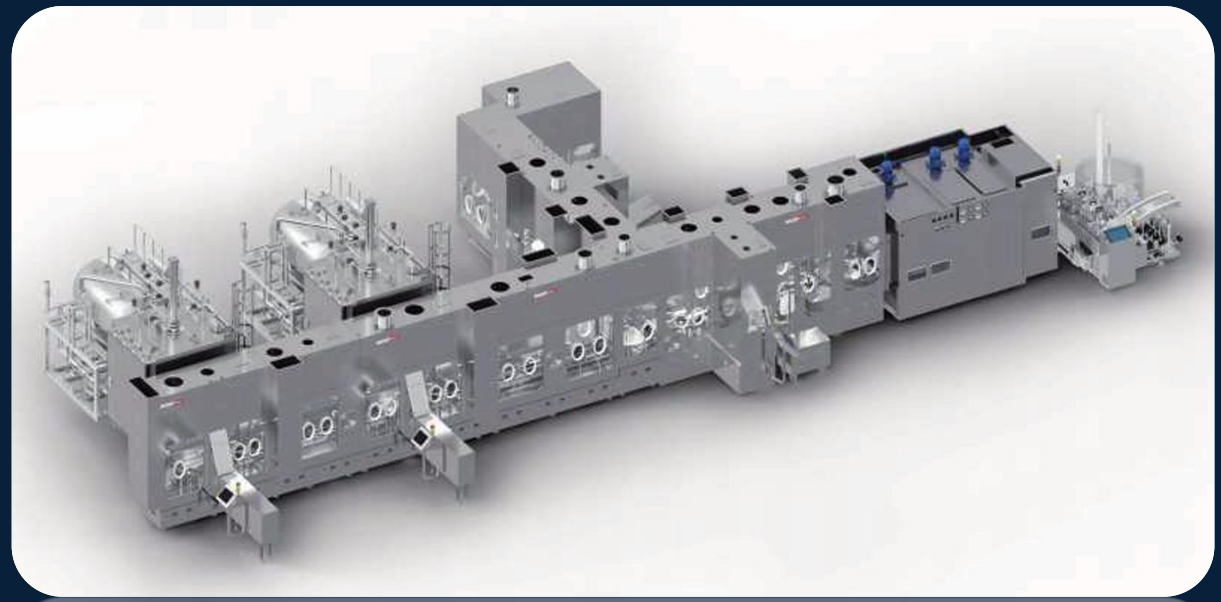
BIO-SUPPORT × TOFFLON

Introduction of Tofflon Freeze Drying System For the Pharma & Biotech 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

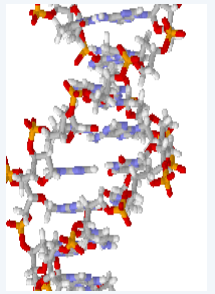
ITEM	DECSRIPTION
Name	Bio-Support Co,. Ltd
Founded	Apr. 19, 2000
CEO	Kim Kyung-min
Address	65, Dongpyeon-ro 13beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
Employee	61 Persons(GMP Consultant 50, GEP Engineer 2)(as of Aug 2026)
Main business	• [GMP & Validation Solution Consulting Biz]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

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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]

Bio-Support Tofflon

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!!



[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)

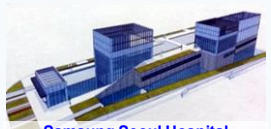

Sama Pharmaceutical
Wonju Plant


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

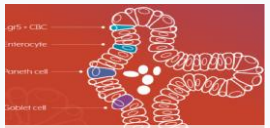

Samjin Pharmaceutical
Osong Factory

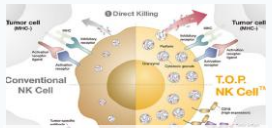

Curocell
ATMP GMP Facility


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

×

Bio-Support GMP Expertise

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

=

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

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

Your Partner for Freeze Drying System

Global Technology × Global GMP Expertise

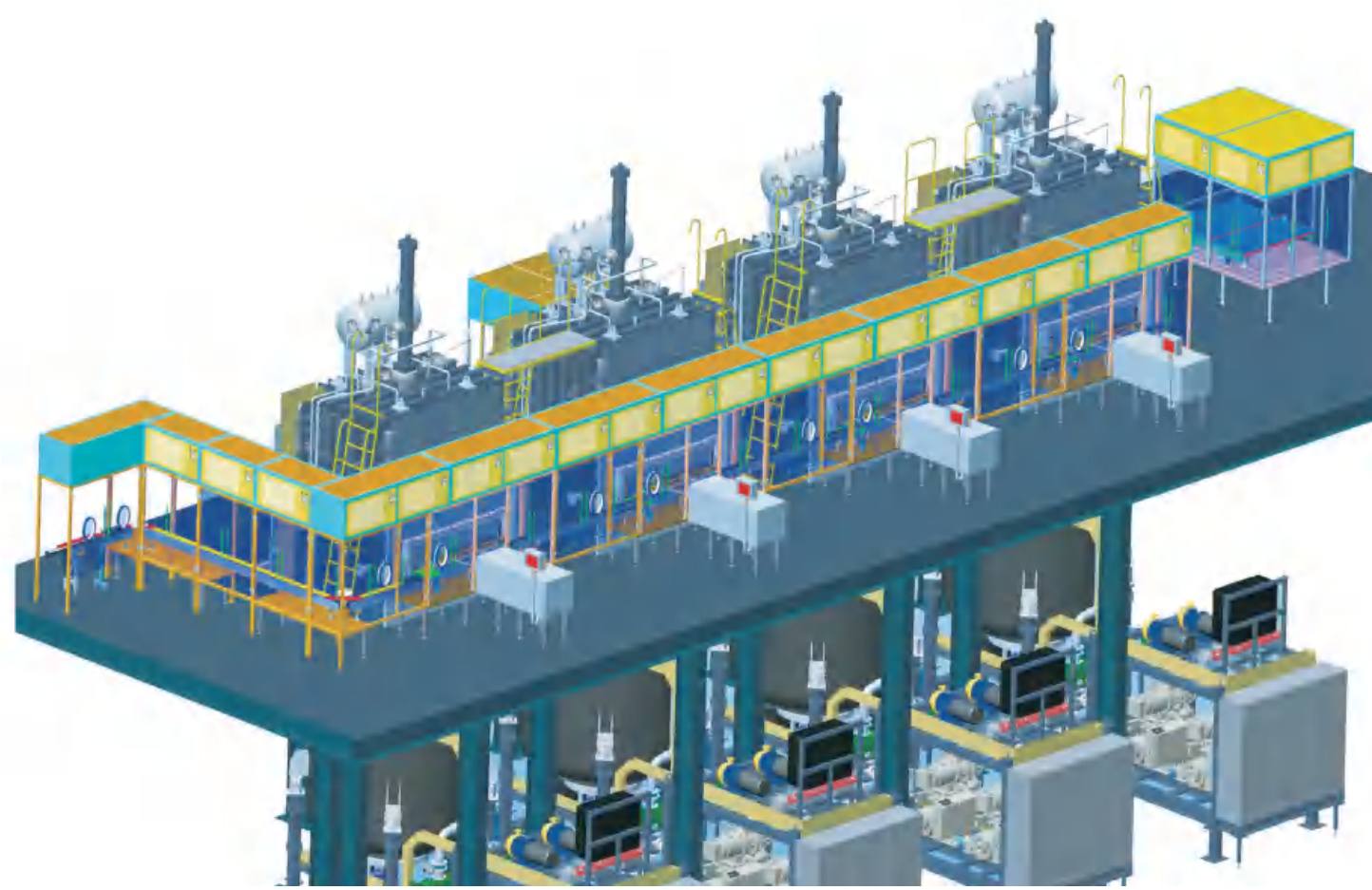
Thank you so much!!!

