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楚天华通医药设备有限公司

TRUKING WATERTOWN PHARMACEUTICAL EQUIPMENT CO.,LTD.

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May 2023 Edition



Pharmaceutical Process System Solution
制药工艺系统整体解决方案

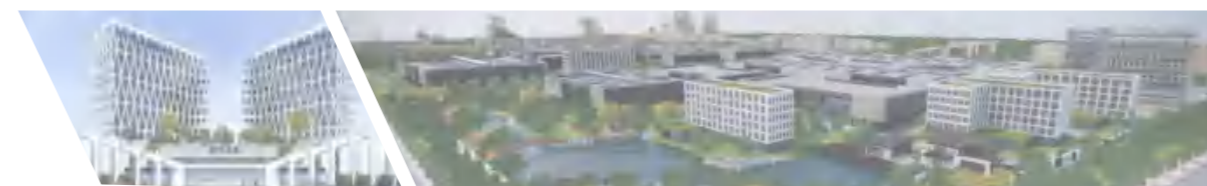
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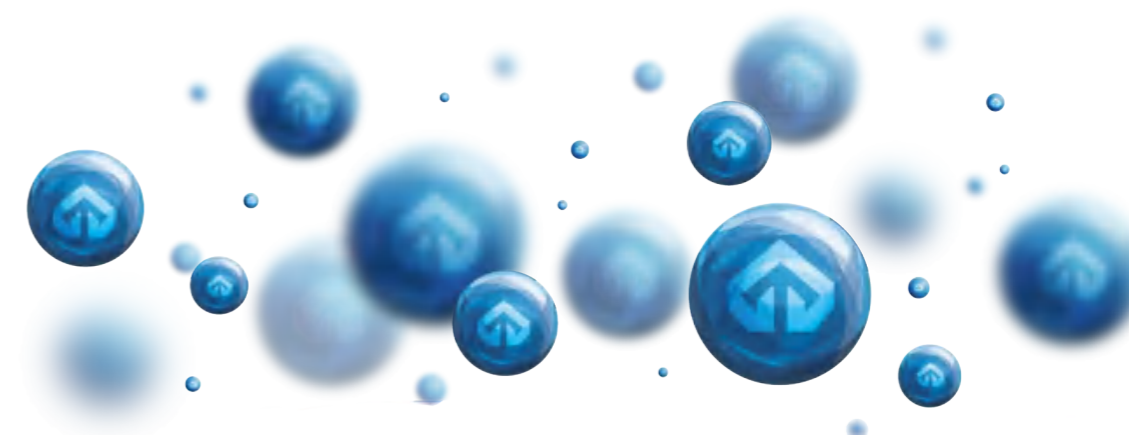
让世界制药工业插上智慧的翅膀
Equip global pharmaceutical manufacturing industry with intelligent wings.

TRUKING

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TRUKING

公司简介 Company profile



楚天华通医药设备有限公司系楚天科技股份有限公司全资子公司，始建于1993年，是目前亚洲领军制药用水系统（制备、储存和分配）、配液系统、不锈钢压力容器、污水处理、蒸发浓缩结晶、换热器研发制造基地，装备及制造工艺处于行业优级水平，员工总数1300余人，资产总额20亿元，服务于全球1000余家制药企业。

公司位于长春九台经济开发区，是中国制药装备行业协会理事单位，中国医药设备工程协会、中国膜工业协会会员单位，获评定为国家级高新技术企业、吉林省专精特新企业、吉林省级企业技术中心，获得省级创新型科技企业、长春市百强民营企业、长春市科技型小巨人企业等荣誉。公司拥有中国特种设备压力容器D级（10MPa以下的一类、二类、三类压力容器）设计与制造资质、压力管道（GC2）安装许可证、建筑机电安装工程专业承包贰级资质、环保工程专业承包贰级、环境工程设计专项（水污染防治工程）乙级、美国ASME（U）钢印设计与制造资质、欧盟CE（PED、MD）认证资质。截至2023年4月，公司共提出中国专利申请320项，有效专利180项，另提出1件PCT国际专利申请。产品已出口美国、意大利、比利时、希腊、土耳其、俄罗斯、韩国、泰国、越南、印尼、印度、埃及、沙特、摩洛哥、秘鲁等30多个国家和地区，国际市场占有率正逐年快速提升。

公司拥有经验丰富的研发技术团队，覆盖工程设计、项目管理、测试调试、验证与咨询服务，联合楚天科技、德国ROMACO集团、四川省医药设计院共同承接制药企业EPCM总包服务，为制药企业提供工程工艺优化、产品的全生命周期管理与服务。

2021年公司确认新建楚天华通医药装备智能制造产业园项目，位于长春市九台经济技术开发区中古医药产业园。项目新购地36.1117万平方米，计划在5年内分三期完成项目整体建设任务，项目建成后，将崛起楚天华通研发中心大楼、智能车间、员工公寓以及商务接待中心等现代化智能配套公用工程。一期工程建筑面积6万平米，预计2023年7月投产。作为楚天华通年产5000台套医药装备的智能制造基地，楚天华通医药装备智能制造产业园项目完成后将大幅提升企业产能，将进一步推动企业战略目标的实现。

公司坚持“做受尊敬的人、造受尊敬的产品、办受尊敬的企业”的核心价值观，秉承“要么唯一，要么第一”的理念，弘扬“因为执着，所以卓越”的精神，将楚天华通打造成全球制药用水系统领军企业之一。

Truking Watertown Pharmaceutical Equipment Co., LTD., a wholly-owned subsidiary of Truking Technology Limited, was founded in 1993. It is the leading R&D and manufacturing base of pharmaceutical water system (preparation, storage and distribution), liquid preparation system, stainless steel pressure vessel, sewage treatment, evaporation, crystallization and heat exchanger in Asia. With more than 1300 employees and 2 billion yuan of assets, the company serves more than 1000 pharmaceutical enterprises around the world.

Truking Watertown is located in Jiutai Economic Development Zone, Changchun. It is a member of China Pharmaceutical Equipment Industry Association, China Pharmaceutical Equipment Engineering Association and China Membrane Industry Association. It has been rated as a national high-tech enterprise, Provincial Specialized and Sophisticated Enterprise, Provincial Enterprise Technology Center. It has been honored as provincial innovative technology Enterprise, Changchun Top 100 Private Enterprise, and Changchun Small Giant Technology Enterprise. Truking Watertown has Chinese special equipment Class D (Class I, Class II and Class III below 10MPa) pressure vessel design and manufacturing license, Pressure pipeline (GC2) installation license, construction mechanical and electrical installation engineering contracting Class II, environmental engineering contracting Class II, environmental engineering design special (water pollution control engineering) Class B, ASME(U) steel seal design and design manufacturing qualification, EU CE(PED, MD) certification qualification. Truking Watertown has applied for 320 patents, 180 patents of which have been authorized until April 2023, and one PCT international patent application. Products have been exported to the United States, Italy, Belgium, Greece, Turkey, Russia, South Korea, Thailand, Vietnam, Indonesia, India, Egypt, Saudi Arabia, Morocco, Peru and other 30 countries and regions, the international market share is rapidly increasing year by year.

Truking Watertown has an experienced R&D technical team, covering engineering design, project management, testing and commissioning, validation and consulting services. Together with Truking Technology, Germany ROMACO Group and Sichuan Pharmaceutical Design Institute, the company jointly undertakes EPCM general contract services for pharmaceutical enterprises, providing engineering process optimization and product lifecycle management and services for pharmaceutical enterprises.

