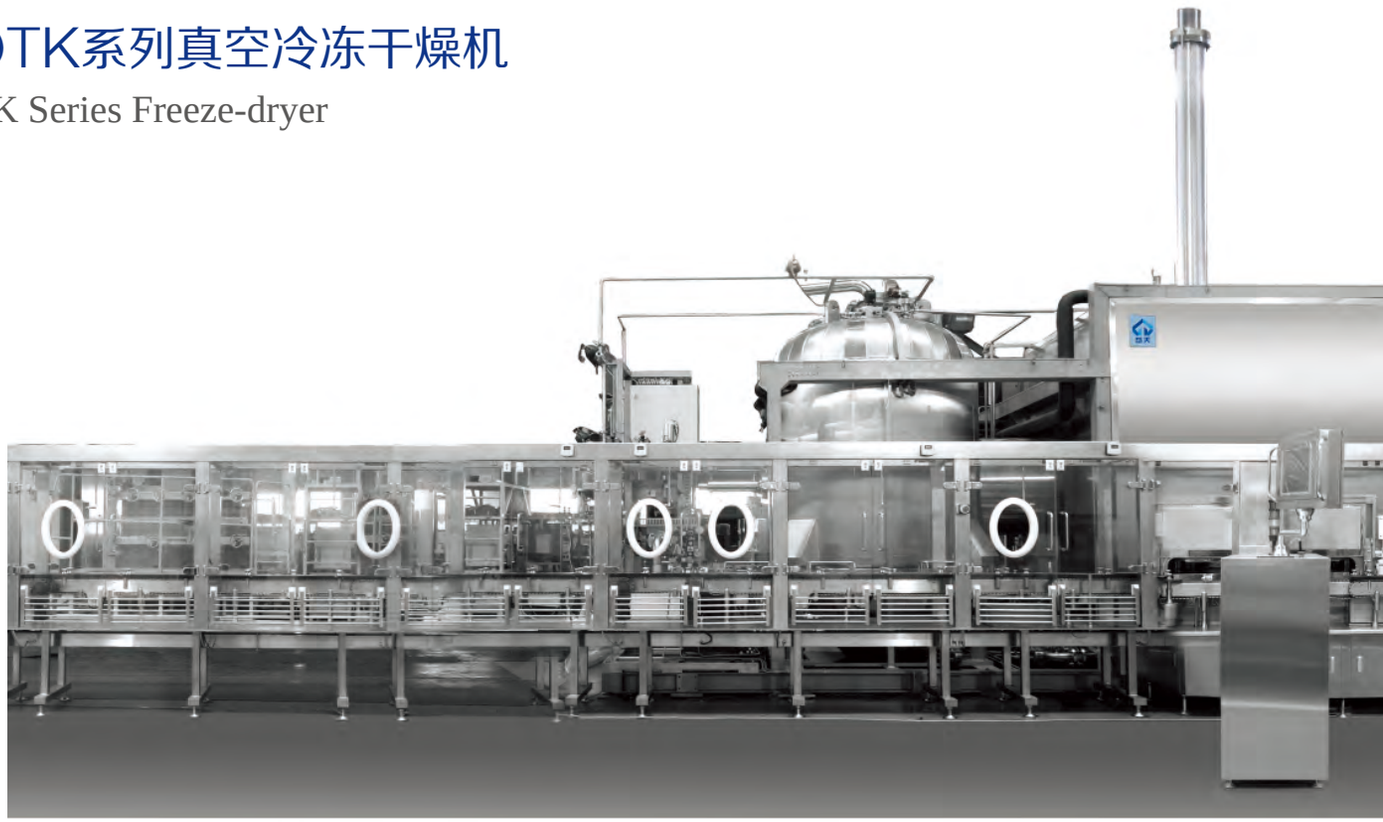
LYOTK系列真空冷冻干燥机

LYOTK Series Freeze-dryer



主要用途 Main application

真空冷冻干燥机主要用于生物制品、化学制品、瓶冻（冻干注射剂）、盘冻（原料药）、天然药物、热敏性药物、抗菌素、口服冻干片剂等制药领域，实现冻干过程，达到干燥目的。

The Freeze dryer is mainly used for the lyophilization of the following products and industry, to dry these products, such as: biological products, chemical products, vial freeze drying, API freeze drying, natural medicine, heat sensitivity products, antibiotics, oral liquid lyophilized tablets etc.

