TRUKING

Blow-Fill-Seal Solution

吹 - 灌 - 封（BFS）解决方案

www.truking.com

让世界制药工业插上智慧的翅膀

Equip global pharmaceutical manufacturing industry with intelligent wings.

TRUKING

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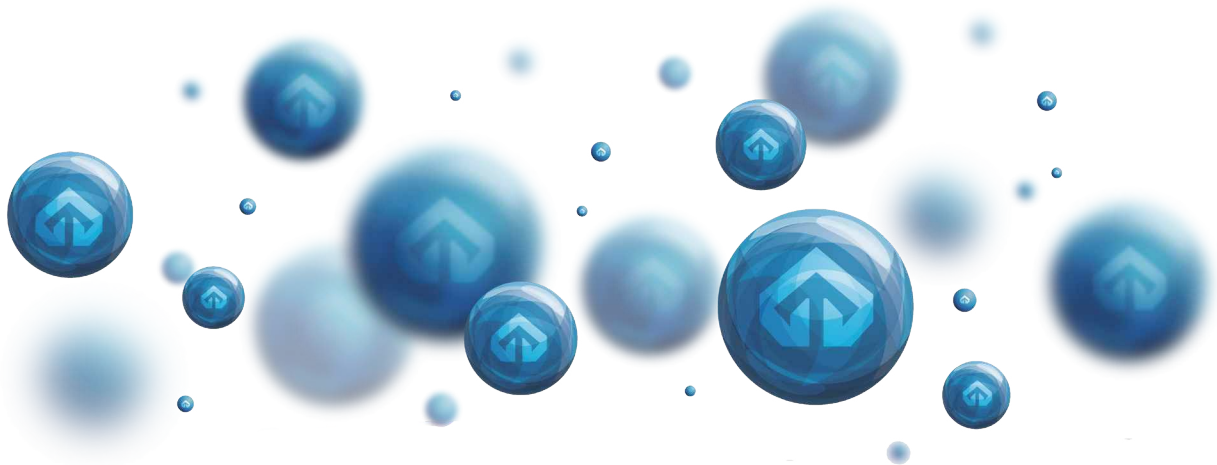


TRUKING

公司简介 Company Profile

楚天科技股份有限公司成立于2000年，是中国医药装备行业的领军企业，也是世界医药装备行业的知名企业之一。主营业务系医药装备及其整体技术解决方案，并率先推动智慧医药工厂的研究与开发。公司系中国A股上市公司。旗下拥有德国ROMACO集团、楚天华通、四川省医药设计院、楚天飞云、楚天源创、楚天微球、楚天思优特、楚天思为康、楚天华兴、楚天长兴、楚天科仪、楚天净邦、楚天派特、楚天博源、楚天新材料、楚天智能机器人等十多家全资或控股子公司，全球员工总数9000余人，总资产110亿元。

公司已有长沙和德国两大运营总部，建有长沙中央技术研究院、欧洲技术研究院和四川省医药设计院等研发机构。设有国家级企业技术中心，国家级创新基地，博士后科研工作站，院士专家工作站等多个技术与创新平台。截至2023年12月31日，共提出5466项中国专利申请，授权专利4313项，有效专利3090项。另提出54件PCT国际专利申请，在美国、俄罗斯、印度、韩国、德国、印尼、日本、欧洲等多国获得26项专利授权。牵头制订了本系统国家行业产品技术标准20多项。集团产品与服务已累计覆盖180多个国家和地区，国际市场占有率正逐年快速提升。