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

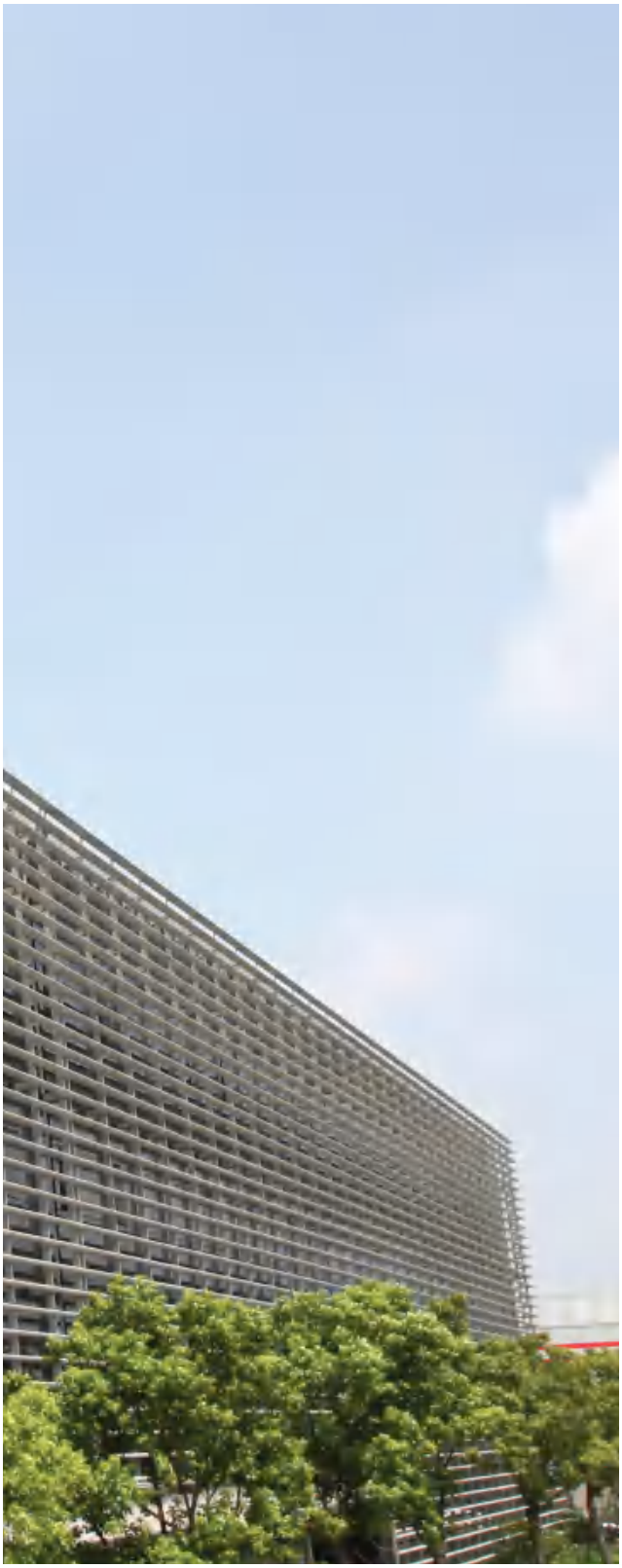


Tofflon Freeze Drying System

For the Pharma & Biotech Industry



Tofflon Science and Technology Group Co. Ltd. (Short for “Tofflon”, Stock Code: SZ 300171) was founded in 1993. It is a comprehensive pharmaceutical equipment supplier to provide process support, core equipment, integrated system and pharma engineering for the pharma and biotech industry in the world. Since its foundation, Tofflon has supplied more than 10,000 equipment and systems for 2,500 pharmaceutical companies across over 50 countries and regions in the world which have been widely applied in the fields of liquid and lyo injectables, chemical API, bioengineering and pharma packaging, etc.



TODAY

Tofflon focuses on studying drug manufacturing science and process equipment manufacturing science, practices drug process knowledge integration with pharma equipment knowledge. Taking “Synergy Global Advanced Technologies” strategy, Tofflon builds comprehensive development institute in Shanghai headquarters, is building design houses and technical centers in USA, Europe and India, establishes joint ventures and technology collaboration with the technical partners from USA, Europe and Japan. Furthermore Tofflon has built six modern pharmaceutical equipment manufacturing bases with global competiveness. It has been approved with all the international regulatory certifications like German TUV ISO9001, ISO14001, OHSAS18001, CE, UL, PED, ASME, etc. Thanks to 4,500 Chinese and foreign employees’ professional works, it can provide competitive pharmaceutical equipment and system solutions valuable for today and future’s competence improvement of the pharma and biotech companies.

FUTURE

To commit to its mission “Expertise in Biopharmaceutical”, Tofflon will continuously work with biopharmaceutical industry to face and meet the challenges and pressures in the industry through developing “innovative drug manufacturing science” and building “advanced drug manufacturing platform”. In the following years, Tofflon will dedicate itself to grown from “China Tofflon to Global Tofflon”, from “Equipment Supplier to Solution Provider” so as to grow up to a total solution provider of pharmaceutical manufacturing systems and engineering for the global pharma and biotech industry to contribute to the maximum benefits and welfare of its served society, customers, stockholders, employees and their families.

Affordable Flexible Reliable

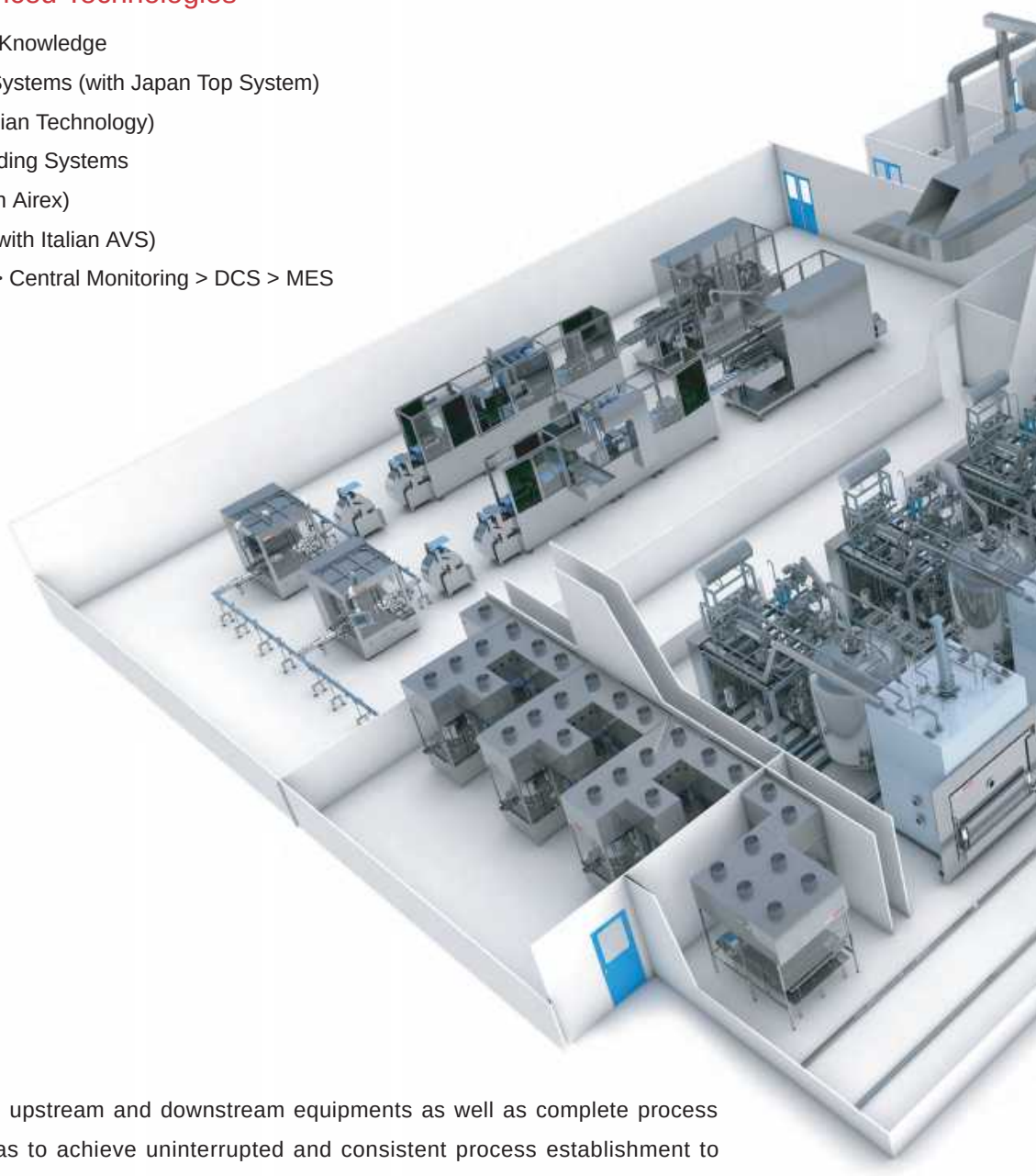
Freeze Drying System

Concept

We believe that “Automation, Isolation, Continuous Processing and Systems Integration” are becoming main stream for aseptic processing of sterile injectables.