主要技术参数 Main technical parameter

产品系列 Model	主要用途 Main application	板层面积 Shelf area	最大凝冰量 Max ice rate	制剂冻干批次装量 Injectable lyo batch qty
LYOTK	中试冻干生产及 大规模工业化冻干生产 Middle & Large Scale production	1㎡-40㎡	20Kg-800Kg	22mm抗生素瓶 2000-80000支 22mmvial 2000-80000pieces 16mm抗生素瓶 4500-162000支 16mmvial 4500-162000pieces
LYOTK LAB	科研实验室进行冻干实验 R & D	0.2㎡-1㎡	4Kg-20Kg	22mm抗生素瓶 400-2000支 22mmvial 400-2000pieces 16mm抗生素瓶 800-4500支 16mmvial 800-4500pieces

注：上表中产能与规格成反比关系，即规格越大，产能越低。具体以投标书描述为准。
Note: In above table, output is reverse to specification. That means smaller specification, larger output.

性能特点 Characteristics

楚天LYOTK系列及LYOTK LAB系列真空冷冻干燥机是为实现高效及经济的冻干工艺而开发的。设计时考虑了最大的冻干产品安全性，适用于各种高价值的冻干产品处理。同时也完整的考虑了操作人员安全及环境安全。通过冻干机产品设计的多样性及稳定性向客户提供更长的设备使用周期。

真空冷冻干燥机可以为用户提供基于稳定质量基础上的多种技术及商务选项，由此客户可根据自己的需要在多种选项中选择配置适用于自己工艺的真空冷冻干燥机。

真空冷冻干燥机是基于多种被证实了的实用技术而设计的，选用高品质且广泛被制药工业接受的原材料及元器件。在制造工艺方面也大量采用了先进的工艺技术，可以保证设备能够完全满足新版GMP标准或EU cGMP、USFDA、WHO等标准的要求。

LYOTRUKING has been developed to ensure an effective and efficient freeze drying process. It is recognized that the products handled inside a freeze dryer may have a high value hence LYOTRUKING freeze dryers are designed to ensure maximum product security. The design also ensures operator and environmental safety whilst being versatile, reliable and providing a long working life.

TRUKING' LYOTRUKING range of freeze dryers adopts a robust base specification that the user may configure to their own needs by selecting from a wide range of options. Through the use of standard modules the LYOTRUKING range enables manufacturing costs and lead times to be reduced whilst ensuring a high level of performance and reliability.

The LYOTRUKING freeze dryer design is based on the use of proven technology, using high quality materials and components which are accepted in the pharmaceutical industry. A high level of manufacturing skills are adopted to produce a LYOTRUKING freeze dryer, making in a machine that is in full compliance with Good Manufacturing Practices (cGMP-standards).

系统构成
SYSTEM Coposition

箱体
CHAMBER

- 箱体采用方形结构，箱体所有被加工面和孔采用先进加工装备一次成型，达到当前国际先进水平；
- 采用R>20㎜的大圆角结构；
- 箱体底部单角倾斜更有利排水；
- 所有内部材料采用316L材料；
- 内表面抛光至镜面<0.4mRa。

- The chamber is square shape. All the surface and holes to be processed of the chamber adopts advanced processing equipments to process at one time;
- The internal corners of rectangular chambers have a radius >20mm ;
- The floor of the chamber is pitched in two planes to ensure drainage;
- Wetted surfaces are made from AISI 316L stainless steel ;
- The internal surfaces of the chamber are mechanically polished to mirror polish <0.4mRa.

