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**VSUN**<sup>®</sup>

## 无菌塑料包装吹灌封系统 Aseptic Blow-Fill-Seal System for Plastic Container Parenterals



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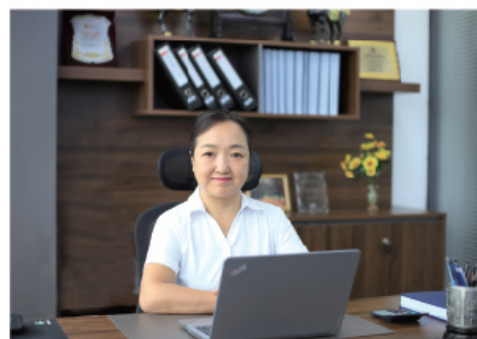
上海位山科技有限公司  
Shanghai Vsun Technology Co., Ltd.



# ENTERPRISE PROFILE

## 企业简介

上海位山科技有限公司是一家专业从事制药设备研发、生产、销售的高新技术企业,公司集设计、研发、生产、销售、GMP 验证、制药工程及服务为一体,致力于为客户提供制药装备整体解决方案。



位山科技位于上海新八景之一的枫泾古镇。占地面积26亩,业务范围涵盖五大洲。二十余年的制药装备行业工程经验能为客户提供满足全球GMP要求的工程方案。2015年,公司引进国内最早研发BFS设备的研发团队,吸收意大利设计的BFS设备技术,成功推出无菌塑料包装吹灌封系统。设备主要特点为集成一体化程度高、占地面积小净化能耗低、所有工序均在无菌条件下完成、设备综合性能高、设备原材料利用率高等,同时可为客户提供BFS工艺系统整体解决方案,实现交钥匙工程。

位山科技将持续优化制药机械设备及增强渠道覆盖体系,积极开拓自有品牌的市场,自主创新产品,秉承一贯的敬业精神服务于全球客户。坚持以“服务一步到位,责任重于泰山”的企业理念,提升企业核心竞争力,一如既往的奋进不息,为缔造中国制药机械的产业丰碑而永远向前!

## 服务一步到位 责任重于泰山

Provide Top Service in One Step and Weight Responsibility Heavier Than Mount Tai



Shanghai Vsun Technology Co., Ltd. is a high tech manufacturer specializing in R&D, production, sales, GMP Verification, pharmaceutical engineering and devote to provide total solution for pharmaceutical industry.

Shanghai Vsun Technology Co., Ltd. is located in Fengjing ancient town which is one of eight beautiful scenes in Shanghai, it covers an area of 26 acres. Our business extends five continents. With our professional experience for pharmaceuticals, we can provide engineering project in compliance with GMP standard for global customers. We owns the first BFS technology R&D team in China and succeeded in manufacturing aseptic Blow-Fill-Seal 3 in 1 machine learned from Italian design in 2015. The main features of BFS machine are high integration, small space area and low energy consumption. All processes can be completed under aseptic conditions. It has high performance and high utilization rate of raw material. Meantime we can also provide total solution for BFS technology and accept turn key projects.

We will continue to promote quality system for pharmaceutical machinery, expand sale channel and also actively develop markets for our own brand, independently create new designs. Our team is dedicated to follow our professional motto "Provide Top Service in One Step and Weight Responsibility Heavier Than Mount Tai". We promise to serve global customers, strengthen core competitiveness, make progress and move forward to the monument of "China's best pharmaceutical industry" all the time.





# R&D CENTER

## 研发中心

上海位山科技有限公司研发部活跃着一批在机械设计，电气自控设计，机电一体化领域有着多年经验的工程技术人员，拥有着先进的实践经历及超前的设计理念。公司与国内外高等院校、设计院、医药研究所、大型制药企业建立着长期合作的关系、互相交流、不断改进和提高制药设备的稳定性、适用性及先进性。公司时刻关注着FDA、CGMP、GMP的最新要求、融合国内外最新技术、为用户提供高性能和高可靠性的制药设备。

Vsun is consist of numerous active R&D members in mechanical design, electrical control design, engineering and mechanical engineering. Our technical engineers are well experienced in mechatronics' field with advanced machine design concepts. We have built long term cooperation with design institutes, medical research institutes, universities and large pharmaceutical enterprise. We built a network that constantly share the most advanced technology to continuously improve the stability and applicability of the pharmaceutical machineries. Our company pay close attention to the latest FDA, CGMP and GMP require-ments and latest technology trend at home and abroad to provide our users with high performance and high reliability of pharmaceutical equipment.