In 2021, Truking Watertown pharmaceutical equipment Intelligent Manufacturing Industrial Park project started, located in Jiutai Economic and Technological Development Zone of Changchun Medicine Industrial Park. The new plant occupies 361,117 square meters. It is planned to complete the overall construction in three phases within 5 years. After the completion of the construction, Truking Watertown R&D Center building, intelligent workshop, employee apartment and business reception center and other modern intelligent supporting utilities will be used. The first phase of the project covers a construction area of 60,000 square meters and is expected to be put into operation in July 2023. As base of Truking Watertown with an annual output of 5,000 sets, pharmaceutical equipment intelligent manufacturing Industrial Park will greatly improve the enterprise's production capacity after the completion of the project, which will further promote the realization of the strategic objectives of the enterprise.

We insist on the core value of being respected person, making respected product and running respected enterprise and adhere to the philosophy to be the unique or to be the first and promote the spirit of Because of persistence, we are superexcellent to make Truking Watertown be one of the leading pharmaceutical water system enterprises all over the world.



产品特点 / Product Characteristics

- ◎ 基于药企药品生产工艺需求进行定制化设计和制造，符合 ASME-BPE、GMP 相关指南和法规。
- ◎ 模块化设计和制造及完整的 FAT 测试，集成度高空间占用率低，有利于提高项目交付效率和交付质量。
- ◎ 罐体内壁机械 / 电解抛光，Ra 可达 0.2μm，满足不同行业用户高标准容器要求。
- ◎ 配液工艺参数实时在线监测，关键工艺参数精确比例控制，可实现自动投料、注水、搅拌、升降温、充氮、药液转移、过滤至灌装、CIP、SIP。
- ◎ 控制系统设计符合 GAMP5 标准、监控和数据采集（SCADA 系统）、生产配方管理，符合 ISA88 标准的生产批次管理、智能维护、远程快速故障诊断功能模块。
- ◎ 专利产品“在线取样系统”（专利号：2022203608803），可实现密闭清洗和灭菌，极大程度降低取样过程的污染，较高的无菌保障水平和操作便利性。
- ◎ 基于风险分析的设计理念，方案设计从产品质量、系统失效 / 故障、数据可靠性、公用工程设施等环节进行优化。
- ◎ 为制药行业降低运营成本、近零排放需求提供可靠的技术支持，推动制药行业向绿色环保工厂模式健康发展。

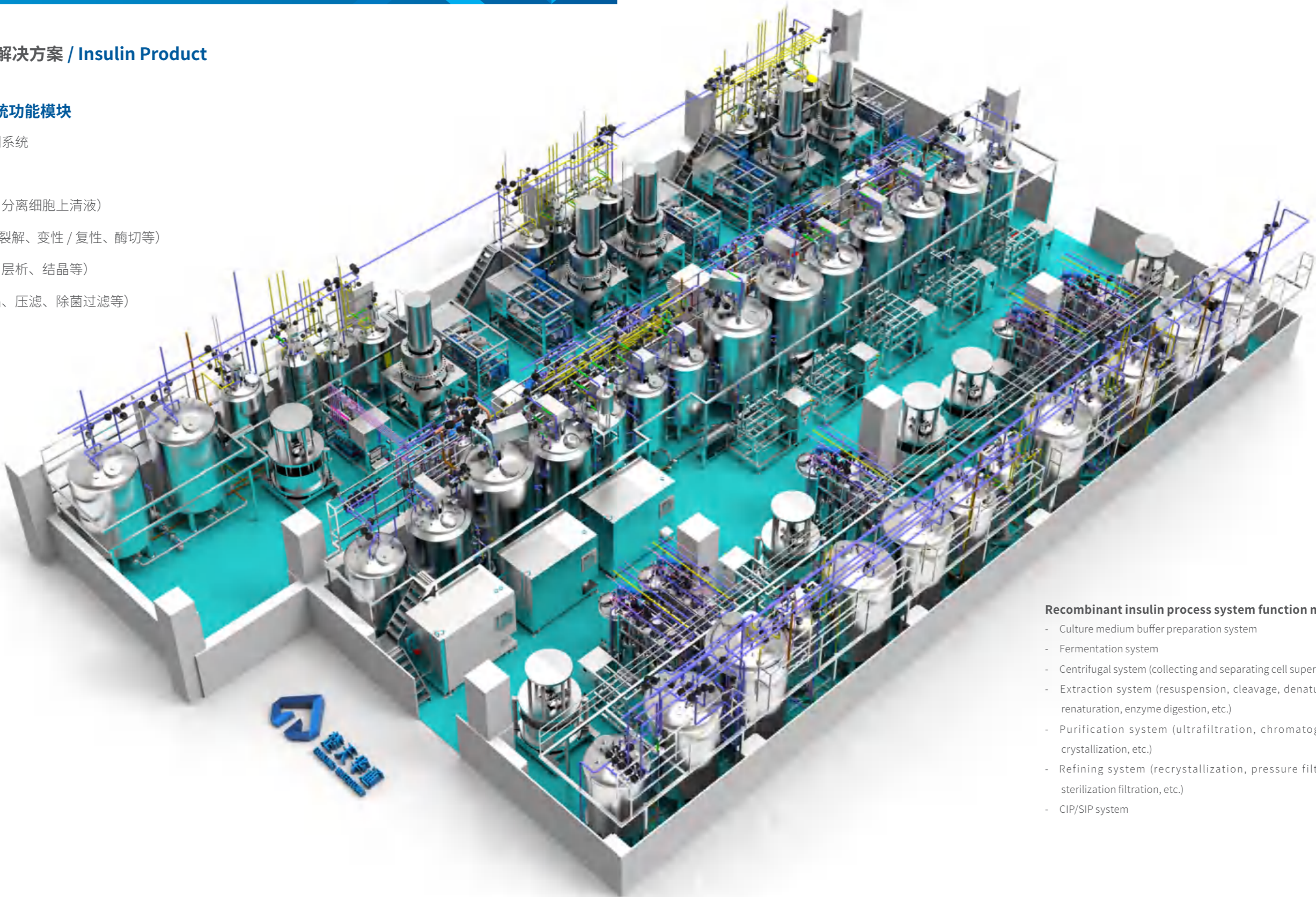
- Customized design and manufacture based on the production process requirements of pharmaceutical companies, in accordance with the relevant guidelines and regulations of ASME-BPE and GMP.
- Modular design and manufacture and complete FAT test, high integration and low space occupancy, conducive to improving project delivery efficiency and delivery quality.
- The inner wall of the tank is mechanically/electrolytically polished with Ra up to 0.2μm, which can meet the high standard vessel requirements of users in different industries.
- Real-time online monitoring of liquid preparation process parameters, precise proportional control of critical process parameters, can realize automatic feeding, water injection, stirring, heating and cooling, nitrogen filling, liquid transfer, filtration to filling, CIP, SIP.
- Control system design conforms to GAMP5 standard, monitoring and data acquisition (SCADA system), production recipe management, production batch management, intelligent maintenance, remote and rapid fault diagnosis function modules in line with ISA88 standard.
- The patented product "online sampling system" (patent No. : 2022203608803), can realize closed cleaning and sterilization, greatly reduce the pollution of the sampling process, high asepsis guarantee level and operation convenience.
- Based on the design concept of risk analysis, the project design is optimized from the aspects of product quality, system failure, data reliability, utilities and so on.
- Pharmaceutical industry to reduce operating costs, near zero emissions demand to provide reliable technical support, promote the pharmaceutical industry to a green factory model of healthy development.