箱门
CHAMBER DOOR

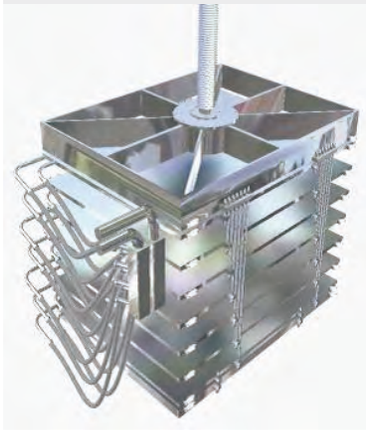
- 箱体上装有主门及装料小门；
- 主门上装有D型密封圈保证密封良好；
- 伺服驱动滑动小门保证装载是最小开度并可与自动进出料系统配合使用；
- 特殊的铰链设计保证主门的轻松开启；
- 全自动主门锁定系统。

- Main door and slot loading door assembled with the chamber;
- D-form gasket has been installed for main door sealing ;
- Servo motor drive sliding slot door to insure the Min open during loading and it can working together with the automatic loading unloading system;
- Special hinge design to ensure the Main door move easily;
- Automatic Main door locking system.

冷阱
CONDENSER

- 根据客户的需求，冷阱可以设计为立式或卧式，并可被安装在箱体的侧部、后部或底部；
- 采用蘑菇阀设计以达到最佳的水蒸气流动及捕冰均匀性；
- 冷阱盘管表面积与板层面积1:1，以保证在大量升华时冷阱的强有力运行。

- The Ice Condenser of Lyotruking can be designed as a vertical type or a horizontal type, also it can be placed on the side/back/ bottom of the chamber depends on the customer's plant layout;
- Mushroom valve design for best vapour flow and ice distribute;
- Condenser coil surface area design based on 1:1 with the shelf area.



板层
PRODUCT SHELVES

- 板层由AISI 316L 不锈钢制成；
- 采用特殊的内焊法，保证良好的板层平整度及密封性；
- 采用带编织网的316L不锈钢软管；
- 表面抛光至0.4 - 0.6mRa并做钝化处理；
- 单板及板层组件的氦质谱泄露测试以保证无泄漏。

- The shelves are manufactured from AISI 316L stainless steel;
- Special "internal welding" technology to ensure the flatness and sealing of the shelf;
- 316L hoses with mesh cover;
- Surface polishing finish within the range of 0.4 - 0.6mRa and passivated;
- Helium leak test for every shelf and shelf stack to ensure no leakage.

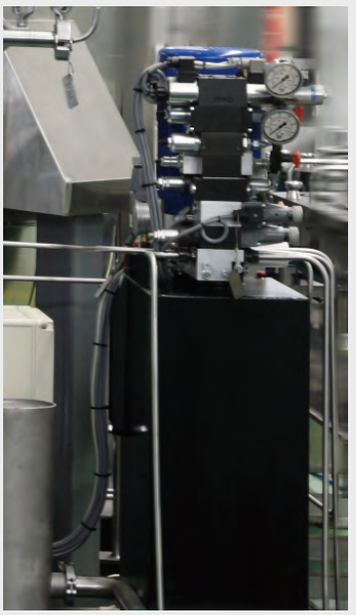
系统构成
SYSTEM Coposition

制冷系统
REFRIGERATION SYSTEM

- 制冷系统的良好设计和组装可以保证药品周期的指标性能可靠实现；
- 压缩机使用R507 或R404A环保制冷剂；
- 每个制冷循环都可以为板层及冷阱分别供冷；
- 所有关键元器件均采用世界知名品牌；
- 可以提供良好的低温性能及最小的泄露风险；
- 螺杆式压缩机可以作为选项提供以替代活塞式压缩机；
- 电子膨胀阀可以作为选项提供以替代热力膨胀阀。
- The refrigeration system is designed and assembled properly to ensure the specified index performance is achieved reliably;
- Each compressor has a discrete circuit adopting either R507 or R404A HFC refrigerants;
- All refrigeration circuits are configured to be able to serve either condenser or shelf cooling;
- All the key components are worldwide brand;
- Providing good low temperature performance and minimising the risk of leakage;
- Screw compressor can be supplied as an option instead of piston compressor;
- Electronic expansion valve can be supplied as an option instead of thermo expansion valve.