# QUALITY ASSURANCE & CONTROL

## 质量管理/控制

上海位山科技有限公司在完善ISO9001:2008全面质量管理体系下规范执行，依据国家，行业及企业标准、确保生产工艺制造过程中的质量关。从设备的进料检查、制程巡检、成品检验、供应商管理、体系文件管理到计量器具管理等，都配有资深的质控管理人员严格实施执行。

Shanghai Vsun Tech Co., Ltd is operating strictly under quality management system ISO9001 : 2008. We are carrying on state, industry and enterprise standards to ensure high quality of manufacturing process. Each step from Incoming inspection, process inspection, finished product inspection, supplier management, system docu-ment management to measuring instrument management and etc. are all assigned with senior quality control staffs for strict enforcement.



# OUR TECHNOLOGY ADVANTAGES

## 我们的技术优势

设备灌装区和机械区的黑/白分区技术	Black zone technology for mechanic and white zone technology for filling can be divided respectively
灌装区A级风淋保护，工艺管路无菌设计（CIP/SIP）	Grade A air shower protection for filling, aseptic design (CIP/SIP) for process piping
精确的时间-压力灌装计量系统，可定制悬浮液、高粘度液体的灌装系统	Accurate time-press dosing system, can be customized suspending liquid, high viscosity liquid filling system
双工位成型技术，符合更高的产能要求	Double working station forming technology, meet higher capacity requirements
伺服液压系统，闭环位移曲线控制，更高的设备稳定性	Servo hydraulic system, closed-loop displacement curve control, higher equipment stability
自主模具设计和开发，能根据客户的需求定制产品模具	Independent research for all moulds design and development, can be customize the product mould according to customer's requirement
广泛的产品应用，符合0.4mL-1000mL产品的生产	Wide range of product applications, filling range from 0.4ml to 1000ml
控制系统设计符合GAMP5&FDA CFR21 Part11的认证要求	Control system design meet GAMP5&FDA CFR21 Part11 certification requirement
更优化的产品壁厚控制方案，原材料利用率提高5%-8%	More optimized thickness control program, rate of raw material utilization increased by 5%-8%
全自动废瓶识别系统，降低操作难度和人员数量	Automatic waste bottle identification system, reduce operation difficulty and worker amount



## AFP无菌塑料包装吹灌封系统(小容量制剂)

AFP Aseptic Blow-Fill-Seal System for Plastic Container Parenterals(SVP)





## AFP无菌塑料包装吹灌封系统双模双出型（小容量制剂）

AFP Aseptic Blow - Fill - Seal System for Plastic Container Parenterals Double Station (SVP)





# SMALL VOLUME PARENTERALS (SVP)

## 小容量注射剂

在小容量注射液的生产中，塑料的使用在大幅度增加。与玻璃安瓿相比，塑料具有使用方便，操作安全，无破损，能避免潜在伤害的危险,生产成本低等优点。

The use of plastic material for small volume parenterals has increased significantly. Comparing to glass ampoule, plastic material has much more advantages such as convenient to use, eliminate potential hazards in handling, safe and environmentally friendly disposal, shatterproof transportation and low manufacturing cost. These are all key factors to determine good manufacturing practice.



