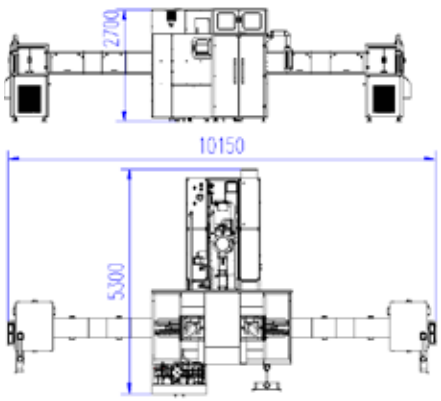
BFS-310/415
(Internal Cutting)



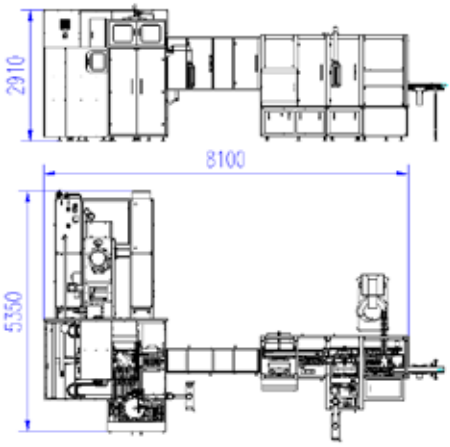
BFS-410
(External Cutting)



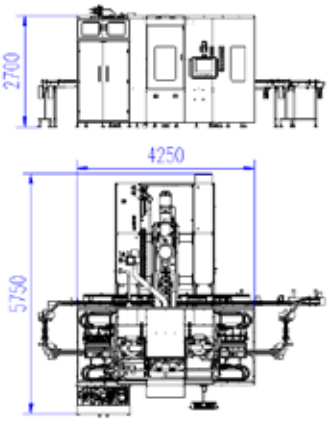
BFS-320/425
(Internal Cutting)



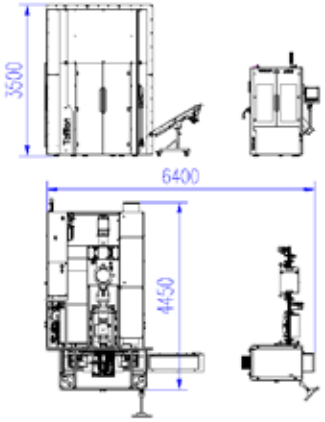
BFS-320/425
(External Cutting)



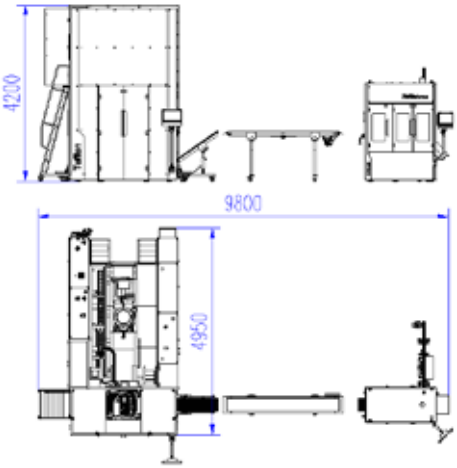
BFS-811



BFS-420



BFS-510



BFS-520

BFS Systems



Auto Palletizing Machine



HVAC



Water Systems



Auto Cartonning Machine



BFS Machine



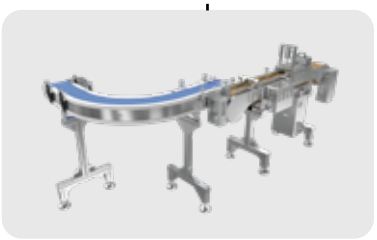
Auto Solution Preparation Systems



Auto Labelling Machine



Auto Leak Detection Machine



Cutter



Autoclave

Case Sharing