真空系统
VACUUM SYSTEM

- 真空系统由世界知名品牌的真空泵及元件组成；
- 如有必要，可提供罗茨增压泵；
- 用于半导体工业的干式真空泵可以作为选项提供以替代普通油封旋片式真空泵；
- MKS电容式真空规可以作为选项提供以取代传统的皮拉尼式真空规；
- 比例掺气阀可以作为选项提供以替代传统的开关式真空控制。
- The vacuum system for the freeze drying process is using worldwide brand name vacuum pump(s) and components;
- Booster pump can be supplied if necessary;
- Dry pump which normally be used for semiconductor industry can be supplied as an option instead of normal two stage, oil sealed, rotary vane vacuum pump;
- The MKS Capacitance type vacuum gauge can be supplied as an option instead of normal Pirani gauge (for chamber vacuum only);
- A proportionally modulated gas admission valve can be supplied as an option instead of normal on/off control.



液压系统
HYDRAULIC SYSTEM

- 液压系统采用欧洲原装品牌配置；
- 提供316L波纹管以覆盖压塞油缸杆，并提供自动完整性测试功能；
- 对于自动进出料的冻干机，楚天提供板层自动定位液压系统；
- 配备板层“自动提升”功能以防止冻干周期中的板层下滑。
- Europe hydraulic units has been used for Lyotruking
- AISI 316L bellows will cover the hydraulic stopping cylinder and with automatic integrate test function
- Automatic shelf positioning hydraulic system can be supplied as an option for auto loading unloading machine
- Automatic “shelf up “ system will be supplied to prevent the shelf drop down during the cycle

循环系统
CIRCULATION SYSTEM

- 循环系统主要元器件均采用欧洲品牌配置；
- 5CST 的美国进口硅油用来做导热介质；
- 全焊接的结构将硅油泄露的风险降到最低。
- For Lyotruking circulation system key components, Europe components has been used;
- 5 Cst USA silicone oil is used for working as a heat media;
- All weld design to minimum the leak risk of the silicone oil.

系统构成
SYSTEM Composition

在位清洗及在位灭菌系统
CIP/SIP SYSTEM

- 在位清洗系统由一系列安装在箱体及冷阱内部汇流管道上的固定和旋转喷嘴构成；
- 所有喷嘴及管道为AISI316L/316不锈钢材质；
- 所有工艺阀门为带反馈的洁净隔膜阀；
- 可以提供双清洗水（纯水及注射水）入口作为选项；
- 压力容器可以承受128°（1.6barg）的蒸汽消毒；
- 完善的安全互锁可以保证灭菌周期的安全进行；
- 无菌过滤器可以和箱体冷凝器系统一起消毒，同时具备不同的完整性测试的选项。

- A series of fixed and rotary spray nozzles mounted on distributing manifolds positioned within the chamber and condenser;
- The nozzles and manifolds are fabricated from AISI 316L /316stainless steel;
- All the processing valves are feedback sterik diaphragm valve;
- Two water media(PW&WFI)inlet can be provided as option;
- Pressure vessels can bear sterilization of 128℃(1.6barg);
- Sterile filter can be SIP together with the chamber and condenser, also with different option for integrate test of the filter;
- The CIP and SIP process is initiated through the LyoTruking SCADA control system and is operated automatically by the PLC.

CIP清洗站
CIP cleaning station

- 自动控制本地设备，执行CIP和SIP功能；
- 在冻干机上执行远程组合控制；
- 手动控制存储罐注水和管道排水过程；
- 降低公用设施的压力，并向多台冻干机提供CIP水源。