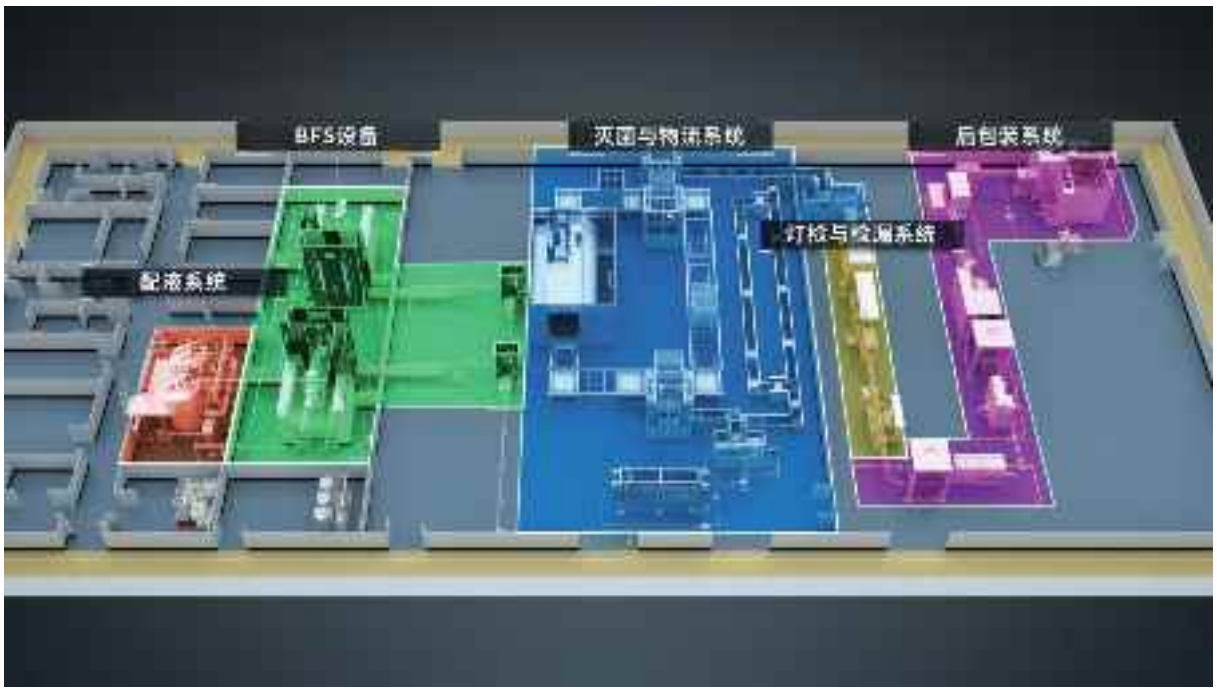
Founded in 2000, Truking Technology Limited has become a leading pharmaceutical equipment company in China and renowned worldwide. The company specializes in pharmaceutical equipment and integrated solutions and takes the initiative to push forward the R&D of smart pharmaceutical factories. It is a listed A-share company with multiple wholly-owned or holding subsidiaries, such as Germany-based Romaco Group, Truking Watertown, Sichuan Pharmaceuticals Design Institute, Truking Feiyun, Truking Ingenuity, Truking Micro-Sphere, Truking SUT, Truking Gene, Wachine, Truking Changxing, Truking Scientific Instrument, Truking Jingbang Engineering Technology, Truking Pitide Biotechnology, Truking Boyuan Intelligent Technology, Truking New Material, Truking Intelligent Robot etc. Truking has over 9000 employees around the globe, with a total asset of over 11 billion RMB.

Truking has two operational headquarters in Changsha, China, and Germany, with research and development institutions including Changsha Central Technology Research Institute, Europe Technology Research Institute, and Sichuan Pharmaceuticals Design Institute. It has established many platforms for technology innovation, such as the National Enterprise Technology Center, National Innovation Center, Post-Doctoral Scientific Research Station, and Academician Expert Workstation. By December 31, 2023, a total of 5,466 patent applications from China have been submitted, with 4,313 patents granted and 3,090 patents currently in force. Additionally, 54 PCT international patent applications were filed, resulting in 26 patents granted in multiple countries including the United States, Russia, India, South Korea, Germany, Indonesia, Japan, and Europe. The company has led the development of over 20 national industry product technical standards for this system. The products and services of the group have now reached over 180 countries and regions, with its international market share steadily increasing year by year.