### 眼, 耳, 鼻护理产品

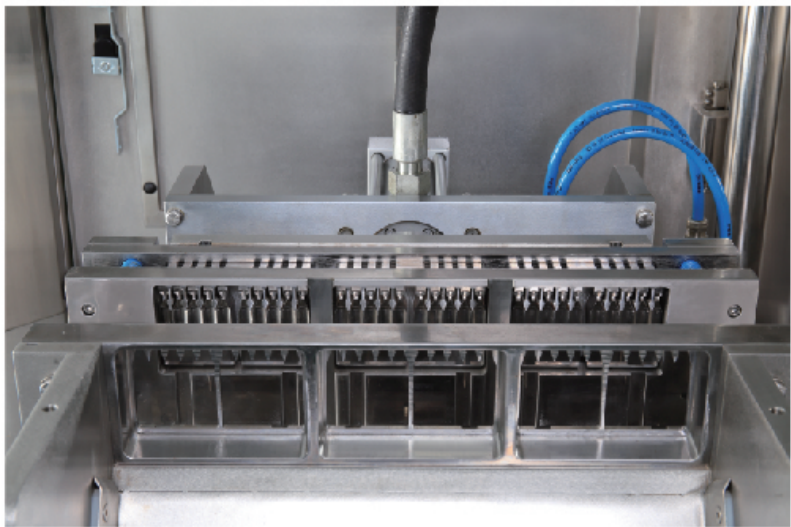
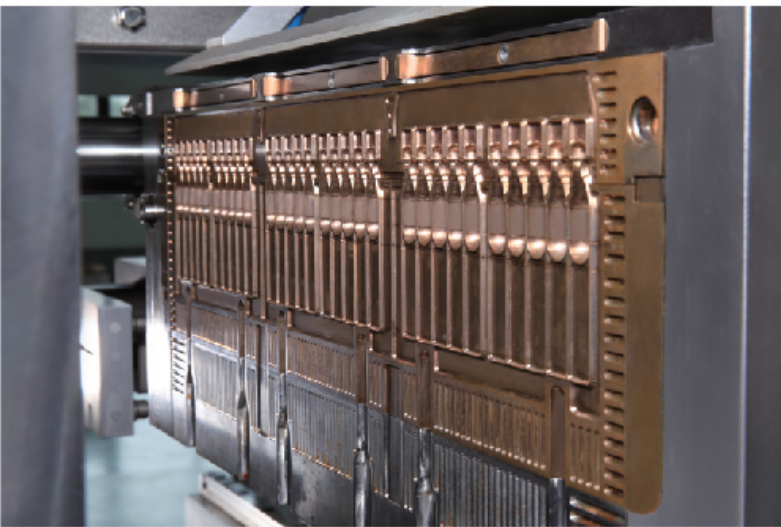
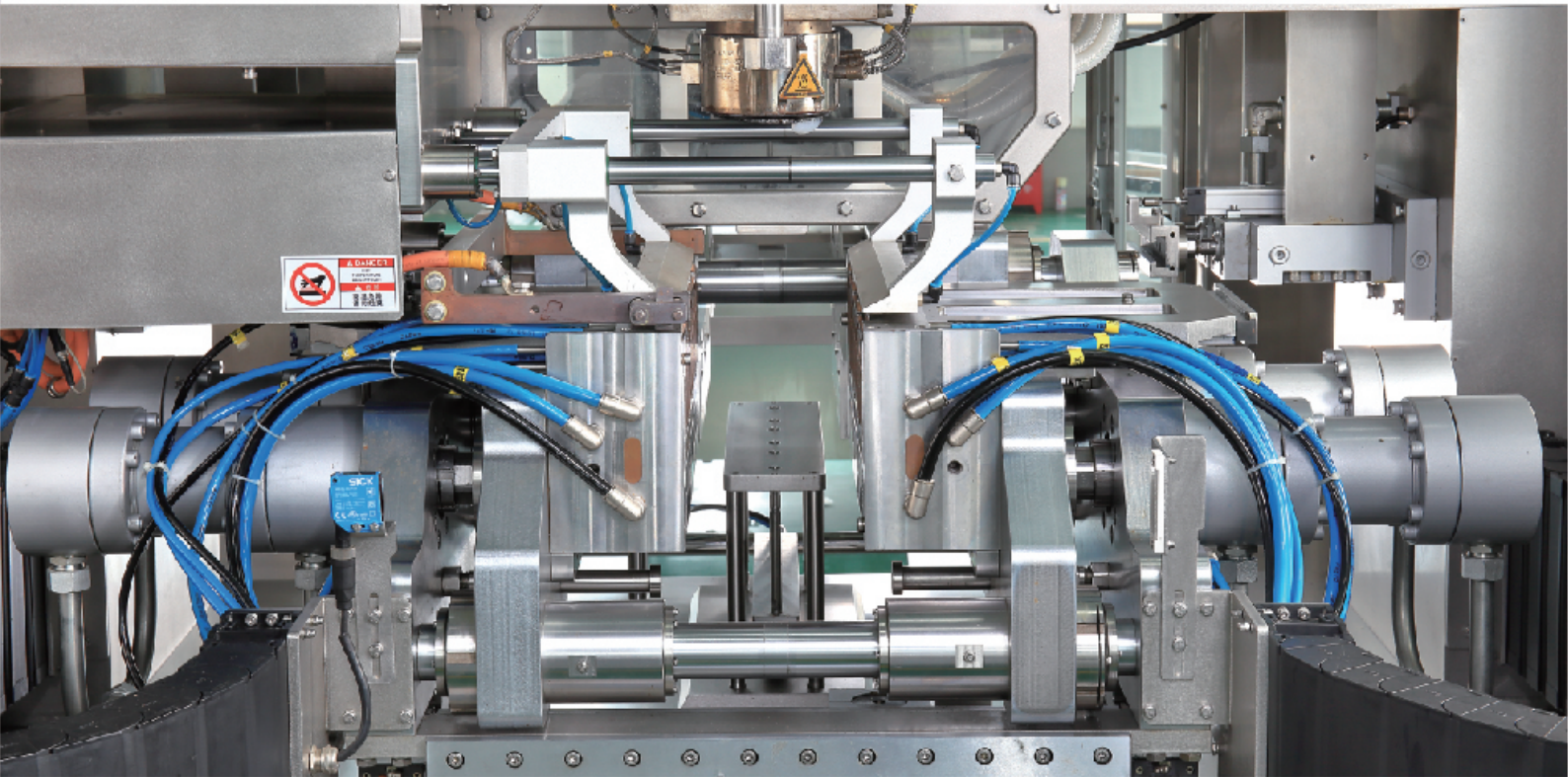
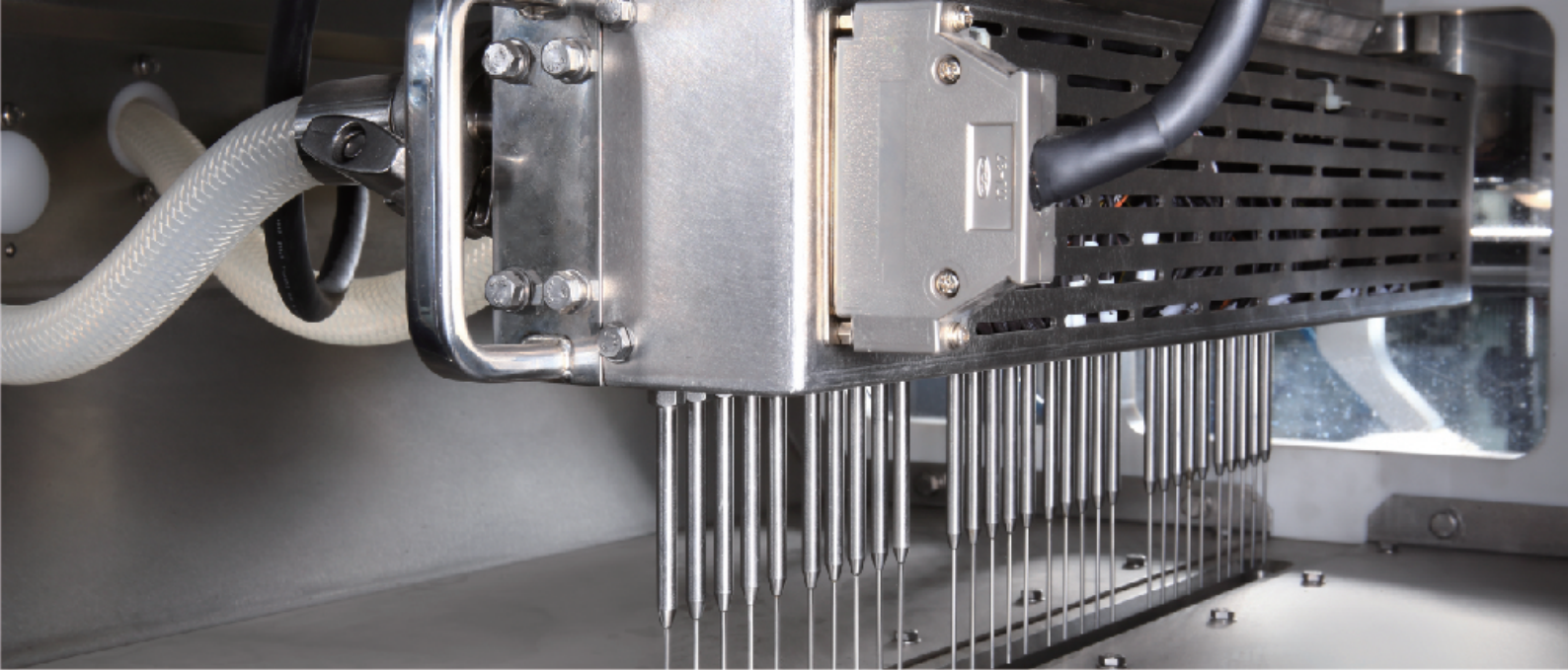
### Eye, Ear, Nose Care Products