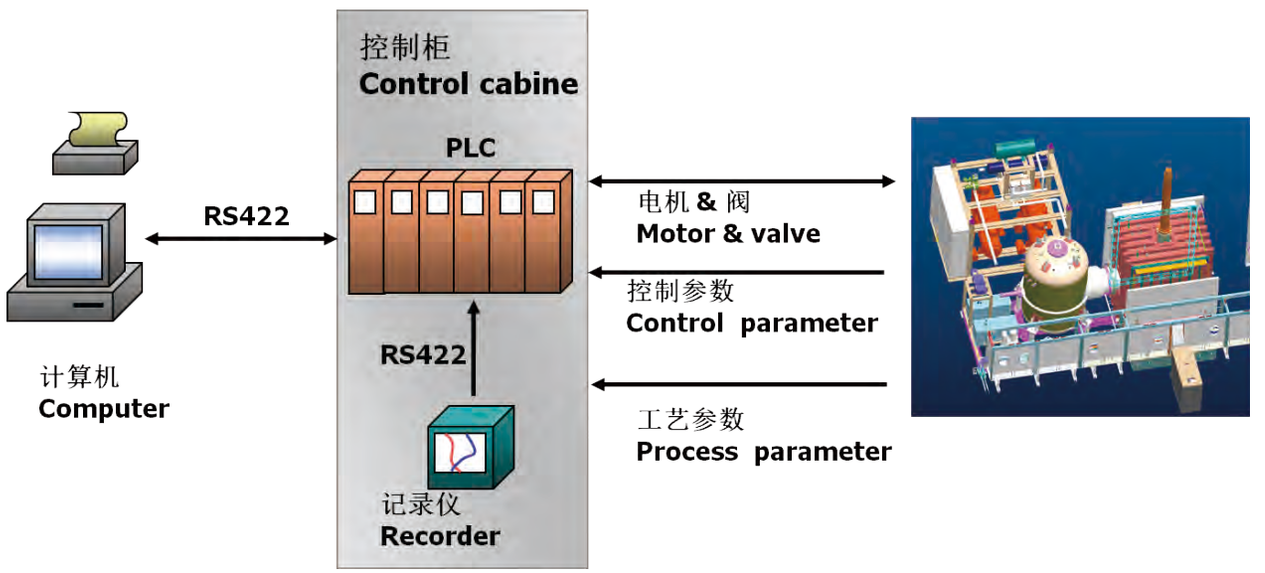
- Auto control the local equipment, to implement the CIP, SIP;
- Implement remote composite control on lyophilizer;
- Manual control buffer tank for water inlet and drainage;
- A CIP station system can be supplied as an option for reduce the utility duty, also can service for servral freeze dryer.

冻干机CIP清洗罐

控制及文件系统
CONTROL & DOCUMENTATION SYSTEM

- SCADA控制系统是基于PLC+PC的架构；
- 使用世界知名品牌PLC及其它控制元件；
- 完全符合FDA 21CFR PARTS 11的要求；
- 可以实现LYOTK系列冻干机的所有周期控制功能；
- 提供打点式记录仪作为周期数据的硬拷贝存储；
- 电子签名及批次报表功能；
- 配方编辑及监控功能；
- GAMP5的文件体系作为选项可以替代新版GMP标准的文件体系，确保产品质量的可追溯性。

- LYOTRUKING SCADA control system is based on the PLC+PC configuration;
- Worldwide brand PLC and others control components can be used;
- Fully follow the FDA 21CFR PARTS 11 requirement;
- Fully automatic control for all the of the LYOTRUKING machine;
- Chart record can be supplied for hard process data record copy;
- E-signature and batch report function can be supplied;
- Recipe edit and monitor function;
- Complete documentation system can fully compliance the cGMP requirement and GAMP5 requirement;
- GAMP5 documentation system is used as option instead of new version GMP documentation,to ensure the product quality traceability.



LALUTK系列自动进出料系统

LALUTK Auto Loadong Unloading System

主要用途 Main application

主要用于抗生素瓶半加塞药品从灌装加塞机至冻干机、冻干机至轧盖机之间无菌传输与联接，具有先进的整体集成化进出瓶机构，完全实现人员隔离状态下的产品自动转运。

It is mainly used for transferring of the half stoppered vials from filling machine to lyophilizer, the sterile transferring from lyophilizer to capping machine, with advanced integrated infeed and outfeed structure. It can realize the product automatic transferring without operator.