吹 - 灌 - 封工艺概述 / Overview of blowing-filling-sealing process

楚天科技 BFS 整体解决方案由 BFS 设备、配液系统、灭菌与物流系统、灯检与检漏系统、后包装系统以及集中控制与调度系统六大核心功能模块组成。以高效节能的工艺装备系统为基础，信息化系统为核心，自动化物流为纽带，实现 BFS 产品高效，高质，安全生产。

Truking BFS turnkey solution consists of six core functional modules: BFS equipment, liquid distribution system, sterilization and logistics system, lamp inspection and leak detection system, post packaging system and centralized control and scheduling system. Based on high efficiency and energy saving process equipment system, information system as the core, and automatic logistics as the link to achieve high efficiency, high quality BFS products, safe production.



工艺流程 / BFS Technical Process

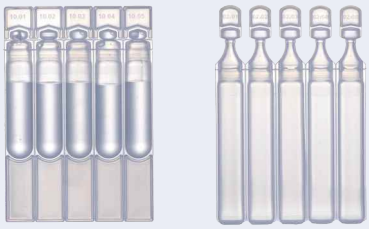
挤塑 Extruding	螺杆将粒子塑化连续挤出通过模头形成管坯。管坯内有无菌空气支撑。塑料热融和挤出的温度为170~220度，是经过实证的无菌挤出和去热源工艺。 The Parison is melted and plasticized by extrusion screw and formed by extrusion head. The Parison is supported by sterile air. The temperature of plastic melted and extruded is 170~220 degrees
成型 Blowing	主模具合拢，通过真空和 / 或无菌压缩空气按照模具的形状，把塑料原料成型容器。 The Parison is formed into container by vacuum and the sterile compressed air according to the mold shape when the main mold closing.
灌装 Filling	通过时间压力法将药液灌装至容器里，并排出无菌空气。药液经过的管路在灌装之前进行在线 CIP 和在线灭菌 SIP，确保药液安全性。 Adopting Time-pressure methods to fill. Before filling, the line can be CIP & SIP to ensure the safety of liquid.
封口 Sealing	灌装结束后，将封口模具合闭，形成容器的顶部，并使瓶子密封。 After filling, the sealing mold is closed to form the top of the container and the bottle is sealed.
出瓶 Outfeeding	瓶子封口结束后模具打开，已经完成成型、灌装并密封的瓶子被送出机器，进行切边。 After sealing, the mold will be opened. The bottle will be transported to punching machine for separating the product and waste.