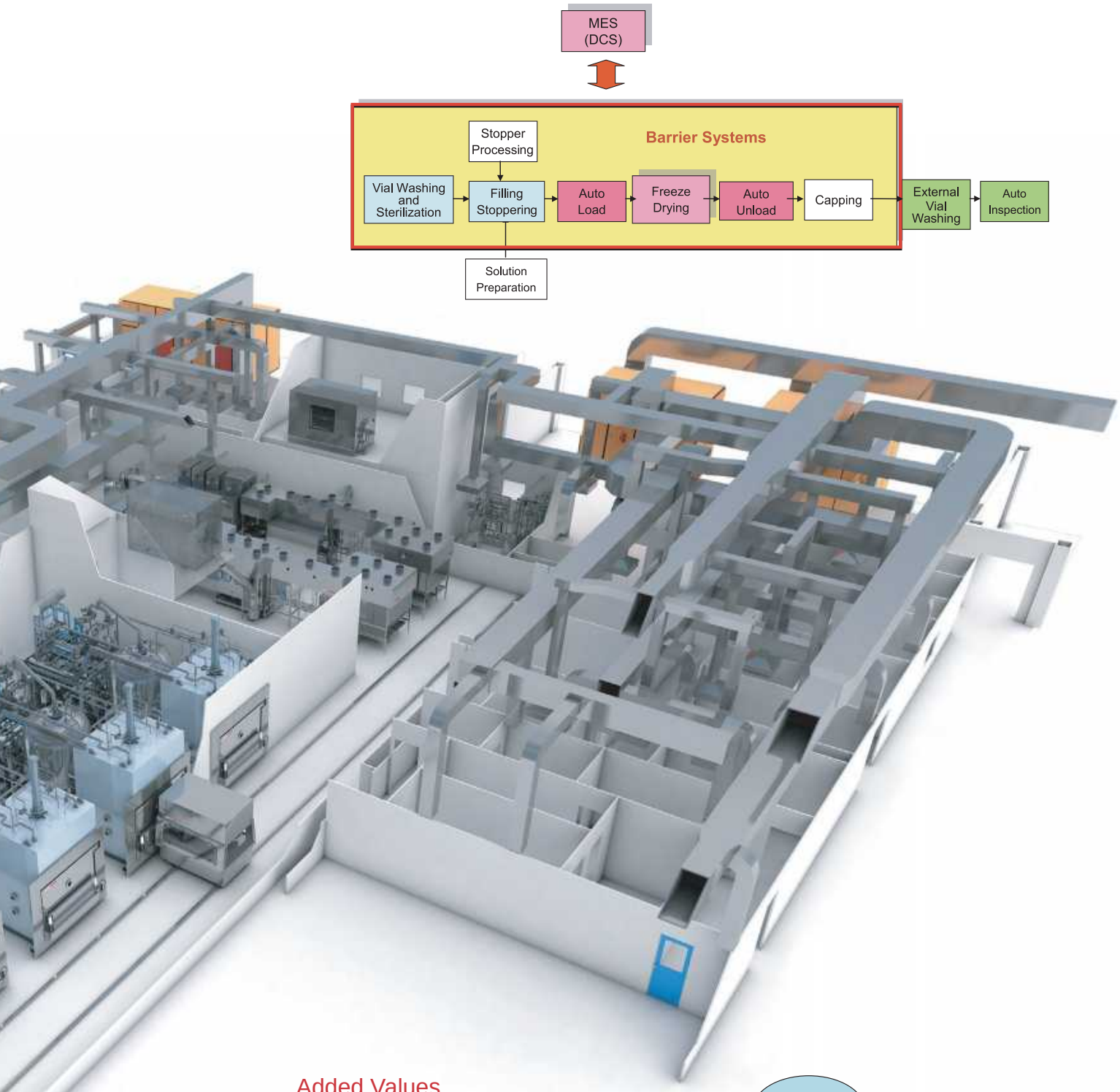
Synergy Global Advanced Technologies

· Lyophilization and Process Knowledge
· Auto Solution Preparation Systems (with Japan Top System)
· Aseptic Vial Filling Line (Italian Technology)
· Freeze Dryer and Auto Loading Systems
· Barrier Systems (with Japan Airex)
· Intelligent Vision Systems (with Italian AVS)
· Automation: Local Control > Central Monitoring > DCS > MES



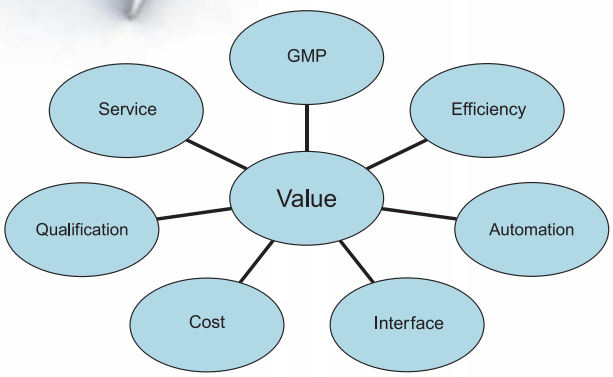
Systems Integration

Mechanical integration with upstream and downstream equipments as well as complete process automation integration so as to achieve uninterrupted and consistent process establishment to continuously improve drug quality and production efficiency.



Added Values

- cGMP Approach
- High Efficiency
- Automation and Isolation
- Simple Interface
- Cost-Effective
- Easy Validation
- Integrated Service
- Faster Time to Market



Freeze Dryers

Technology from the Largest Freeze Dryer Manufacturer in the World

Supplies and Services



· Laboratory Freeze Dryers (LYO-0.2 ~ 1m^2)

· Pilot Freeze Dryers (LYO-2 ~ 5m^2)

· Production Freeze Dryers (LYO-7.5 ~ 20m^2)

· Mass-Production Freeze Dryers (LYO-25 ~ 50m^2)

· Equipment Qualification and Software Qualification

Chamber / Condenser / Shelves

· GB-150 / PED / ASME Code Pressure Vessel.

· cGMP guidelines and US-FDA recommendation.

· All chamber edges and corners are rounded to facilitate cleaning.

· Chamber dead legs are limited to a length to diameter ratio L/D≤3 and are sloped to ensure free draining. Where the length to diameter ratio can not be achieved, cleaning action is provided with spray-nozzle.

· Chamber cooling jackets for rapid cool down after sterilization with steam.

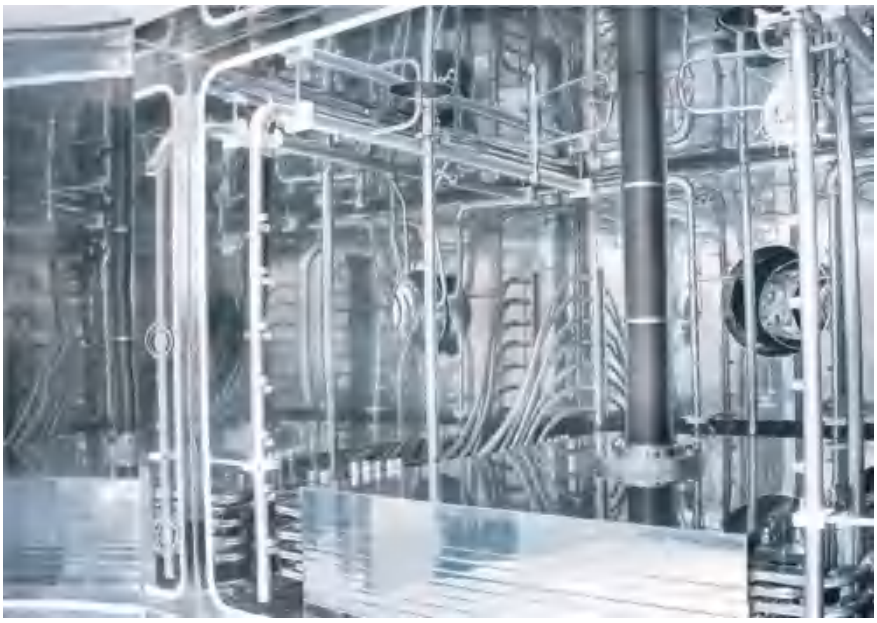
· Condenser coils are made from polished and AISI-316L stainless steel tubing.

· Condenser coils design offers a high level of ice trapping.

· For production freeze dryers, there is optional shelf double spacing mechanism to meet requirements of different size vials.

· Optional customized shelves design for auto loading systems

· Chamber – condenser isolation valve: mushroom valve – hydraulically driven or butterfly valve – pneumatically driven



Refrigeration System

· Modular design to achieve reliable and high efficiency production.

· Advanced pipeline process technology prohibits leaks.

· World-class refrigeration units ensure reliability with long service life.

· Each compressor has an independent circuit to cool shelves or condenser.

· Safety protection for compressors in high pressure, low pressure, motor overheat, differential oil pressure, unstable current, short circuit, lacking phase and cooling water flow, etc.

· Environment friendly HFC refrigerant: free of CFC and HCFC.

· Vibration absorbers to reduce vibration and noise.