生物药板块 Biopharmaceutical

 胰岛素产品解决方案 / Insulin Product

重组胰岛素工艺系统功能模块

- ◎ 培养基缓冲液配制系统
- ◎ 发酵系统
- ◎ 离心系统（收获、分离细胞上清液）
- ◎ 提取系统（重悬、裂解、变性 / 复性、酶切等）
- ◎ 纯化系统（超滤、层析、结晶等）
- ◎ 精制系统（重结晶、压滤、除菌过滤等）
- ◎ CIP/SIP 系统



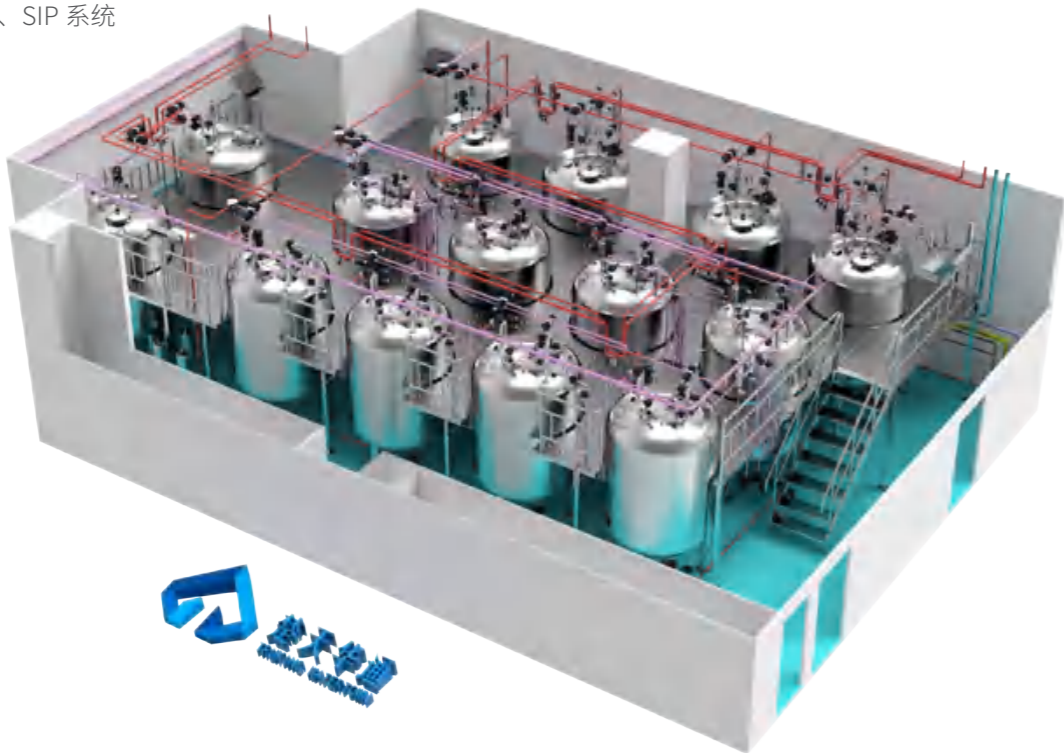
Recombinant insulin process system function module

- Culture medium buffer preparation system
- Fermentation system
- Centrifugal system (collecting and separating cell supernatant)
- Extraction system (resuspension, cleavage, denaturation/renaturation, enzyme digestion, etc.)
- Purification system (ultrafiltration, chromatography, crystallization, etc.)
- Refining system (recrystallization, pressure filtration, sterilization filtration, etc.)
- CIP/SIP system

 疫苗产品解决方案 / Vaccine Product

上、下游工艺系统功能模块

- ◎ 培养基缓冲液配制系统
- ◎ 补料系统 (C/N 源、矿盐等)
- ◎ 细菌发酵系统
- ◎ 病毒培养系统
- ◎ 分离收获系统
- ◎ 灭活 / 脱毒系统
- ◎ 超滤 / 纯化系统
- ◎ 配苗 / 半成品配制系统
- ◎ 制剂配液系统
- ◎ CIP、SIP 系统



Upper and lower process system function modules

- | | |
|---|---|
| - Culture medium buffer preparation system | - Inactivation/detoxification system |
| - Feeding system (C/N source, mineral salt, etc.) | - Ultrafiltration/purification system |
| - Bacterial fermentation system | - Vaccine preparation/semi-finished products preparation system |
| - Virus cultivation system | - Preparation system |
| - Separate collecting system | - CIP and SIP system |

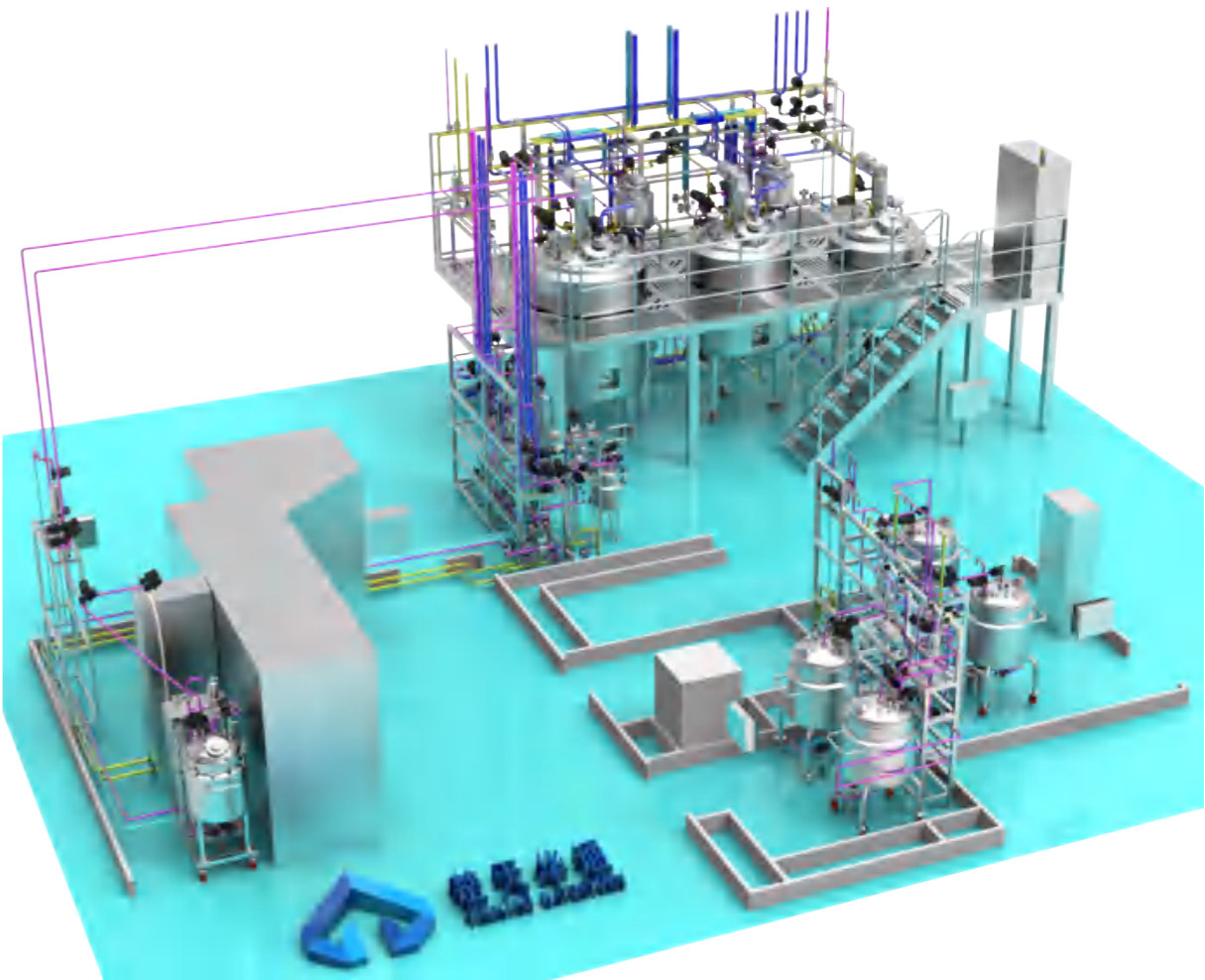
 单克隆抗体产品解决方案 / Monoclonal Antibody Product