BFS 产品应用领域 / Application Fields

注射剂
IInjectable

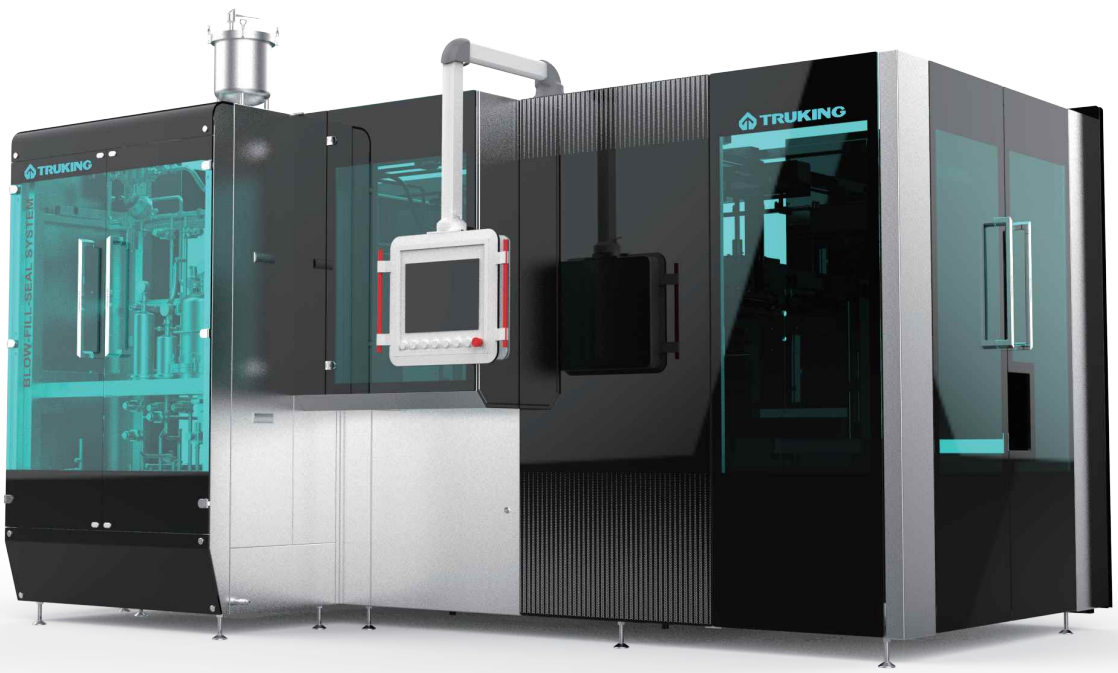
滴眼剂
Ophthalmic

吸入制剂
Inhalation



次抛
Disposable

往复式吹灌封（BFS）设备
Shuttle Type BFS Machine



主要用途 / Main Application

吹灌封技术即吹瓶 (Blow)- 灌装 (Fill)- 封口 (seal), 简称 BFS。该技术是通过在一台设备连续运行的工艺中，模具在挤出工位和灌装工位往复运动，完成对产品的成型、灌装和封口，所有这些工序都是在无菌条件完成的，整个循环在 12~14 秒以内完成。

BFS 技术在国际上已经使用了约 40 年，经验证污染率能够达到 0.1% 以下，结合培养基灌装数据的总结与分析，BFS 系统的污染率为 0.001%。

Blow-fill-seal technology referred to as BFS. The technology is to complete the forming, filling and sealing of the product by reciprocating the die in the extrusion station and the filling station in a continuous operation process of one piece of equipment, all of which are completed under aseptic conditions , the whole cycle is completed within 12~14 seconds.

BFS technology has been used for about 40 years in the world, and it has been proved that the contamination rate can reach less than 0.1%, Based on the summary and analysis of the media filling data, the contamination rate of BFS system is 0.001%.

性能优势 / Performance & Advantages

◎ 设备产能：

往复式 BFS 设备稳定产能 24000pcs/h (2mL), 为国内 BFS 设备最 大稳定产能，技术成熟，稳定可靠。

◎ 挤出系统：

欧洲研究院设计，精密加工模头，伺服驱动，管胚动态排气补气，保证挤出系统的稳定性。容器壁厚均一性 ±0.05mm。

◎ 成型系统：

模具开合模和封口模具开合模采用伺服液压系统进行 PID 闭环曲线控制，减少设备的冲击和震动，避免模具磨损。伺服摆动油缸驱动高速移模，降低容器敞口暴露的风险。

◎ 灌装系统：

时间压力法灌装，采用高频响电磁阀岛控制装量。配置自动废瓶识别技术，混悬液产品均一性偏差 ±0.5%，残氧量＜ 1%

◎ 成型模具

模具制造中心精密制造，材料选用进口无毒高导铜合金加工，保证模具使用寿命，提高产品外观质量。

◎ 液压系统：

伺服液压泵站，出口压力 PID 调节，油缸动作闭环曲线控制，手动状态下，液压泵站低速运行，便于设备调试维护以及提高人员的安全保护。

◎ 控制系统

采用 SIEMENS 运动控制器和工业电脑控制，实现电子签名和电子批记录，满足数据完整性的验证要求。

+ Equipment capacity

The stable capacity of 24,000pcs/h (2ml), is the largest capacity of shuttle type BFS machine, with the mature technology and stable production.