传统的眼耳鼻护理产品为了保证药液在瓶盖打开以后有可控的保质期，通常需要添加防腐剂。而BFS设备生产的一次性使用定量安瓿瓶就避免了药液中防腐剂的使用，消除患者出现过敏反应的风险。

Old style optical, aural, nasal care products need adding preservative in order to assure a controllable shelf life after opening. Whereas no preservative needed for the disposable & quantitative ampoules produced by BFS machine. Therefore, there is no allergy risk for patients.

类别 Type	机型 Model	规格 Specification	挤出头数 No.of Extruding Heads	模具腔数分布 Distribution of Cavity	总腔数 Total Cavities	产能(单位:pcs/h) Capacity
SVP系列 小容量制剂	AFP1	0.4-2ml	1	1x ( 5+5 )	10	3000
		5-20ml	1	1x 6	6	1800
	AFP3	0.4-2mL	3	3x ( 5+5 )	30	9000
		5-20mL	3	3x6	18	5400
	AFP4	0.4-2mL	4	4x8	32	9600
		5-20mL	4	4x5	20	6000
	AFP3D	0.4-2mL	3	2x3x ( 5+5 )	60	15000
		5-20mL	3	2x3x6	36	9000
	AFP4D	0.4-2mL	4	2x4x8	64	16000
		5-20mL	4	2x4x5	40	10000

**备注** 其他特殊系列产品可根据客户要求定制化设计。  
**Note** Other special series products can be customized by customer's requirement





## AFP无菌塑料包装吹灌封系统(大容量制剂)

AFP Aseptic Blow-Fill-Seal System for Plastic Container Parenterals(LVP)