单克隆抗体产品工艺系统功能模块

- | | |
|---------------|------------------|
| ◎ 培养基配制系统 | ◎ 离心系统 |
| ◎ 缓冲溶液配制、暂存系统 | ◎ 收获系统 |
| ◎ 细胞培养系统 | ◎ 超滤 / 层析 / 纯化系统 |
| ◎ 细菌发酵系统 | ◎ 灭活系统 |
| ◎ 补料系统 | ◎ CIP 系统 |

Monoclonal antibody products function modules

- | | |
|---|--|
| - Culture medium preparation system | - Centrifugal system |
| - Buffer solution preparation, temporary storage system | - Harvesting system |
| - Cell culture system | - Ultrafiltration/chromatography/purification system |
| - Bacteria fermentation system | - Inactivated system |
| - Feeding system | - CIP system |



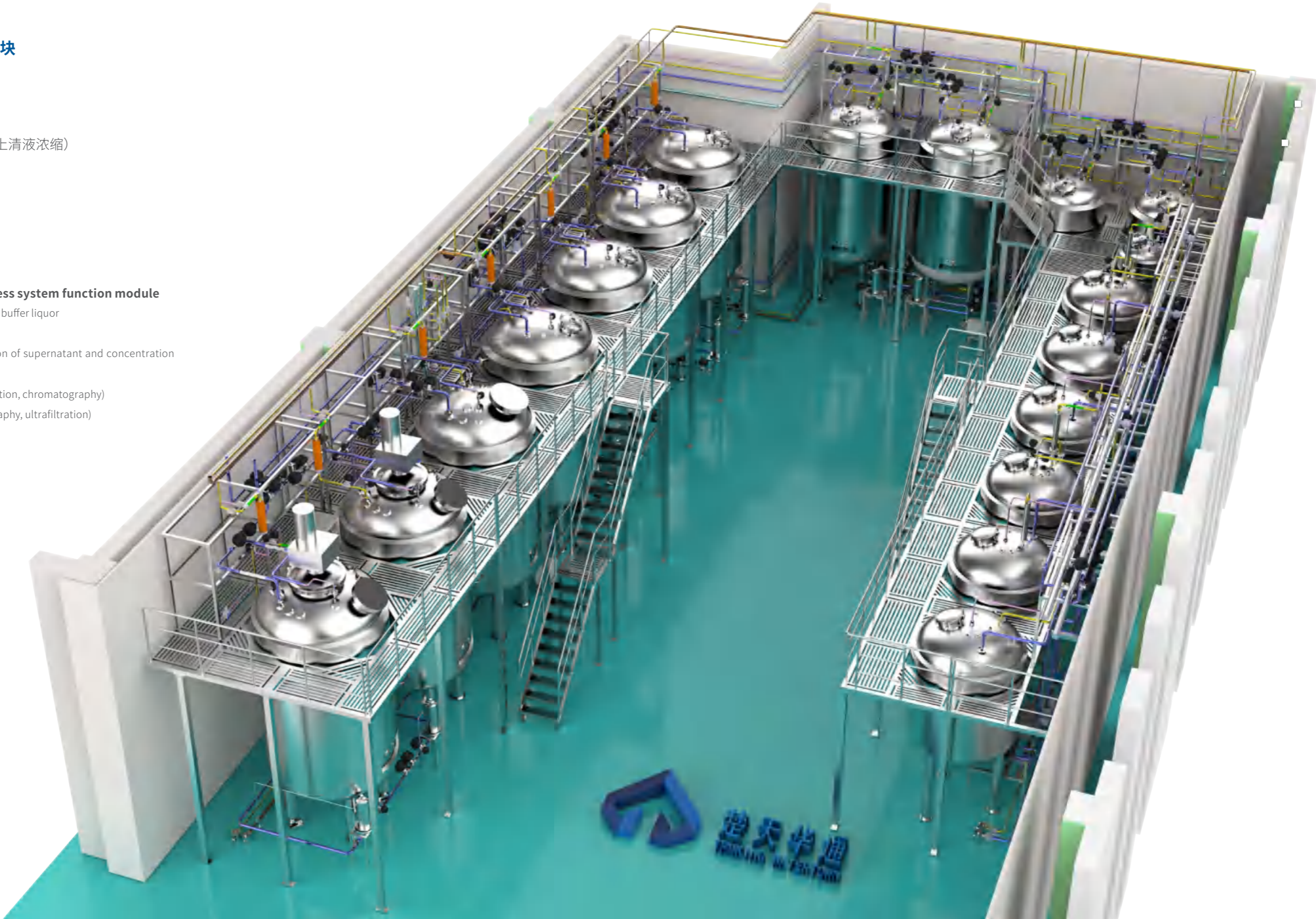
 重组蛋白产品解决方案 / Recombinant Protein Product

重组人白蛋白工艺系统功能模块

- ◎ 母液及缓冲液配制系统
- ◎ 发酵系统
- ◎ 收获系统（离心收集上清液、上清液浓缩）
- ◎ 粗纯（多步超滤、层析）
- ◎ 精纯（多步层析、超滤）
- ◎ CIP 系统

Recombinant human albumin process system function module

- Preparation system of mother liquor and buffer liquor
- Fermentation system
- Harvesting system (centrifugal collection of supernatant and concentration of supernatant)
- Coarse purification (multi-step ultrafiltration, chromatography)
- Fine purification (multi-step chromatography, ultrafiltration)
- CIP system



化学药板块 Chemical Medicine

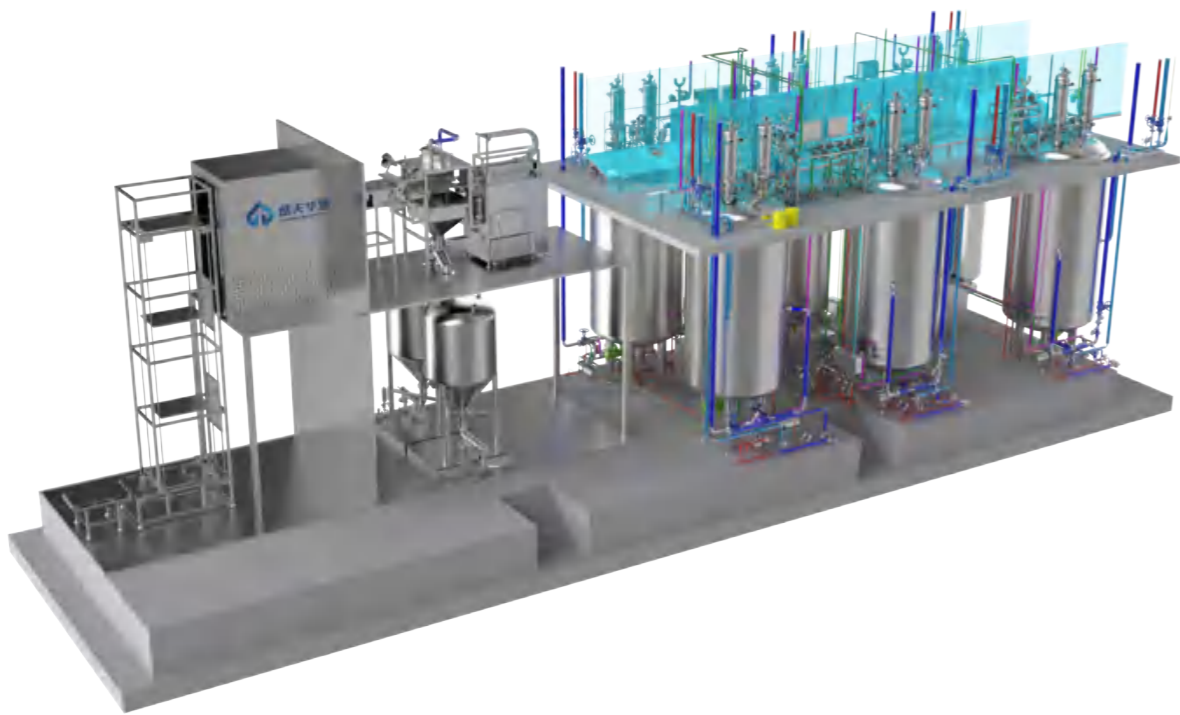
大容量注射液产品解决方案 / Large Volume Injection Product