· The flow rate of refrigerant is controlled by an expansion valve to achieve the precise temperature.

· Compressor: Copeland®, Bitzer®or Kobelco®, Mycom®.





Vacuum System

· Vacuum pump plus mechanical booster pump (for large scale freeze dryers) used to achieve better vacuum. (i.e. less than 0.01mbar vacuum)

· Vacuum anti-suck valve closes automatically in case of power outage so as to preserve vacuum environment.

· Vacuum pump: Edwards®

· Optional Edwards®dry pump to avoid product contamination from back-streaming vacuum oil.

· Vacuum gauge: MKS®capacitance manometer or Edwards® APG-MP vacuum gauge

· Vacuum control: Needle valve or MKS® PID control valve





CIP / SIP

· Rotary sprayer and fixed wide-angle nozzles ensure maximum cleaning coverage.

· Pure steam sterilization minimizes contamination risks for sterile drugs.

· Ports, gaskets and viewing glasses are suitable for high temperature.

· The steam supply clean pipeline is made from polished stainless steel and is orbitally welded, tested and documented by boroscope inspection.

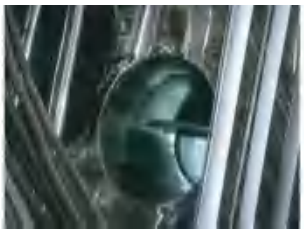
· Temperature control and monitoring are done at the coldest point of the system.

· CIP/SIP runs automatically.

· Interlocking mechanism ensures safety during sterilization process.

· External CIP system (tank and pump) as option






Control System

· 21 CFR Part 11 and cGAMP compliance.

· Access control according to authority levels.

· Audit trail recording user actions and changes to process parameter.

· Query the curve and data table record.

· Query alarm record.

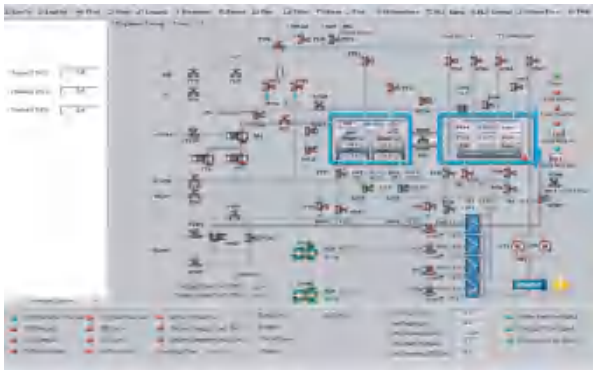
· Database management and maintenance.

· Manual or automatic control available.

· Recipe management.

· PLC / Touch Screen: Omron® / Siemens® / AB®

· Breaker / Contactor / Relay: ABB®



Technical Specifications

LYO	Model/Unit	0.5	1	2	3	5	7.5	10	15	20	25	30	40	50
Usable Shelf Area	m^2	0.54	1.08	2.16	3.24	5.40	7.56	9.72	14.40	19.73	24.67	29.60	41.86	50.83
Ice Capacity	kg	10	20	40	60	100	150	200	300	400	500	600	800	1000
Vials Capacity (Φ22mm-10ml)	vials	1090	2160	4360	6550	10900	15280	19650	29100	40000	50000	60000	86450	106000
Vials Capacity (Φ16mm-5ml)	vials	2080	4100	8200	12300	20500	28700	36900	54700	75200	94000	112800	163800	201900
Shelf Dimension (L)	mm	450	600	900	900	1200	1200	1200	1200	1495	1500	1800	2000	2000
Shelf Dimension (W)	mm	300	450	600	600	900	900	900	1200	1200	1495	1495	1495	1495
Number of Shelves	loaf	4+1	4+1	4+1	6+1	5+1	7+1	9+1	10+1	11+1	11+1	11+1	14+1	17+1
Shelf Spacing	mm	80	100	100	100	100	100	100	100	90	100	100	90	90
Power Supply	kw	10	17	26	34	44	59	74	89	118	143	158	191	247
Cooling Water	m^3/hr	4	5	8	10	13	16	20	24	34	34	40	40	60
Overall Dimension(L)	mm	1600	2200	3600	3900	4500	4700	5200	6500	7300	7300	7600	8000	8100
Overall Dimension(W)	mm	1100	1200	1750	2200	2300	2300	2200	2300	3000	3000	3000	3200	4800
Overall Dimension(H)	mm	2100	2500	2850	3100	3100	3400	3800	3900	4200	4200	4200	4600	4800
Approximate Weight	ton	2.5	3	4	5.5	7.5	10	11	13	18	20	25	32	40

Utility Requirement

· 380V,50Hz / 440V,60Hz,3-phase,5 wires

· Cooling water for compressor

(1.5≤P≤2bar,T≤25℃)

· Steam for sterilizing or defrosting

(2≤P≤3bar)

· WFI for cleaning

(P≥4bar,T=80℃)

· Compressed air for pneumatic system

(5≤P≤8bar)

· Inert gas for vacuum release

(0.5≤P≤1bar)

Available Options

· Screw compressor

· Dry pump

· Filter Integrity Test (WIT)

· CIP external system (tank and pump)

· Slot door

· Silicone oil jacket for cooling & heating

· Low temperature trap

· LN_2 refrigeration system

· Metered dosing system

· Vial sampling thief

· Eutectic test device

Technical Data

· Shelf temperature range: -55℃ to + 80℃

· Shelf cooling rate: 20℃ to -40℃ ≤ 60min

· Shelf heating rate: Approx. 1℃ /min

· Condenser final temperature: ≤ -75℃

· Condenser cooling rate: 20℃ to -40℃ ≤30min

· Final vacuum: ≤ 0.01mbar

· Evacuation Rate: 1000mbar to 0.1mbar≤30min

· Leakage Rate: ≤ 0.03mbar•L/sec

Auto Loading Systems for Vials

Technology Based on Hundreds of Practical Projects Experience

Motivation for Automation



· Fewer clean room personnel

  Higher level of sterility assurance

  Reduced bio-burden

  Lower operating costs

· Operator protection when dealing with potent products

· Repeatable standards with less reliance on SOP's.

Tofflon Design Features

· cGMP guidelines and FDA compliance.

· Flexible and wide range of solutions.

· Fully integrated design with RABS and Isolator.

· Servo controlled mechanisms without any pneumatic or hydraulics meet cGMP requirements for cleanliness.

· "Gap-less" design for vials transfer.

· No moving parts above open vials to disturb air flow, avoiding any potential risk of contamination.

· Vials moved to shelf automatically without the use of trays or fences.

· Tool-less operation for quick vial size changes.

· Designed for easy maintenance and service.

· Fallen vials reject box.

· Serpentine buffer conveyor.

Fixed Loading Systems (Row-by-Row)

Features

· Loading speed up to 600vpm (2ml).

· Accommodate a wide range of vial size (2ml ~ 100ml).

· Can be used with one or more freeze dryers, more depending on cycle time and logistics and environment.

· Conveyors required to transport vials from filler to loader.

· Mainly loading and unloading from the same side.

· Suitable for RABS or Isolator.





Flexible Loading Systems (AGV)



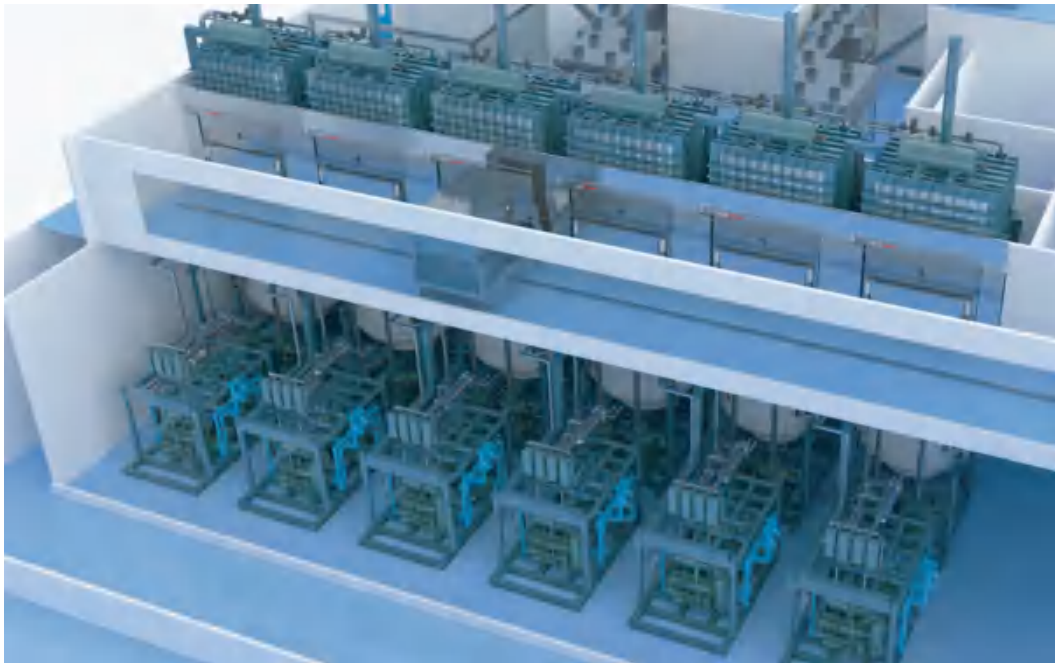
Features

· Loading speed up to 600vpm (2ml)
· Accommodate a wide range of vial size (2ml ~ 100ml)
· Mainly used in multiple of Lyos installations
· Vials are loaded shelf by shelf.
· Utilizes an automatic guided vehicle (AGV)
· Mainly loading and unloading from the same side.
· Suitable for pass-through configuration.
· Suitable for traditional LAF or RABS.
· Easy extension for future update.