+ Extruding system:

Designed from Truking（European）R&D Center,the extrusion die is manufactured with advanced machining, adopts the servo motor to drive, tthe Parison dynamic exhaust and fill gas to ensure the stability of the extruding system.Container wall thickness uniformity ± 0.05mm.

+ Molding system:

A servo hydraulic system is used to control the PID closed-loop curve to reduce the assault and vibration of the equipment and avoid the wear of the mould. Servo swing cylinder drives high¬speed mold shifting to reduce the risk of container exposure.

+ Filling system:

Adopting time-pressure methods to fill using high frequency solenoid valve control loading. Equipped with automatic identification technology of waste cylinders, the suspension uniformity deviation ±0.5%, and the remaining oxygen <1%

+ Mold:

Adopting the precision manufacturing technology, manufactured by Truking mold center. and selects the imported non-toxic high-conductivity copper alloy for materials processing, to guarantee the service life of the mold and improve the product appearance quality.

+ Hydraulic systems:

Servo hydraulic pump station, PID adjustment of outlet pressure, closed-loop curve control of cylinder action. In the manual state, the hydraulic pump station runs at low speed, which is convenient for equipment debugging and maintenance and improves the safety protection of personnel.

+ Control system

Adopt SIEMENS motion controller and industrial computer to control, the action execution is more accurate implementation of electronic signature and electronic batch records to meet the data integrity verification requirements

BFS 设备选型表 / Equipment Specification

设备型号 Machine Type	产品规格 Specification	模具腔数 Mould Cavity	总腔数 Total Cavity	产能 / 时 Capacity
APS3	0.2-3mL	3×（5+5）	30	9000
	5-20mL	3×6	18	5200
APS4	0.2-3mL	4×7	28	8400
	5mL-20mL	4×5	20	5500
APSD3	0.2-3mL	2×3×（5+5）	60	18000
	5mL-20mL	2×3×6	36	10000
APSD4	0.2-3mL	2×4×7	56	16500
	5mL-20mL	2×4×5	40	11000
APSG4	0.2-2mL	4×10	40	12000
	5mL-20mL	4×6	24	6500
APSDG4	0.2-3ml	2×4×10	80	24000
	5mL-20mL	2×4×6	48	13000

设备型号 Machine Type	产品规格 Specification	模具腔数 Mould Cavity	总腔数 Total Cavity	产能 / 时 Capacity
APS6	250mL	6	6	1650
	500mL	6	6	1550
	1000mL	6	6	1300
APS8	100mL	8	8	2300
	250mL	8	8	2200
	500mL	8	8	2050
APSD6	250mL	2×6	12	3080
	500mL	2×6	12	2880
	1000mL	2×6	12	2450
APSD8	100mL	2×8	16	4200
	250mL	2×8	16	4100
	500mL	2×8	16	3850

连续式吹灌封（BFS）设备
Continuous Type BFS Machine

主要用途 / Main Application

◎ 连续式 BFS 设备将塑料粒子在高温高压的状态下塑化和除菌，挤出形成单个椭圆形型坯。无菌气体对椭圆形型坯进行正压保护，灌装针处于型坯内部，在无菌的密闭空间内完成灌装。灌装后的容器带传送至冲裁设备，将产品和废料分离。根据结构的不同，连续式 BFS 分为多模连续式和单模连续式两种：

+ 多模连续式：型坯持续挤出输送至连续循环的模具链，模具链上安装有多套模具，旋转的模具完成容器的成型后，药液通过灌装针进行药液灌装，然后旋转的模具链上的下一套模具将容器密封，同时完成下一组产品的容器成型，连续循环运行。产品容器成型、灌装和封口的循环步骤在 3~4s 内完成。
+ 单模连续式：型坯持续挤出输送至一套垂直运行的模具上，模具分为瓶身模，瓶头模，左右对中开合模，型坯挤出速度与模具垂直运行机构下行速度同步，不断形成容器 - 灌装 - 封口的 BFS 循环，循环步骤在 7~10 秒内完成。