工艺系统功能模块

- ◎ 全自动粉体输送投料系统
- ◎ 一步配制系统（稀配）
- ◎ 两步配制系统（浓配 + 稀配）
- ◎ 黑白区域隔离系统
- ◎ CIP、SIP 系统

Process system function module

- Automatic powder conveying feeding system
- One-step preparation system (dilute distribution)
- Two-step preparation system (concentrated + dilute)
- Black and white zone isolation system
- CIP and SIP system



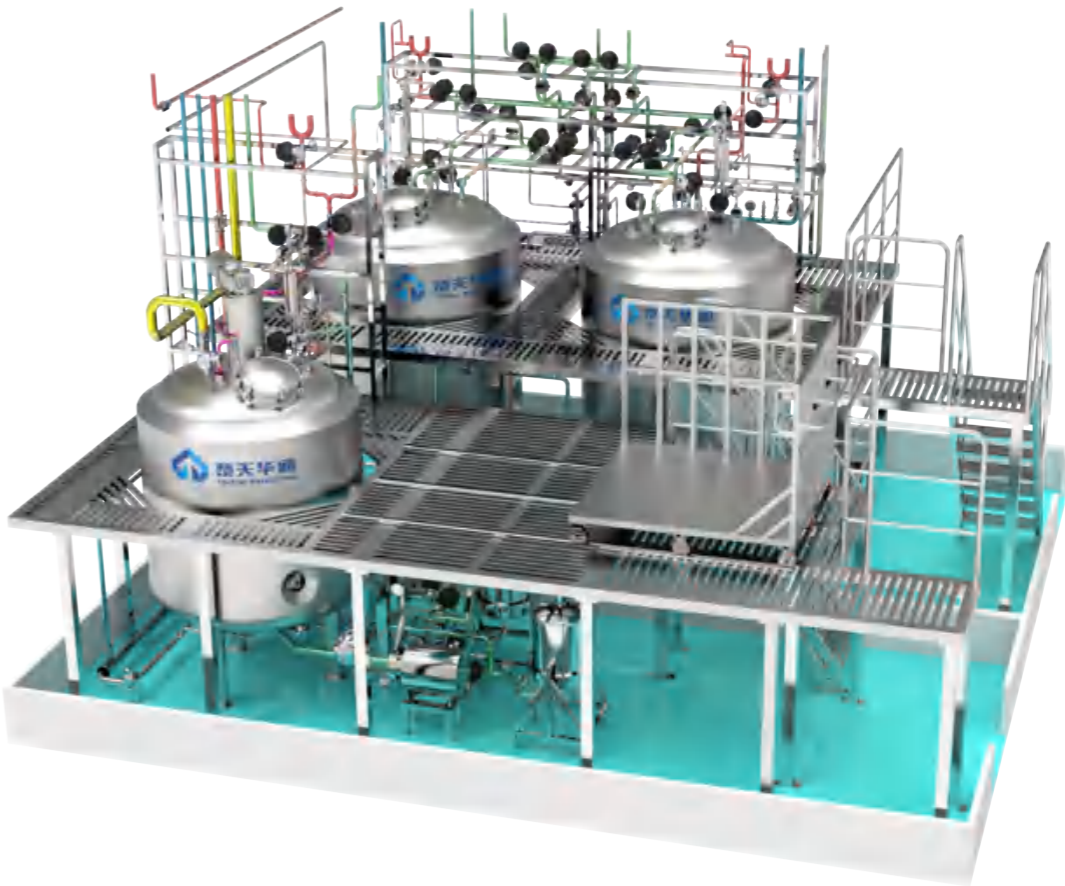
小容量注射液产品解决方案 / Small Volume Injection Product

工艺系统功能模块

- ◎ 配制系统（浓配 + 稀配 + 暂存）
- ◎ 物料提升系统
- ◎ 真空上料系统
- ◎ 除菌过滤系统
- ◎ 滤芯完整性在线检测系统
- ◎ CIP、SIP 系统

Process system function module

- Preparation system (concentrated + dilute+ temporary storage)
- Material lifting system
- Vacuum feeding system
- Bactericidal filtration system
- Filter element online test system
- CIP and SIP system



 无菌冻干粉末产品解决方案 / Sterile Lyophilized Powder Product

工艺系统功能模块

- ◎ 配制系统（浓配 + 稀配 + 暂存）
- ◎ 物料提升系统
- ◎ 真空上料系统
- ◎ 除菌过滤系统
- ◎ 滤芯完成性在线检测系统
- ◎ CIP、SIP 系统

Process system function module

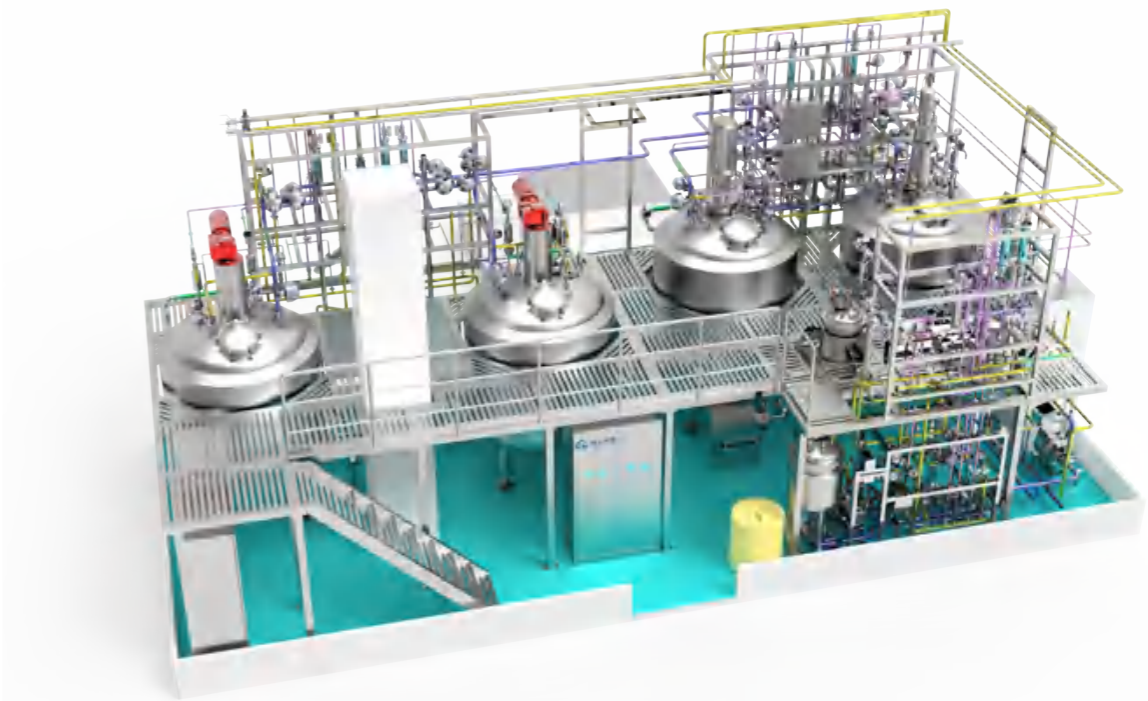
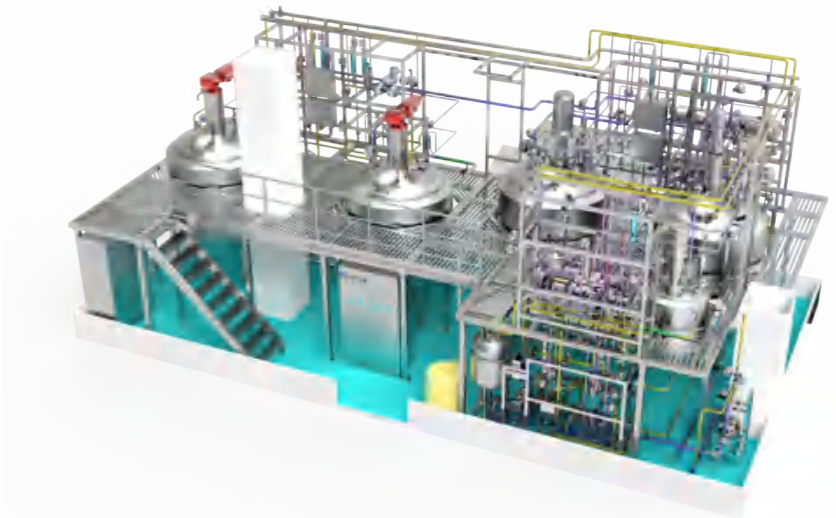
- Preparation system (concentrated + dilute + temporary storage)
- Material lifting system
- Vacuum feeding system
- Bactericidal filtration system
- Filter element online test system
- CIP and SIP system