Mixed Loading Systems (Mixed)

Features

· Combination of fixed and flexible loading systems.
· Fixed Loading & Flexible Unloading.
· Flexible Loading & Flexible Unloading
· Mainly used in multiple Lyos installations
· Loading area and unloading area can be different clean rooms.
· Flexible lyo production shift arrangement.
· Freeze dryer mainly designed with two-floor and pass-through systems.



API Auto Loading Systems

Technology Successfully Approved by US-FDA and EU-GMP

Today sterile API manufacturing demands automated handling system solutions for aseptic application to meet increasing cGMP expectations, especially for generic API large-scale manufacturing with aim to export to regulated markets. Meanwhile the solution should keep cost competitiveness and production efficiency as well. Tofflon API Auto Loading Systems work for these requirements. They include alternative designs with trays or without trays for different products, offer package solution from aseptic process to package process and meet both aseptic requirements and operator protection for potent products. The installed systems have been successfully approved by international regulatory authority.

API Auto Loading Systems With Trays

Features

· Aseptic tray transfer instead of manual transfer.
· Automatic loading instead of manual loading.
· No friction between trays and shelves to avoid metal particle generation during loading and unloading process.
· Aseptic unloading instead of manual unloading.
· Cleanable and sterilizable: Available with cleaning and sterilization in place or being disassembled for separate cleaning and sterilization.
· Operator protection when dealing with potent products
· Systematic solution from aseptic process to package process.



API Auto Loading Systems Without Trays

Features

· No trays (shelf as a tray) to reduce contamination risk and costs related with tray.

· Automatic and closed loading instead of manual loading.

· Faster freeze drying cycle to increase productivity.

· Aseptic unloading by auto robot instead of manual unloading.

· Cleanable and sterilizable.

· Operator protection when dealing with potent products.

· Systematic solution from aseptic process to package process.





Aseptic Packaging

· Packaging container washing, sterilization and aseptic transfer within barrier systems.

· Intermediate bulk container grinding, lifting and mixing

· Dry powder aseptic dispensing into packaging container within barrier systems.



Barrier Systems

Advanced Isolator Technology from Japan Airex

Tofflon Airex

Tofflon Airex is a joint venture between Airex (Japanese barrier isolator technology leader) and Tofflon (Chinese leading Freeze Drying System Brand). Through synergy of “Automation, Isolation, Continuous Processing and Systems Integration” design concept, world leading isolation technology, global quality and scale manufacturing competence and years of knowledge of serving local customers, Tofflon Airex offers safe, qualified, affordable and integrated barrier systems for pharma and biotech industry to accelerate the popular application of isolation technology in dynamic global emerging markets.





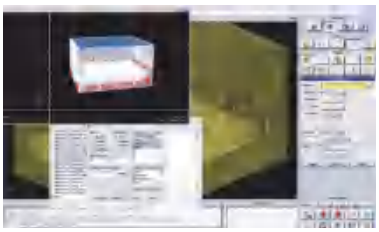
	oRABS	cRABS	Isolator
Airflow	Unidirectional	Unidirectional	Unidirectional or turbulent
Pressure	Positive	Positive	Positive or negative
Decontamination	Manual high-level disinfection	VHP	VHP
Surrounding environment classification	Grade B	Grade B	Grade C or Grade D
Freeze Dryer Auto Loading Systems			
Fixed (Row-by-Row)	+ + +	+ + +	+ + +
Flexible (AGV)	+ + +	-	-
Containment Potential for Hazardous Products			
Aseptic	+ + +	+ + +	+ + +
Toxic	-	+ +	+ + +
Cleaning and Decontamination			
CIP/WIP	-	+	+ + +
H_2O_2 Decontamination	-	+ + +	+ + +
Risk			
Sterility Assurance Level	+ +	+ + +	+ + +
Impact of Operator	+ +	+ +	+ + +
Others			
Cost Sensitive	+ + +	+ +	+
Operation Flexibility	+ + +	+ +	+

Note: - Not Recommended + Suitable ++ Good +++ Very Good

Key Technologies

Process

"A Barrier is not only a machine, it is a process".



Ergonomics



Environment Monitoring

(Air Velocity / Differential Pressure / Temperature / Relative Humidity / H_2O_2 Condensation / Viable and Non-Viable Particulates / Microorganism)



Cleaning and Decontamination



Qualification

CONSTRUCTION

- Leakage test
- Glove test
- Airflow pattern
- Illumination test
- Filter integrity test
- Mock up
- Noise test …….



ENVIRONMENT

- Pressure test
- Airflow test
- Particle counting
- Microbe sampling …….



CLEANING AND DECONTAMINATION

- Riboflavin test for CIP
- CI test for HPVS distribution
- BI test for HPVS
- Decontamination cycle development …….



Applications

A Barrier Systems for Sterile Injectables Production

(For Filling Line and Freeze Dryer Auto Loading Systems)



B Barrier Systems for API Handling

(For Weighing, Dispensing, Tank Charging, Filtering-Washing-Drying, Sampling, etc)



API Weighing Isolator

Toxic API Weighing Isolator

API Dispensing Isolator

Tank Charging Isolator

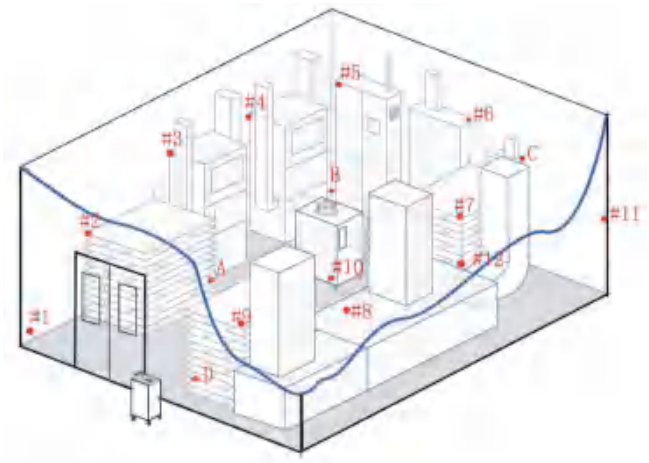
C Barrier Systems for Laboratory

(For Sterility Test, etc)





D VPHP (Vapor Phase Hydrogen Peroxide)
(For Freeze Dryer, Passbox, Clean Room and Isolator)



E Aseptic Material Transfer
(RTP, Passbox, LAF Cart, α/β valve , etc)





F Ancillary Equipment and Components
(Glove Leak Tester, Glove / Sleeves, Half-Suits, etc)

Glove/Sleeves



Glove Leak Tester



Auto Solution Preparation Systems

Automation Trend Technology from Japan TOP System

Automation Trend

Today Solution Preparation Systems are developing from manual, semi-auto to auto control.

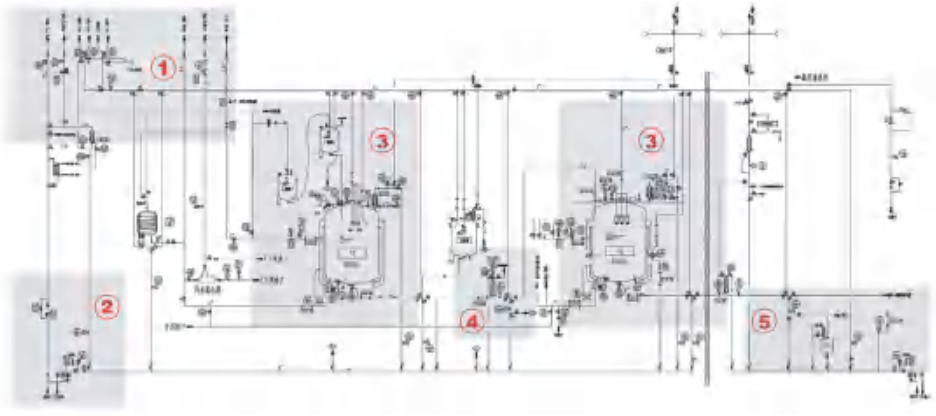
Auto Solution Preparation Systems offer the following benefits:

· Predictable, repeatable and verifiable process.