性能特点 Characteristics

- 提高产品无菌保障水平，降低生产质量控制风险；
- 减少无菌室人员，从而减少室内微生物负荷；
- 采用集成控制系统，实现进出料系统与冻干机、灌装线和轧盖机的控制互锁；
- 完整的电气安全回路，可靠的检测数据分析与报警功能；
- 人性化操作界面，灵活的控制模式，可编辑生产配方，可追溯完整操作记录。

- It can improve the product sterile assurance level, reduce the product quality control risk;
- Reduce the operators in sterile room, and reduce the microbe load in the room;
- Adopt integrated control system, to realize the interlocking between loading and unloading system, filling machine and capping machine;
- A complete electric safety circuit, reliable detecting data analysis and alarm function;
- User friendly HMI, flexible control model, editable production recipe, and traceability operation record.

主要技术参数 Main technical parameter

机型与产能 Model & Capacity		LALUTK-06	LALUTK-09	LALUTK-12	LALUTK-15
抗生素瓶规格（直径x高度）Vial size(Body Diax height)	2ml(φ16×35)	12000 pcs/h	18000 pcs/h	24000 pcs/h	30000 pcs/h
	10ml(φ22×49.7)	11000 pcs/h	15000 pcs/h	21000 pcs/h	25300 pcs/h
	20ml(φ27×58)	7000 pcs/h	10000 pcs/h	12000 pcs/h	20000 pcs/h
	30ml(φ32×70)	5500 pcs/h	7200 pcs/h	9000 pcs/h	16500 pcs/h
	50ml(φ42.5×73)	/	/	5000 pcs/h	/
	100ml(φ51.6×94.5)	/	/	3000 pcs/h	/

注：上表中产能与规格成反比关系，即规格越大，产能越低。具体以投标书描述为准。
Note: In above table, output is reverse to specification. That means smaller specification,larger output.

进料对接系统
Infeed joint system

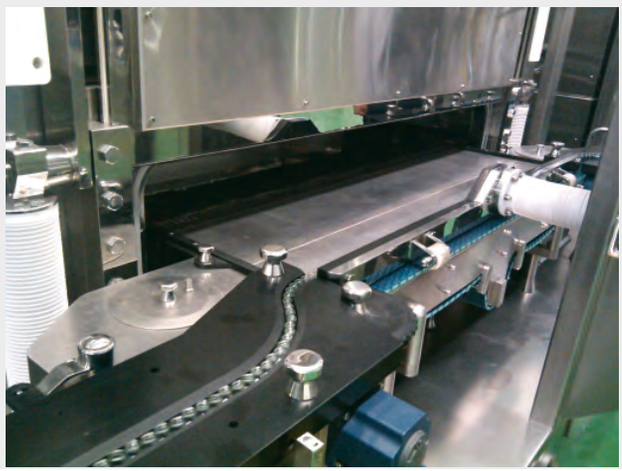
- 配置进料过渡集成传送带，灵活的实现与上游设备对接；
- 高效、便捷的瓶子缓冲方式，实现灌装速度与冻干机进料速度匹配；
- 机械部件层流保障设计，清洗卫生设计，无卫生死角。

- Equip infeed transit integrated conveyor belt, to joint with the upstream machine flexibly;
- High efficiency and convenient buffer for vial to realize the filling speed match with lyophilizer infeed speed;
- Mechanical parts has good LAF assurance design, and good cleaning design without cleaning deadleg.

前推杆进料系统
Front pusher system

- 灵活的进料控制，实现抗生素瓶进入板层；
- 完整的推杆位置安全监测；
- 进料方式有：单排进入、多排部分进入、多排整体进入

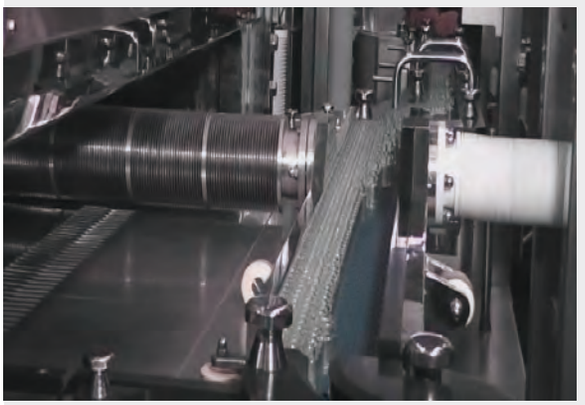
- Push the vials in to chamber;
- With flexible control integrate pusher position safety monitoring;
  Infecd method by Row loading;
- Row by Rows loading;
  Full Pack loading.