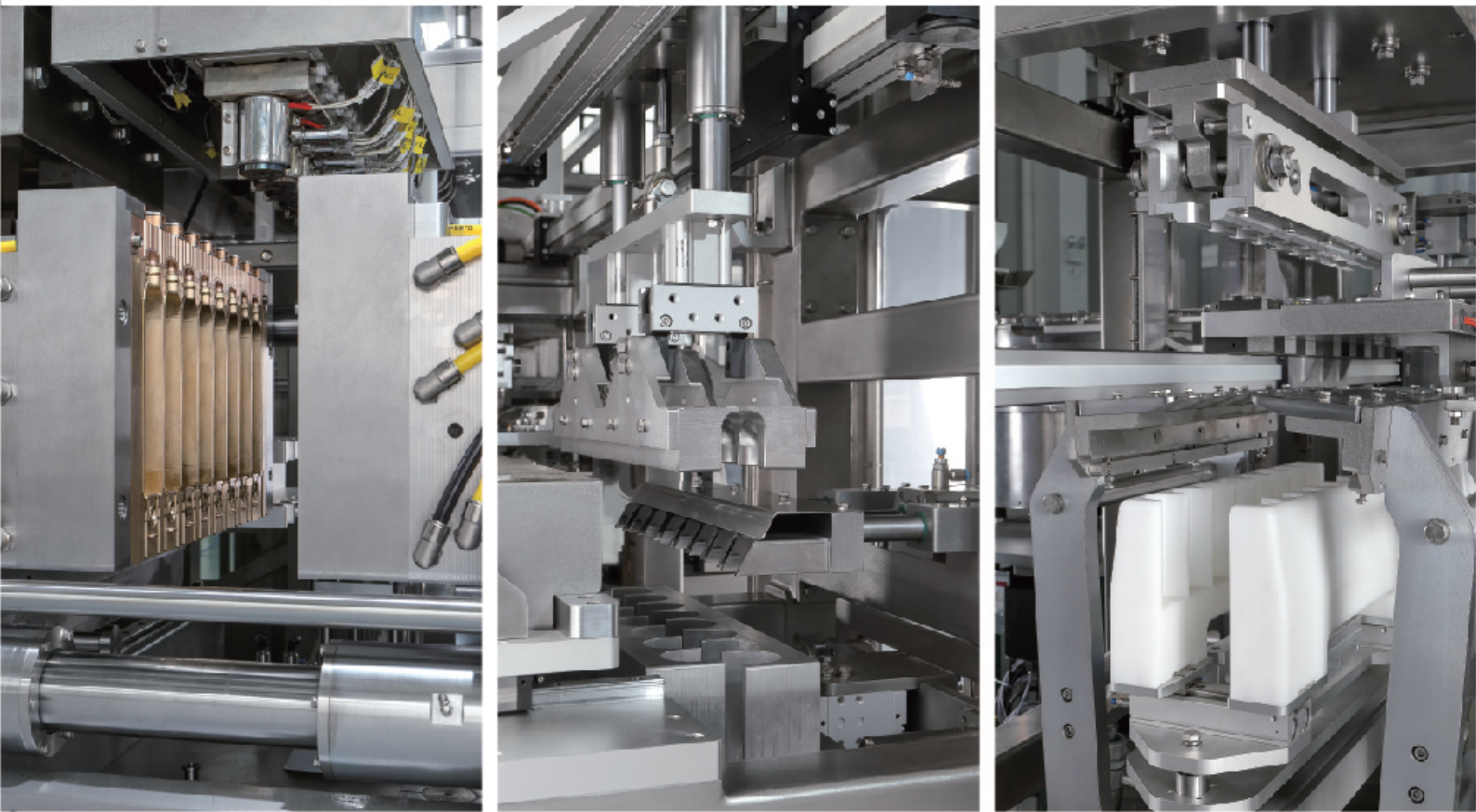


# LARGE VOLUME PARENTERALS(LVP)

## 大容量注射剂

塑料为大输液产品的使用者带来很多便利。一些不含添加剂的惰性塑料具有很低的渗透性, 在医院里使用非常安全,方便。这类塑料是符合 FDA 要求的。这类环保包装可降解或再生利用,不会导致环境污染。

Plastic materials provide several advantages to the producer and user of large volume parenterals. These plastic materials follow FDA regulations which are inert, no additives added, low water vapor permeability and safe to handle in hospitals. The packages are environmentally friendly, degradable and reusable without any pollution risks. The bottlepack technology makes production with such pure materials possible. No additional active additives are required.