· Greatly reduce personnel manual mistakes.

· Stable and controllable quality.

· Modular design and installation.



Key Features

· Automatic Processing

· Filter Integrity Test in Situ after SIP

· Automatic CIP

· Automatic SIP

· Control System in compliance with USFDA 21 CFR Part 11 and GAMP 5

Key Systems



(1) Auto Utility Module
· Combined WFI, PW and PS supply
· WFI cooled by sanitary heat exchanger
· Sterile filters sterilizable
· WFI loop sterilizable



(2) Auto Drainage Module
· With online conductivity sensor
· With CIP sampling valve



(3) Auto Processing Tank
· Cooling jacket to control tank temperature
· With magnetic stirrer
· Online load cell weighing
· With fixed spraying ball (international patent)



(4) Auto Filters Module
· CIP/SIP on line
· Pressure gauges to be installed before and after sterile filter to online monitor filter differential pressure
· Filter Integrity Test in Situ after SIP



(5) Integration with Filling Machine
· Buffer tank CIP/SIP on line
· Interlock with filling machine



(6) Sampling
· Single sampling
· Multiple sampling
· Aseptic multiple sampling (aseptic sampling bag)

Design, Manufacture and Quality Control



(1) Electro Polish



(2) Fixed Spraying Ball



(3) Orbital Welding and Boroscope Inspection





(4) Modular Design and Installation



(5) Magnetic Stirrer

Experience of Hundreds of Projects

Case A For Infusion Drugs

· CIP/SIP on line

· Filter Integrity Test

· Two heat exchangers in series to control WFI temperature for solution preparation

· Hydrochloric acid transported and measured by peristaltic pump

Case B For Vaccines

· CIP/SIP on line

· Filter Integrity Test in Situ after SIP

· The jacket can use hot water, cool water or steam to control tank temperature.

· Aseptic feeding process

Case C For Ampoule Drugs

· CIP/SIP on line

· Auto compounding, filtration and filling.

· With 0.45um pre-filtration

· Filter Integrity Test in Situ after SIP

· The jacket can use hot water and cool water to control tank temperature





Case D For Lyophilized Oncology

· The integrity test of the 0.22um filter before and after production.

· The temperature of the product should be kept 0～5℃ during compounding, filtration and filling. So the pipe has insulation

Case E For Herbs

· Plate filtration process

· Ultra filtration process

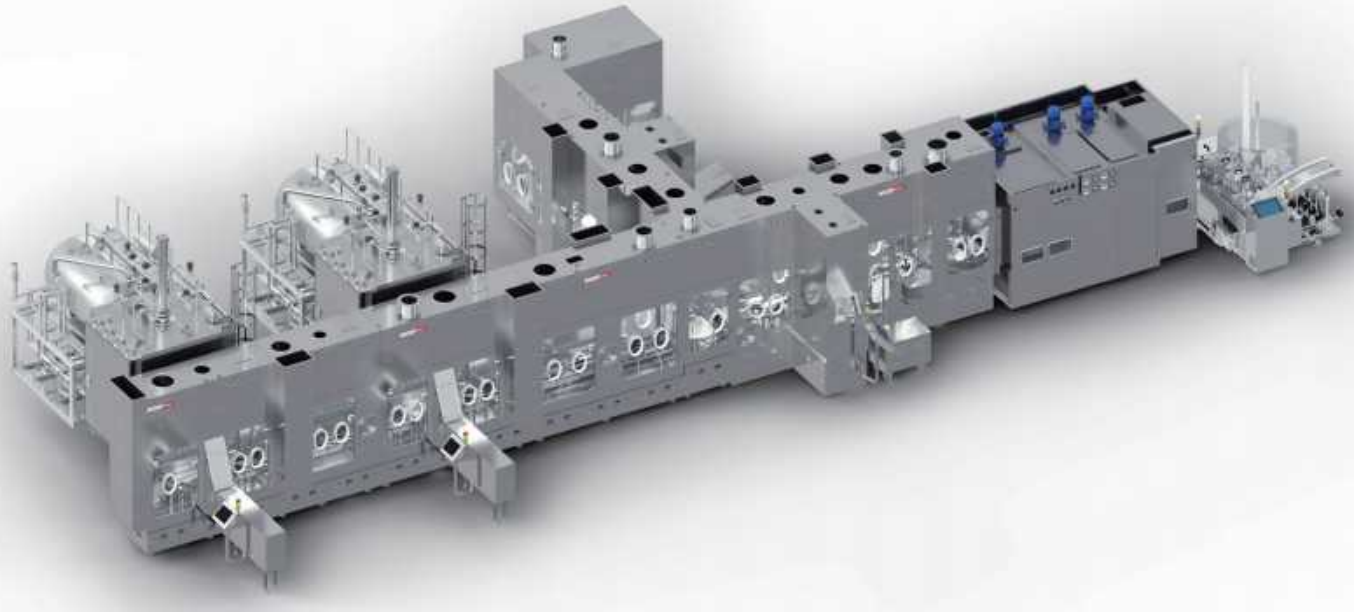
· PH control process

· Temperature control (cool, heat, boiling, etc.)



Aseptic Vial Filling Line

The Latest Technology from Italy





FWL Rotary Washing Machine

· Stainless steel 304 grippers
·Gripper turning in situ, no forwardback-ward movement
·Exhaust fan to exhaust vapors during operation created by the hot WATERÒRINSE
· Hard aluminum-alloy big rotary drum and internal gear are integrated design to improve reliability and precision



FTL Sterilization Tunnel

· Automatic door position control
· Automatic pressure balance
· Negative pressure sealing for HEPA
· Double cooling zone (option)
· Sterilizable cooling zone (option)
· Automatic discharge of final vials (option)



FFT Linear Filling Machine

· Robot technology
· Piston pump filling or peristaltic pump filling
· Process area and maintenance area are separated to avoid the risk of cross contamination
· Vial on-line rejection and sampling
· No vial, no filling and no vial, no stopper
· Suitability for RABS or isolator by design
· Servo motor control





FCR Capping Machine

· Individual knife or Big fixed knife
· No vial, no capping
· Aluminum vacuum sweeper for asepticenvironment protection
· On-line rejection before and after capping
· Automatic adjustment of capping pressure.