后推杆出料系统
Back pusher system

- 多模式动作控制，实现出料推杆的控制数据安全传递；
- 出料推杆的充气密封专利结构；
- 完整的推杆位置安全监测。

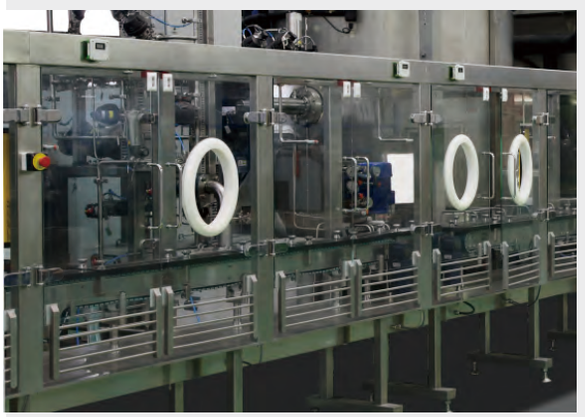
- Multi model action control, to realize the control date safety transfer for outfeed pusher;
- Pressurized sealing patent structure for the outfeed pusher;
- Integrated pusher position safety monitoring.



出料系统
Outfeed system

- 配置出瓶轨道小瓶流动检测；
- 出料过渡集成传送带，实现与轧盖机有效整合对接。

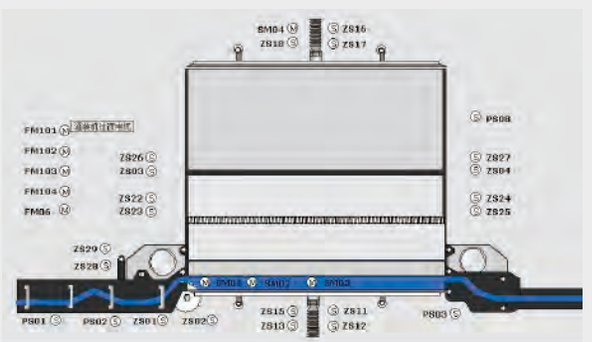
- Equip with vial flowing detection device for the outfeed;
- Outfeed transit integrated conveyor belt, to realize the joint with capping machine.



无菌隔离系统
Sterile isolation system

- 可选择配置ORABS系统或CRABS系统；
- 配置有防护门安全开关、急停按钮，钥匙开关等安全部件。可选项包括：层流装置、在线尘埃粒子监测、在线风速监测、沉降菌与浮游菌采集、安全光幕等。

- ORABS and CRABS system are on option;
- It can be equipped with: safety door sensor, emergency button, key locker etc;
  Options are as follows: LAF device, on line particle monitoring device, on line velocity monitoring, viable and non viable collecting, optical sensor.



控制与文件系统
Control and documentation system

- 友好的人机界面，基于世界知名品牌的PLC及运动伺服控制系统，在无菌室内操作；
- 与冻干机的数据传输及共享，并与灌装加塞机及轧盖机的实时联动运行；
- 具有批次记录功能、错误恢复功能；
- 与RABS等隔离系统的控制整合；
- GAMP5的文件体系作为选项可替代新版GMP的文件体系，确保产品质量的可追溯性。

- User friendly HMI, using world brand PLC and motion servo control system, operation in the sterile room;
- Data transferring and sharing with lyophilizer, and interlocking with filling machine and capping machine;
- Batch number record function, error recover function;
  Integration with RABS and other isolation system;
- GAMP5 documentation system is used as option instead of new version
- GMP documentation, to ensure the product quality traceability.