类别 Type	机型 Model	规格 Specification	挤出头数 No.of Extruding Heads	模具腔数分布 Distribution of Cavity	总腔数 Total Cavities	产能(单位:pcs/h) Capacity
LVP系列 大容量制剂	AFPL6	500mL	6	6	6	1150
		1000mL	6	6	6	1080
	AFPL8	100mL	8	8	8	1950
		250mL	8	8	8	1800
		500mL	8	8	8	1550
	AFPL6D	500mL	6	2×6	12	2350
		1000mL	6	2×6	12	2160
	AFPL8D	100mL	8	2×8	16	4000
		250mL	8	2×8	16	3600
		500mL	8	2×8	16	3100

**备注** 其他特殊系列产品可根据客户要求定制化设计。  
**Note** Other special series products can be customized by customer's requirement



# MAIN ADVANTAGES OF BFS PLASTIC AMPOULE

## BFS塑料包装主要优势

与传统药品包装方式相比，BFS塑料包装的主要优势

Main advantages of BFS plastic ampoule comparing with the old style glass ampoule.

### 药液无针抽取

No needle extract medicine liquid.

### 手指不会割伤或刺伤

Finger won't be injure or stab wounds.

### 药液内没有玻璃、细菌或塑料颗粒

There are no glass debris,bacteria or plastic granule in medicine liquid.

### 操作过程中不会造成容器损坏

Operation process will not result in damage of the container.

### 储存及运输方便

Storage and transportation is convenient.

### 安全、无污染的废弃物处置

Waste treatment of plastic ampoule is safe and no pollution.

### 吹灌封一次成型，药液暴露时间短，污染风险小

Blow-Fill-Seal with once molded forming,shorter time for liquid exposure,low risk for pollutio.

# ASEPTIC PACKAGING PROCESS

## 无菌包装工艺

由于容器是在一台单机上成型、灌装并封口，整个工艺过程在无菌层流空气的保护下完成，所有的工艺介质（药液、空气等）均经除菌过滤，因此产品受到生产环境污染的可能性非常低；在整个工艺过程中容器开口时间暴露于生产环境中不足1.5秒，故三合一无菌灌装工艺成为了需要防止微粒及微生物污染的产品的首选。

As the container is made, filled and sealed within a single machine and protected by sterile laminar air, the chance of contamination is very remote. Moreover, during the whole cycle, all process media (solution, air & etc.) are previously sterile filtered and open containers remain exposed to the clean room air for less than 1.5 seconds. The Blow-Fill-Seal technology becomes the process of choice when contamination of particle and microbial are primary concerns in production.

AFP设备可自动完成系统的在线清洗（CIP）和在线灭菌（SIP）。针对包含过滤器在内的所有灌装管路、所有瓶胚支撑的无菌空气管路以及所有吹制成型和灌装缓冲罐无菌空气管路彻底的清洗和灭菌，以保持设备的无菌状态。同时可通过外置的过滤器完整性测试仪器进行完整性检测。

The AFP machine is designed to carry out automatic cleaning in place(CIP) and automatic sterilization in place(SIP) to clean and sterilize complete filling path,complete path of sterile air for parison,and path of air for blowing and buffer tank including filters for maintaining the sterile status of the machine.Additionally,integrity of the filter can be tested in place by attaching external integrity testing equipment.

产品所有工序都是在无菌条件下完成，产品不会暴露在有菌环境中。这种无菌、无颗粒、无热源的吹灌封技术被美国药典作为高效无菌生产工艺收载。

All these functions are accomplished under aseptic condition and products will not expose to any bacterial environment. This kind of Blow-Fill-Seal technology which operating without bacterial, particles nor pyrogen is highly recommended by USP.

## BLOW-FILL-SEAL TECHNIQUE

### 吹灌封技术

三合一（吹瓶-灌装-封口，简称BFS）无菌灌装技术是指在一台单机上，使之在完全受控的环境下完成包装容器的成型、药液的灌装和容器的封口的一项先进技术，其能使药品的包装及其内容物保持无菌状态。

The Blow-Fill-Seal Technique has been developed so that formation of the container, filling and sealing takes place in a single machine under a controlled environment that enables the packaging of a pharmaceutical liquid in an aseptic manner.

图为AFP® 系统生产注射剂时的主要工序。

The picture show the major phases in the integrated packaging of parenteral solutions using the AFP® system.



### 挤塑 Extrusion

用高速螺杆将热塑性材料连续挤压成管状，由无菌空气冲洗的管坯穿过成型模具。

With high speed screw rod, thermo-plastic material is continuously extruded in a tubular shape. Aseptic air blows to the plastic tube parison,and the parison goes through the forming mould.

### 吹瓶 Blowing

主模合并把管坯底部密封，切刀切断管坯，管坯顶部被开口的保持夹定位，无菌空气均需保护模具中敞口的管坯。

通过真空和或者无菌压缩空气按照设计的模具形状把塑料原料成型成容器。

The main forming mould closes and the bottom of plastic parison is sealed. The cutting knife cut the parison. The top of plastic parison is located by the open protecting clamp. Aseptic air continuously protects the open tube parison.