Technical Specifications

Washing Machine	FW			
Model	**FW02060**	**FW02080**	**FW02100**	**FW02120**
Vial Specifications	2ml ~ 50ml	2ml ~20ml	2ml ~ 20ml	2ml ~10ml
Product Speed	200 vpm (8R)	300 vpm (8R)	400 vpm (8R)	500 vpm (8R)
Broken Rate	≤0.01%	≤0.01%	≤ 0.01%	≤0.01%
Qualified Rate	≥ 99.9%	≥ 99.9%	≥ 99.9%	≥ 99.9%
Compressed Air	0.6~0.7Mpa	0.6~0.7Mpa	0.6~0.7Mpa	0.6~0.7Mpa
Air Consumption	60m^3/h	69m^3/h	81m^3/h	93m^3/h
WFI Pressure	0.25 ~0.4Mpa	0.25 ~0.4Mpa	0.25 ~0.4Mpa	0.25 ~0.4Mpa
WFI Consumption	0.6m^3/h	0.7m^3/h	0.8m^3/h	0.9m^3/h
Vapor Exhaust	600m^3/h	600m^3/h	600m^3/h	600m^3/h
Power	12Kw	12Kw	12kw	12 kw
Weight	2,800Kg	2,800Kg	3,500Kg	3,500 Kg
Dimensions (L×W×H) (mm)	2,400×2,400×2,200	2,400×2,400×2,200	2,600 ×2,700×2,200	2,600 ×2,700×2,200
Sterilization Tunnel	**FT**			
Model	**FT0120**	**FT0130**	**FT0140**	**FT0150**
Vial Specifications	2ml ~ 100ml	2ml ~100ml	2ml ~ 100ml	2ml -100ml
Belt Width	850mm	850mm	850mm	850mm
Product Speed	200 vpm (8R)	300 vpm (8R)	400 vpm (8R)	500 vpm (8R)
Broken Rate	≤0.005%	≤0.005%	≤0.005%	≤0.005%
Qualified Rate	≥99.9%	≥99.9%	≥99.9%	≥99.9%
Power	82Kw	95Kw	125 Kw	160 Kw
Weight	5,200Kg	6,100Kg	7,300Kg	8,600 Kg
Dimensions (L×W×H) (mm)	3,600×2,400×2,300	4,550×2,450×2,300	5,400×2,450×2,300	5,900×2,550×2,300
Filling Machine	**FF**			
Model	**FF0610**	**FF0610S**	**FF0212**	**FF0216**
Vial Specifications	2ml ~100ml	2ml ~100ml	2ml ~ 100ml	2ml ~100ml
Product Speed	300 vpm (8R)	400 vpm (8R)	400 vpm (8R)	500 vpm (8R)
Filing Accuracy (±2σ)	±0.5% (V≥2ml) ±1% (V<2ml)	±0.5% (V≥2ml) ±1% (V<2ml)	±0.5% (V ≥ 2ml) ±1% (V<2ml)	±0.5% (V≥2ml) ±1% (V<2ml)
Broken Rate	≤0.01%	≤0.01%	≤0.01%	≤0.01%
Qualified Rate	≥99.8%	≥99.8%	≥ 99.8%	≥99.8%
Power	15Kw	25Kw	20kw	21kw
Weight	5,000 Kg	5,000Kg	3,000Kg	3,000Kg
Dimensions (L×W×H) (mm)	6,700×2,300×2,700	7,000×2,500×2,700	5,850×2,900×2,700	5,850×2,800×2,700
Capping Machine	**FC**			
Model	**FC0220**	**FC0230**	**FC0240**	**FC0250**
Vial Specifications	2ml ~100ml	2ml ~100ml	2ml ~100ml	2ml ~100ml
Product Speed	200 vpm (8R)	300 vpm (8R)	400 vpm (8R)	500 vpm (8R)
Broken Rate	≤0.01%	≤0.01%	≤0.01%	≤0.01%
Qualified Rate	≥99.5%	≥99.5%	≥99.5%	≥99.5%
Power	9.5Kw	9.5Kw	9.5Kw	9.5Kw
Weight	1,500Kg	1,500Kg	1,500Kg	2200Kg
Dimensions (L×W×H) (mm)	3,000×2,200×2,700	3,000×2,200×2,700	3,000×2,200×2,700	3,000×3,000×2,700

Ampoule Filling Line





ACX Rotary Washing Machine

· Compact footprint and flexible layout

· In-feed conveyor with double-section design to avoid cross contamination

· Ultrasonic washing

· Alternant washing by water and compressed air

· Gripper turning in situ, no forward-backward movement

· Hard aluminum-alloy big rotary drum and internal gear are integrated design to improve reliability and precision

· Servo motor driven

SZA Sterilization Tunnel

· Negative pressure sealing for HEPA

· Stainless steel materials to be used inside tunnel to avoid oxidation risk

· Automatic air balance

· Door position control (manual or automatic)





AGF Filling and Sealing Machine

· Ceramic piston pump filling or stainless steel piston pump filling

· Servo motor driven

· Nitrogen gas flushing before and after filling

· With LAF or RABS protection

Washing Machine	AW	
Model	**FW05120**	**FW05160**
Ampoule Specifications	1ml ~ 20 ml	1ml ~ 20 ml
Product Speed	450 apm (2ml)	600 apm(2ml)
Broken Rate	≤0.2%	≤0.2%
Qualified Rate	≥99.9%	≥99.9%
Compressed Air	0.6~0.7Mpa	0.6~0.7Mpa
Air Consumption	87m^3/h	99m^3/h
WFI Pressure	0.25 ~0.4Mpa	0.25 ~0.4Mpa
WFI Consumption	0.9m^3/h	1m^3/h
Vapor Exhaust	600m^3/h	600m^3/h
Power	12Kw	12Kw
Weight	3,500Kg	3,500Kg
Dimensions(L×W×H) (mm)	2,460×2,700×2,100	2,460×2,700×2,100

Sterilization Tunnel	AT	
Model	**FT0430**	**FT0460**
Ampoule Specifications	1ml ~ 20 ml	1ml ~ 20 ml
Belt Width	600mm	600mm
Product Speed	300 apm (2ml)	600 apm (2ml)
Broken Rate	≤0.02%	≤0.02%
Qualified Rate	≥99.9%	≥99.8%
Cooling Type	Air cooling: Room Temperature	Air cooling: Room Temperature
Air Consumption	2,100 ~ 3,000m^3/h	2,300 ~ 3,500m^3/h
Water Consumption	N/A	N/A
Power	40Kw	72Kw
Weight	2,500Kg	4,000Kg
Dimensions(L×W×H) (mm)	2,700×1,650×2,400	4,500×1,650×2,400

Filling and Sealing Machine	AF			
Model	FF0508	FF0510	FF0512	FF0516
Ampoule Specifications	1ml ~ 20ml	1ml ~ 20ml	1ml ~ 10ml	1ml ~ 10ml
Product Speed	320 apm (2ml)	400 apm (2ml)	500 apm (2ml)	600 apm (2ml)
Filling Accuracy	± 1%	± 1%	± 1%	± 1%
Broken Rate	≤0.1%	≤0.1%	≤0.1%	≤0.1%
Qualified Rate	≥99%	≥99%	≥99%	≥99%
0.05Mpa Gas Consumption	0.8m^3/h	0.8m^3/h	0.8m^3/h	1m^3/h
0.4Mpa Oxygen Consumption	1m^3/h	1m^3/h	1m^3/h	1.2m^3/h
Power	6Kw	6Kw	6Kw	7Kw
Weight	2,700Kg	2,700Kg	2,700Kg	3,200Kg
Dimensions(L×W×H) (mm)	3,500×1,750×2,700	3,500×1,750×2,700	3,500×1,750×2,700	4,100×1,850×2,700

Intelligent Vision Systems (TIVS)

Innovative Inspection Technology from Italy



Liquid Ampoule/Vial TIVS

· Ampoule size: 1 ~ 20ml
· Liquid vial size: 2 ~ 30ml
· Working speed: 400pcs/min
· Inspection precision: ≥40μm (adjustable)

A Tip Inspection



B Particle 1 and Filling Level Inspection



C Particle 2 Inspection



D Cosmetic Inspection



Freeze-dried Vial TIVS

· Vial size: 2 ~ 30ml
· Working speed: 400pcs/min
· Inspection precision: ≥40μm (adjustable)

A Tip Inspection



B Bottom Inspection

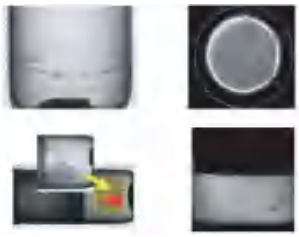


C Top Cake Foreign Particle Inspection

D Side Cake Surface Foreign Particle Inspection



E Cosmetic Inspection



Features and Advantages

Continuous Tracking and Photographing System

· Inspection span for each container reaches 0.6 second

· Fast mechanical respond, patented direct drive motor and digital CAM which is of smaller backlash, faster responding and high precision compared with traditional mechanical transmission.

· GigE camera from Germany without vision conversion card achieves high responding speed

· Advanced EtherCAT achieves high data transmission speed

· Soft PLC achieves high image processing speed

Patented Gripper Design Without Base

· Bottom inspection without blind area and containers can be inspected 100%

· Gripper opening and closing pressure can be set precisely

· Soft gripper can handle different shape of containers



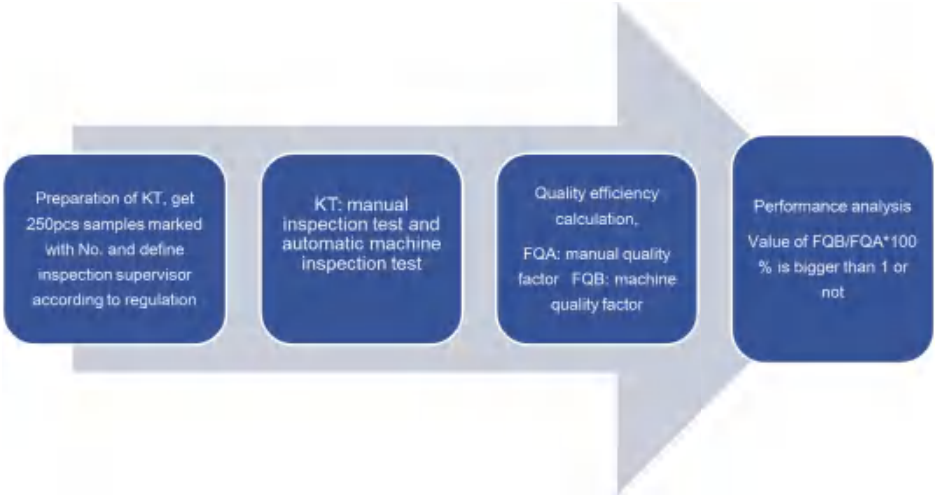
Carousel Suspension Design

· Easily access

· Inspection area is separated from mechanical transmission.