+ Continuous BFS equipment plasticizes and sterilizes plastic particles under the state of high temperature and high pressure for extrusion molding of the single oval parison. The sterile gas plays the role of positive pressure protection of the oval parison. The filling pin is located inside the parison and completes the filling in a sterile confined space，The container belt used for filling is sent to the blanking equipment to separate the products from the wastes. According to the different structures, Continuous BFS is divided into two types as below:
+ Multi-mode Continuous BFS equipment: which is continuously extruded and delivered to a continuous circulating mold chain, and the mold chain is installed with several sets of molds. Upon rotational molding of container, the medical solution will be filled by filling pin, then the container is sealed by the next set of mold on the rotational mold chain, and meanwhile, the container molding of the next group of products is completed to proceed the circulating operation.The cycle of container molding, filling and sealing is finished within 3-4s.
+ Single-mode Continuous BFS equipment: The parison is continuously extruded and transported to a set of vertical running mold. The mold is divided into bottle body mold, bottle head mold, left and right center opening and closing mold, the parison extrusion speed and the vertical operating mechanism of the mold downward speed synchronization, and constantly form a container - filling - sealing BFS cycle, the cycle step is completed in 7 -10s.

性能优势 / Performance & Advantages

◎ 设备产能：

欧洲研究院设计，连续式 BFS 设备最大稳定产能 33300pcs/h (2mL)，产品材料利用率高达 83%。

◎ 挤出系统：

封闭式单一挤出型坯，模头采用欧洲进口合金材料，五轴高速机床加工，特殊表面涂层处理，螺杆采用伺服驱动，管胚动态排气补气，保证挤出系统的稳定性和容器壁厚均一性。

◎ 成型系统

多模连续式设备多套模具安装在连续旋转的链条上，链条采用合金材料并进行热处理，保证使用寿命。

单模连续式设备模具开合采用伺服液压驱动，增大合模力，提高产品成型质量。

◎ 灌装系统：

灌装针安装在挤出模头内部，无菌空气保护，在封闭的型坯内完成产品的灌装。灌装采用时间压力法，采用高频响电磁阀岛控制装量，最高灌装精度达到 ±0.01mL.

◎ 成型模具

模具制造中心精密制造，采用进口原材料。

◎ 控制系统

采用 SIEMENS 运动控制器和工业电脑控制，实现电子签名和电子批记录，满足数据完整性的验证要求

+ Equipment Capacity

The maximum stable production capacity of continuous BFS equipment designed by Truking (European) R&D Center is 33000pcs/h (2ml), and the utilization rate of plastic materials is up to 83%.

+ Extruding system

For the closed single extrusion parison, the die head is made of Europe -imported alloy materials that are processed by five-axis high-speed machine tool, adopting special coating for surface, and servo motor for extrusion screw. For Parison, adopting dynamic exhaust and air make-up so as to maintain the stability of extrusion system and uniformity of container wall thickness.

+ Molding System:

Multi-mold continuous equipment uses multiple pairs of molds installed on a continuous rotating chain, and the chain is made of alloy materials and thermally treated to guarantee its service life.

Single-mold continuous type equipment adopts the servo-hydraulic to open, close, lift and lowers the mold, which increases the closing force and improves the molding quality of the products.

+ Filling System:

The filling needles is installed inside the extrusion die head, protected by sterile air, and used to complete the filling of product in a closed parison. Time pressure method is used for filling, and high-frequency response electromagnetic valve island is adopted to control the filling volume, and the maximum filling accuracy can be up to ±0.01mL.

+ Forming Mold

The mold is manufactured by Truking mold center. The mold raw material is imported.

+ Control System

SIEMENS motion controller and industrial computer are used as control unit to realize electronic signature and electronic batch recording, so as to meet the requirements for data integrity verification.