 复杂注射剂·脂肪乳产品解决方案 / Complex Injection & Fat Milk Product

脂肪乳制备工艺系统功能模块

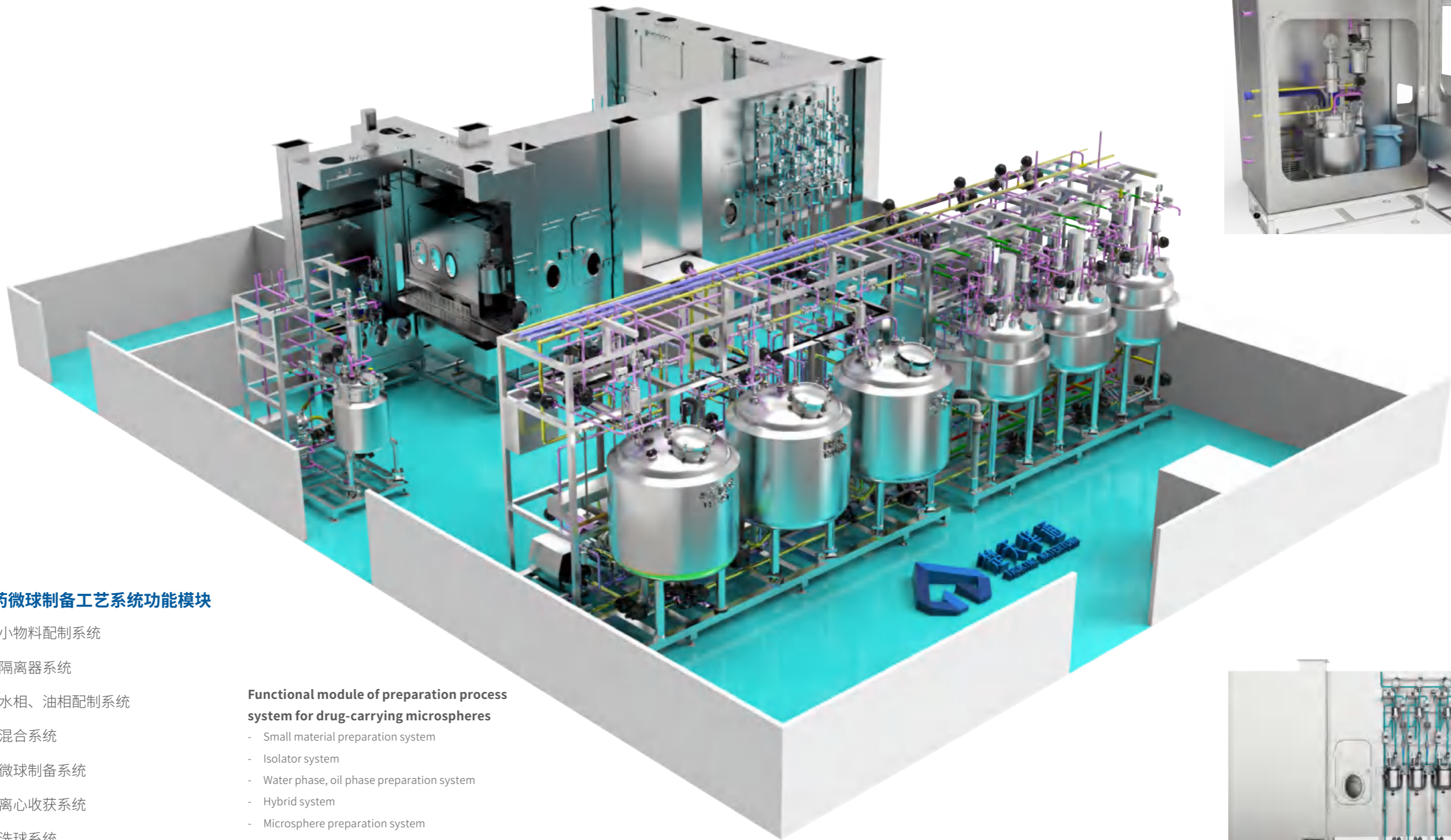
- ◎ 水相配制系统
- ◎ 油相配制系统
- ◎ 初乳配制系统
- ◎ 高压均质系统
- ◎ 成品过滤系统
- ◎ 水浴控温系统
- ◎ CIP、SIP 系统



Fat milk preparation process system function module

- Water phase preparation system
- Oil phase preparation system
- Colostrum preparation system
- High pressure homogenization system
- Finished product filtration system
- Water washing temperature control system
- CIP and SIP system

 复杂注射剂·微球产品解决方案 / Complex Injection and Microsphere Product

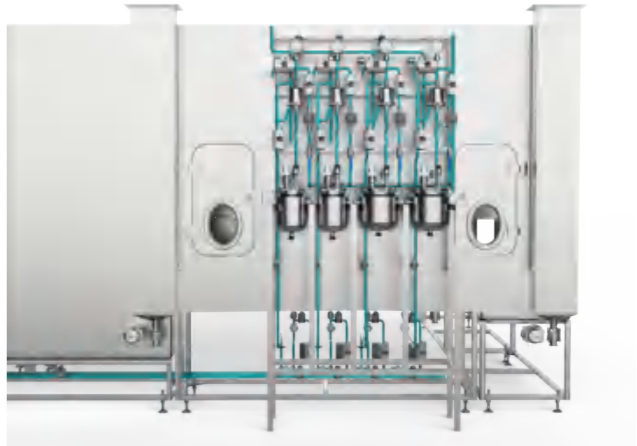


载药微球制备工艺系统功能模块

- ◎ 小物料配制系统
- ◎ 隔离器系统
- ◎ 水相、油相配制系统
- ◎ 混合系统
- ◎ 微球制备系统
- ◎ 离心收获系统
- ◎ 洗球系统
- ◎ 水浴控温系统
- ◎ CIP、SIP 系统