The plastic material is formed into containers as determined by the design of the mould by vacuum and/or aseptic compressed air

### 灌装 Filling

药液立即被灌装在容器里，并排除无菌空气。灌装系统采用时间压力法灌装，并配置有CIP/SIP。产品灌装过程中一直在无菌空气（相当于A级）的保护下进行。

The containers are filled immediately and the air in the container is displaced. In the filling process, the containers are protected by the aseptic air as Grade A.

### 封口 Sealing

在这个环节中，塑模顶部与开口保持夹之间的塑坯仍处在半熔化状态下，然后头模合并，形成容器的顶部，并使瓶子密封。

At the same time, the tube parison between top of plastic mould and the open protecting clamp remains semi-melting condition, and then the sealed mould closes and forms the top of the container and keeps the container sealed.

### 出瓶 Outfeeding

密封后，模具打开，灌装和密封的瓶子被送出机器，接着开始下一个循环。

After sealed, the mould is opened, and the containers are totally formed, filled, sealed and is ready to outfeed. Then the machine starts the next cycle.



# THE LAYOUT OF BFS WORKSHOP

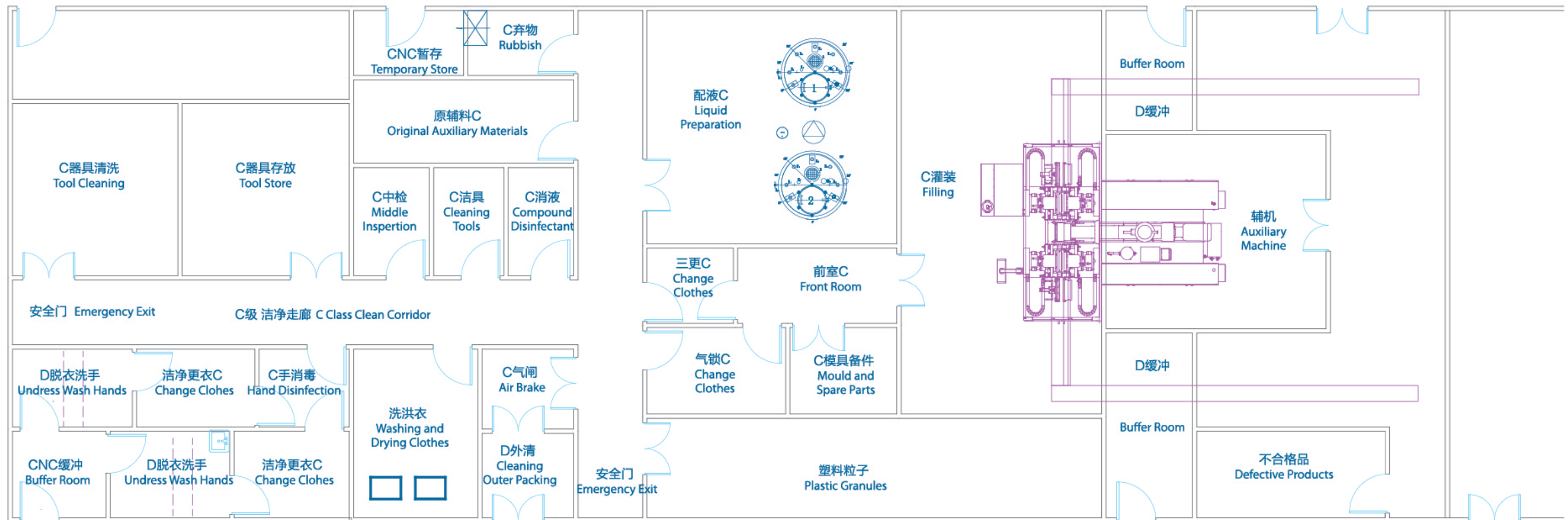
## BFS车间案例

上海位山科技同时可配套提供灭菌系统、灯检检漏系统、自动包装系统、装箱码垛系统、配液系统、水处理系统、空调净化系统和工程设计验证服务，提供完整的无菌塑料包装注射剂生产工艺系统化工程解决方案。

AFP®系列吹灌封设备具有严格的设计标准，友好的人机界面，低能耗，高产能，符合所有现行法规标准的要求！

We can also provide complete solution for our Aseptic Blow-Fill-Seal system consist of dynamic water shower sterilizer, automatic conveying system for sterilizing products, light inspection and electric spark inspection system, automated packaging systems and robotic stacking system.

AFP® Blow-Fill-Seal has strict design standards, operator-friendly interface, low equipment wear, high process repeatability and reliability, thus meeting all current pharmaceutical regulations of the health authorities.