BFS 设备选型表 / Equipment Specification

设备型号 Machine Type	模具腔数 Mould Cavity	最大容量（ml） Max. Volume	最大容器宽度（mm） Max. container width	产能 / 时 Capacity/hour
APSC15	10	30	28	10000
	15	15	18	15000
	20	8	13	20000
	25	2	10	29000
APSC20	10	8	28	11250
	15	8	18	16900
	20	4	13	24000
	25	2	10	33300
APSC1	10	30	28	4500
	15	15	18	6750
	20	10	13	9000
	30	5	10	14000

服务理念

400-9988-900

秉承“一切为客户着想，为一切客户着想，为客户着想一切”的理念，以“为客户创造价值”为己任，楚天专注于打造一流的研发、设计、销售、制造、服务团队及服务管理体系，为客户提供高效、优质的产品与服务。

◎ 项目规划支持

楚天拥有系列专业医药设计院、产品研究院，一批行业资深科研技术人员，无菌制药工艺的验证专家、教授等，为客户的项目提供科学、有效的技术规划支持。

◎ 过程保障服务

楚天推出的医药装备整体解决方案，实现药品生产过程的全自动化、无菌化，智能检测、分选，以及计算机验证保障，生产出让市场“放心”的产品。

◎ 走进园区服务

楚天作为设备供应商，不仅仅将行业法规标准融入到产品设计、制造中，还让法规标准以讲座、交流的形式走进园区，与药企的工艺、生产形成互动与融合。

◎ 设备管理咨询服务

楚天致力于满足客户效益最大化需求，提供一揽子的设备管理模式，协同药厂实现投入最小化，产出最大化。

◎ 坚持“以客户为中心”， 以匠人之心打造极致服务体验，为客户创造更多价值

34 全国 34 个省（市）

365 全年 365 天

7x24 7X24 小时服务时间

◎ 我们随时待命为客户单位设备正常运行保驾护航

+ 现场安装、调试、验收
+ 设备工艺、操作、维护等相关培训
+ 周期性的定期上门维护与回访
+ 设备各部件性能的检测与保养
+ 备品备件的及时供应
+ 产品技术升级与技术二次开发
+ 设备大修

Service Concept

400-9988-900

Adhering to concept of “all for customers, for all customers”, and with the mission of “creating value for customers”, TRUKING focuses on building first-class R&D, design, sales, manufacturing, service teams and service management system to offer high-efficient and high-quality products and services for the customers.

◎ Project Planning Support

TRUKING has a series of professional medical and pharmaceutical design institutes, product research institutes, a group of senior scientific research and technical personnel, aseptic pharmaceutical process verification experts, professors, etc., to provide scientific and effective technical planning support for customers' projects.

◎ Process Assurance Service

TRUKING launched the overall solution for medical & pharmaceutical equipment realizing the full automation and aseptic production process, intelligent detection and sorting of the drug, as well as computer verification assurance so as to produce assured products for market.

◎ Service In The Park

As an equipment supplier, TRUKING not only integrates industrial regulations and standards into product design and manufacturing, but also introduces the industrial regulations and standards into Truking industrial park in the form of lectures and exchanges to interact and integrate with the technology and production of pharmaceutical enterprises.

◎ Equipment Management Consultation Service

TRUKING aims to satisfy the maximum benefited demands of the customer and to provide a package of equipment management services to realize minimization investment and maximization production output together with pharmaceutical factories.

◎ Adhere to the philosophy of "customer-centric", TRUKING creates the extraordinary service experience with the spirit of the craftsman, to create more value for customers.

◎ We are always ready to escort the normal operation of the customer's equipment.

+ Onsite equipment installation, commissioning, acceptance
+ Training for equipment process, operation and maintenance
+ Periodic door-to-door maintenance and return visit
+ Performance test and maintenance for machinery parts
+ Timely supply of spare parts
+ Product technology upgrading and secondary development
+ Equipment overhaul

www.truking.com

TRUKING

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