Functional module of preparation process
system for drug-carrying microspheres

- Small material preparation system
- Isolator system
- Water phase, oil phase preparation system
- Hybrid system
- Microsphere preparation system
- Centrifugal harvesting system
- Ball washing system
- Water washing temperature control system
- CIP and SIP system



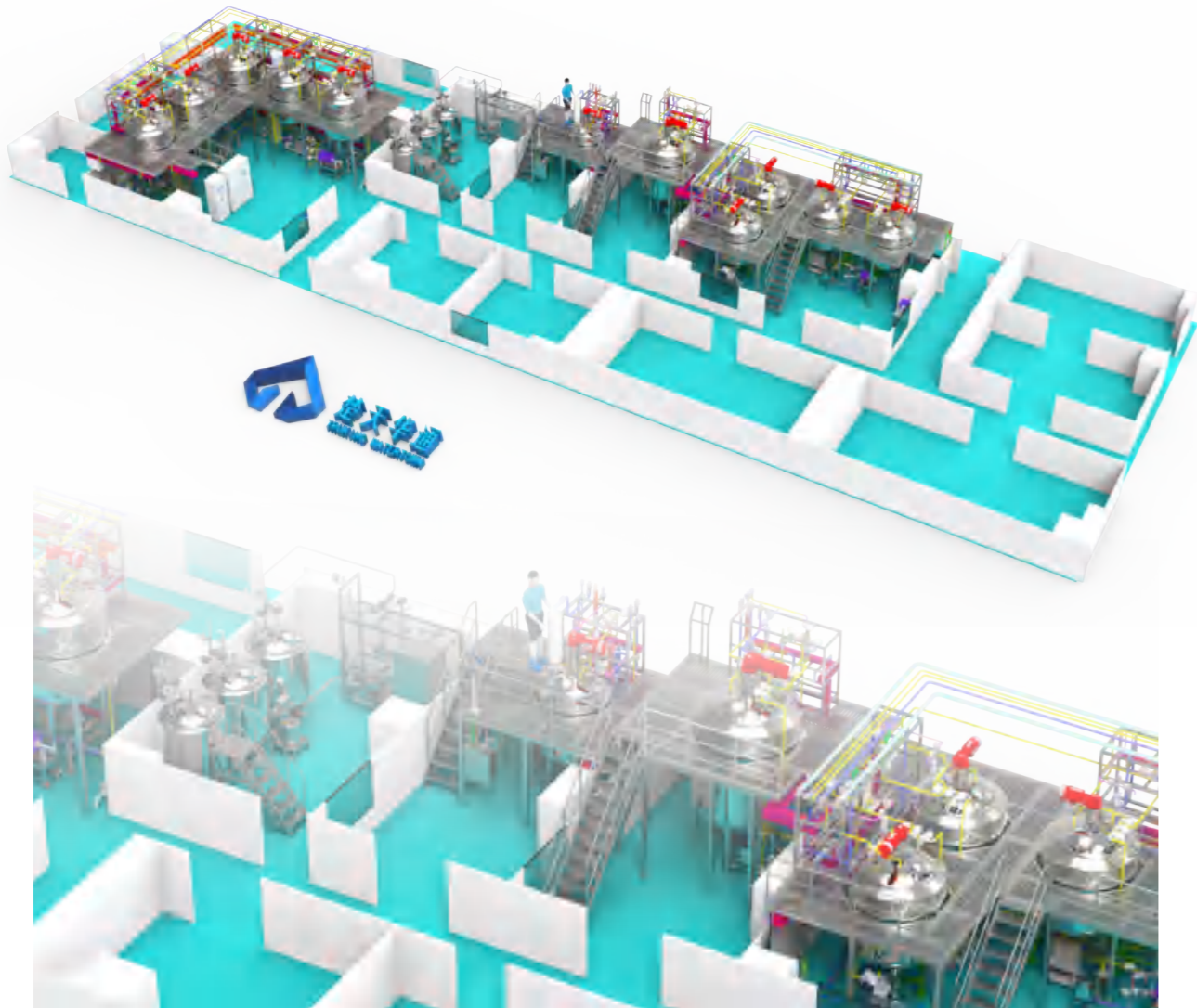
口服制剂板块 Oral Preparation

口服制剂系统功能模块

- ◎ 真空上料系统
- ◎ 烱糖 / 化糖系统
- ◎ 冷沉系统 (中药)
- ◎ 配制系统
- ◎ 成品过滤系统
- ◎ CIP 系统

Oral preparation system function module

- Vacuum feeding system
- Closing sugar/melting sugar system
- Cold precipitation system (Traditional Chinese medicine)
- Preparation system
- Finished product filtration system
- CIP system



原料药板块 Active Pharmaceutical Ingredients (API)