# TOTAL SOLUTION

## 整体解决方案



## QUALITY ASSURANCE

### 质量保证

熟悉各国法规标准，拥有国际GMP先进理念。

集咨询、设计、制造、施工安装、自控、验证、服务、管理于一体。

拥有严格的质保流程，为客户提供完整的文件体系和验证服务。

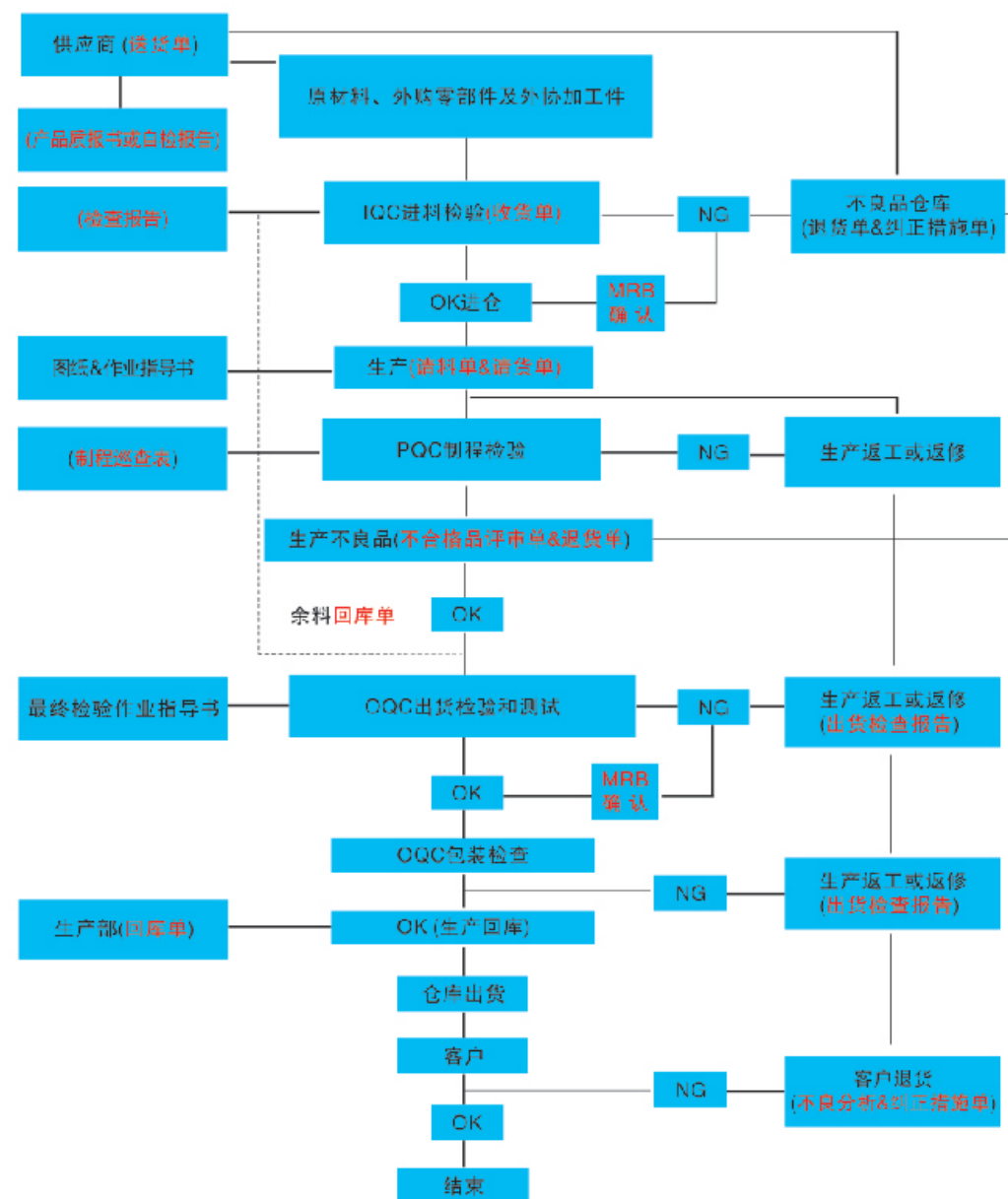
Match with international standards and regulations, FDA/EMA/WHO/EUGMP advanced concepts.

Total solution for consulting, designs, manufactures, installations, controls, verifications, services and managements.

Best quality assurance to provide complete documentation and verification service for customers.



## 检验流程 INSPECTION PROCESS



## GOOD AFTER SERVICE 售后服务

售后服务是我们与全球用户进行沟通的重要环节，以此实现高水平的客户满意度和建立长期的客户关系。我们保证安全快速地提供产品备件。高素质、经验丰富、上进心强的售后服务团队能够为客户提供安装、调试、培训服务。

After sales service is an important link with our customers throughout the world. High levels of customer satisfaction as well as lasting customer loyalty are our top priorities. Ensuring fast and safe delivery of replacement parts is an important element of our service. Our after sales service provides comprehensive services through highly qualified, professional, experienced and highly motivated staff.