· Easy cleanness, liquid would not erode transmission system

International KNAPP Test



Lyophilization Process Support



Mission

· To help customers know the risk in freeze-drying process and avoid it.

· To improve lyophilized drug quality, to reduce cost and to enhance productivity for the pharma and biotech industry.

· To introduce GMP concept into freeze dying process to ensure all the steps in compliance with regulatory expectation.

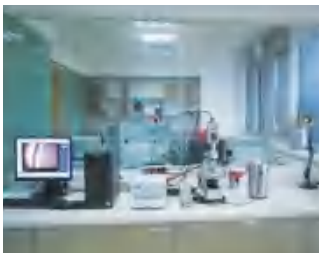
· Through studying lyophilization and process knowledge, to offer strong foundation for Tofflon freeze drying system solution for the pharma and biotech industry

Knowledge and Experience

· Until 2014, more than 800 lyophilized drugs' thermal property detection and more than 700 lyophilized drugs' freeze drying cycle development

· Strong experience to solve different lyophilized product defects and well-established database for tested lyophilized products.

· Sound experience on development of freeze drying cycle for different lyophilized drugs including chemical drugs, biological drugs, antibiotics, herbs as well as lyophilized tablets, pre-filled syringe and lyophilized films, etc






Lyophilization Service

Contents	Period
Lyophilization training	Within 2 weeks
Parameter determination	1 –4 weeks
Cycle development and optimization	4 –16 weeks
Cycle scale up	2 –8 weeks
Trouble shooting	4 –16 weeks

Lyophilization Research

A Lyophilized Tablet

· Fast dissolving speed
· Easy to deliver, no need water
· Less hurt to stomach
· Improve drug bioavailability, good for large molecules drug



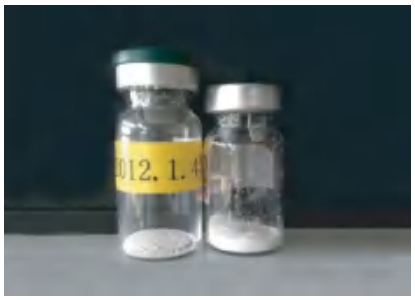
B Dual-Chamber Syringe

· Easy to use
· More safety to patient
· Less contamination
· Less residual



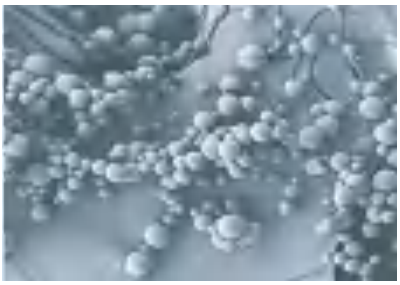
C Spray Freeze Drying

· Faster sublimation rate
· Reduce contamination risk
· Simplify freeze drying process
· Good for protein and peptide lyophilization
· Particle size can be controlled as per request



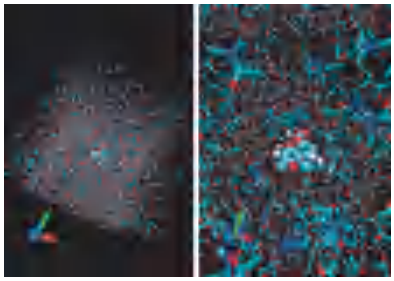
D Microsphere Lyophilization

· Using membrane filtration process
· Microphere size controllable by membrane size
· Uniform microsphere size
· Closed process makes easy operation and aseptic protection



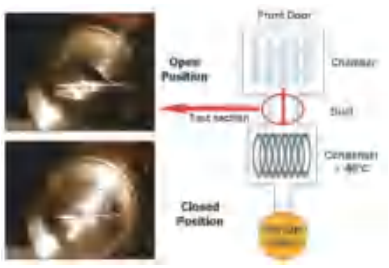
E Molecule Simulation

· To give prediction for freeze-drying cycle design or formulation design
· To give ideas for formulation design
· Explanation of the phenomenon in freeze-drying process



F MTM Development

· To monitor primary drying using the pressure increase in the freeze-dryer chamber during a shortest period.
· The results of each MTM measurement can be used for process optimization



Manufacturing and Quality Control



Thanks to Tofflon thousands freeze dryer shelves manufacturing experience, innovative vacuum brazing technology and know-how and advanced vacuum brazing equipments, we make

· Greater shelves strength
· Reduced shelves weight
· Eliminating shelves welding distortion
· Increased shelves heat exchanger area



The world's largest freeze drying system manufacturing base (250,000 m^2)



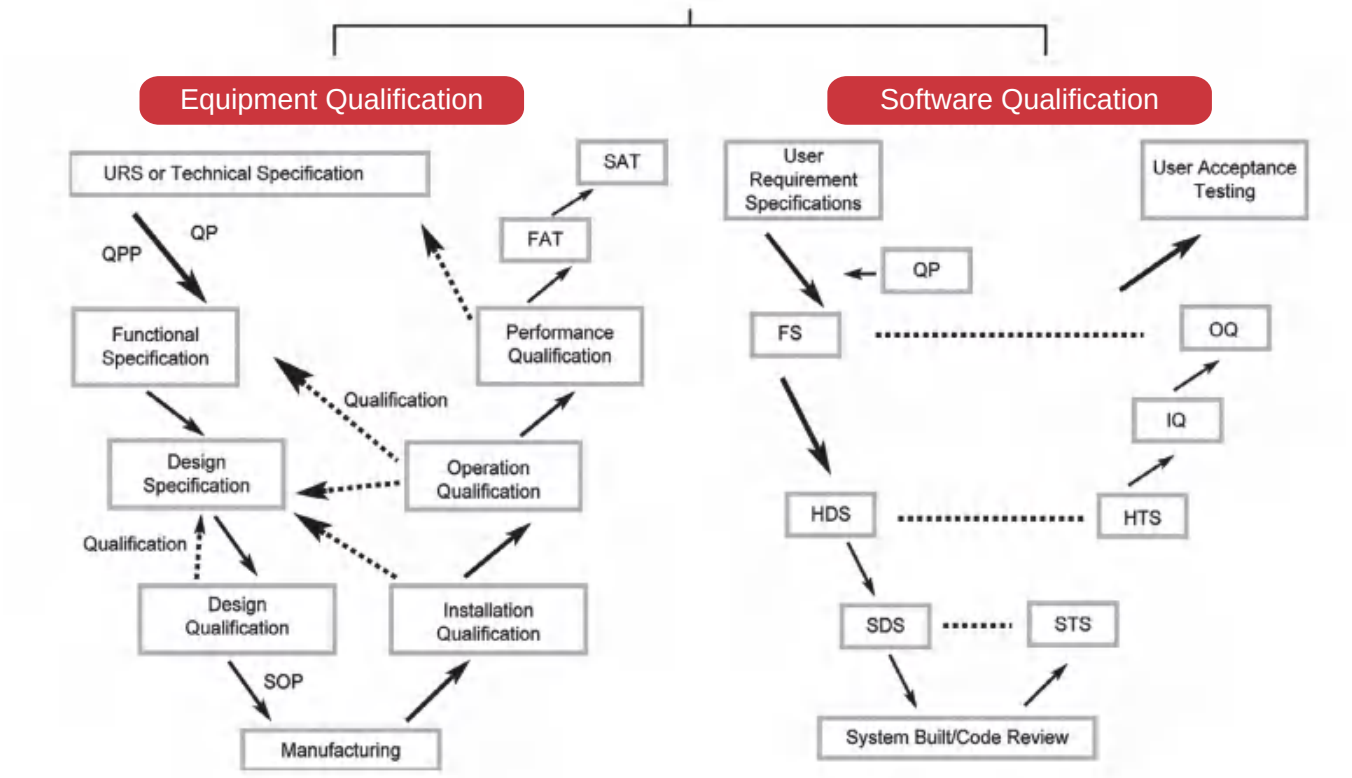
· 5 modern manufacturing parks
· 3 R&D centers
· Critical Process: semi-auto or auto process
· CNC manufacturing center
· 6S workshop management
· International regulatory compliance (CE / UL / PED / ASME / GAMP)

Scientific In-Process Quality Control

· Kaye Validator
· Helium Leak Detector for Leakage Test
· Boroscope Inspection with Photos and Video Records
· Alloy Analyzer to Test Stainless Steel Materials
· Pressure Calibrator
· Temperature Calibrator
· Temperature Uniformity Test
· SIP Temperature Distribution Test
· CIP Riboflavin Test
· Filter Integrity Test, etc.



cGMP Documentation and Qualification



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