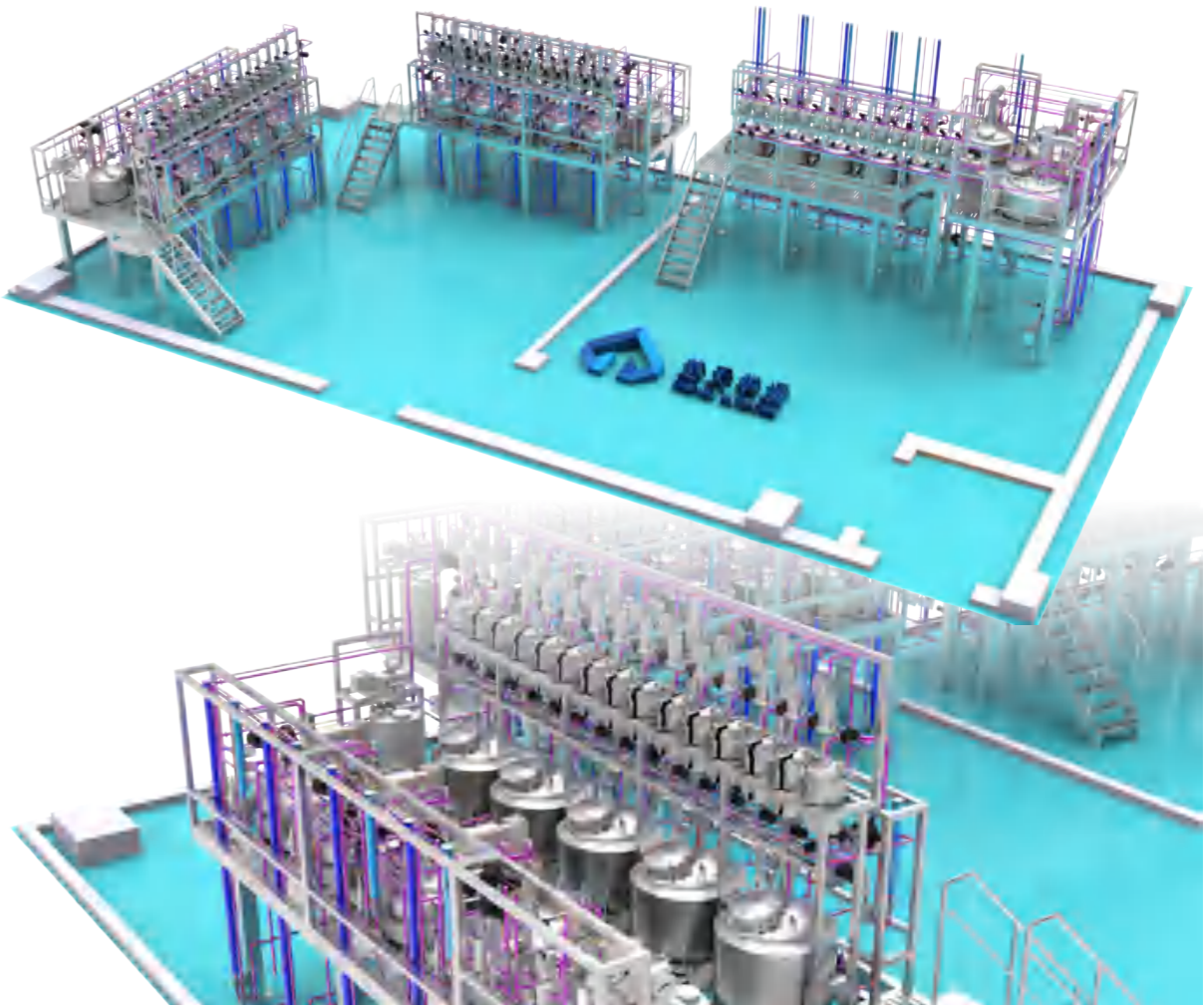
多肽类产品解决方案 / Polypeptide Product

多肽类产品工艺系统功能模块

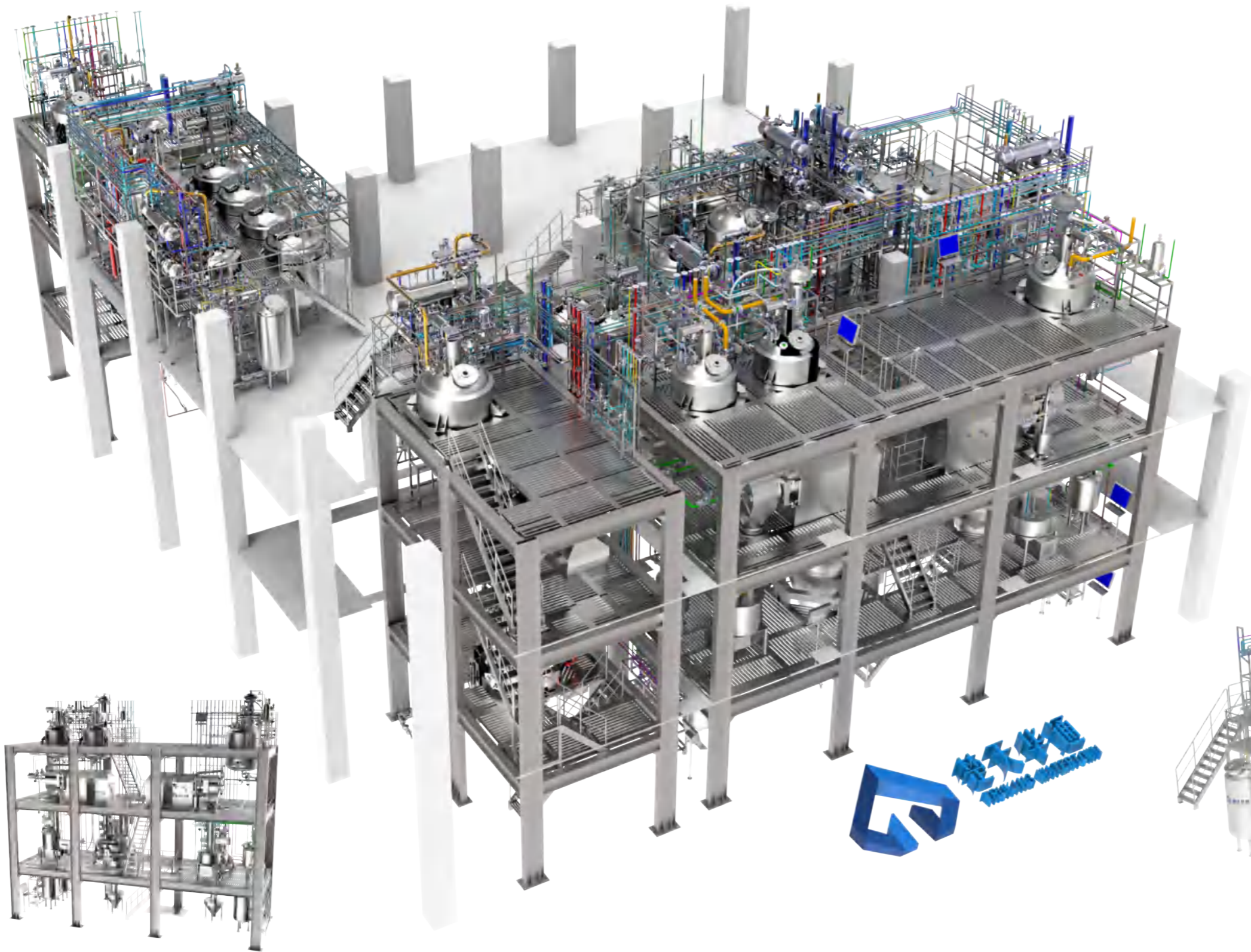
- ◎ 流动相配制系统
- ◎ 样品配制系统
- ◎ 层析 / 纯化系统
- ◎ 馏分收集系统
- ◎ 废液处理系统
- ◎ CIP 系统

Polypeptide product process system function module

- Mobile phase preparation system
- Sample preparation system
- Chromatography/purification system
- Distillate collection system
- Waste liquid treatment system
- CIP system



 精制反应配制产品解决方案 / Refining Reaction Formulates Product

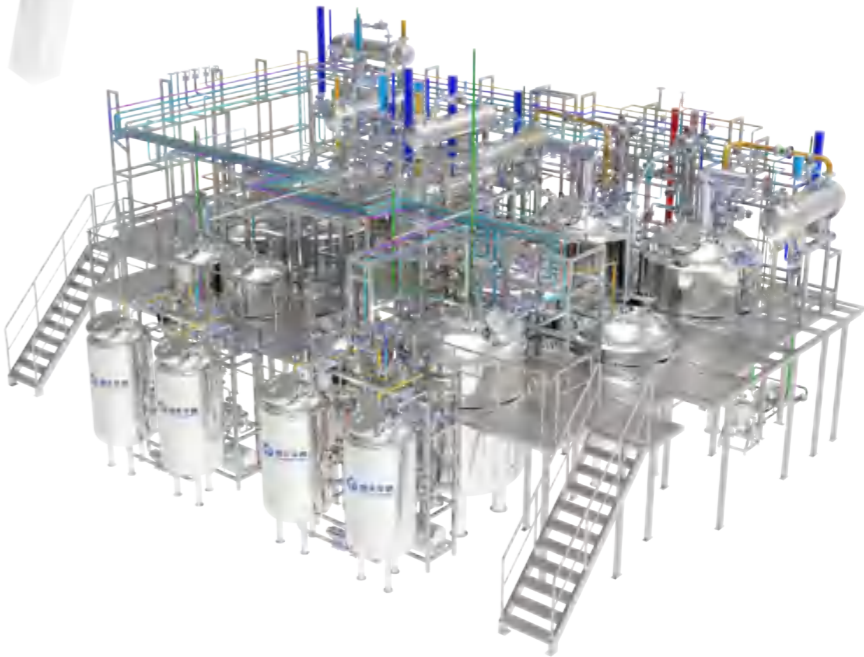


精制反应工艺系统功能模块

- | | |
|--------------|----------|
| ◎ 溶解配制系统 | ◎ 反应精制系统 |
| ◎ 浓缩结晶系统 | ◎ 溶媒回收系统 |
| ◎ 离心干燥系统 | ◎ 树脂交换系统 |
| ◎ 母液收集系统 | ◎ 废液处理系统 |
| ◎ 粉体干、湿料输送系统 | ◎ CIP 系统 |

Refining reaction process system function module

- Dissolution preparation system
- Concentrated crystallization system
- Centrifugal drying system
- Mother liquor collection system
- Dry and wet powder conveying system
- Reaction refining system
- Solvent recovery system
- Resin exchange system
- Waste liquid treatment system
- CIP system



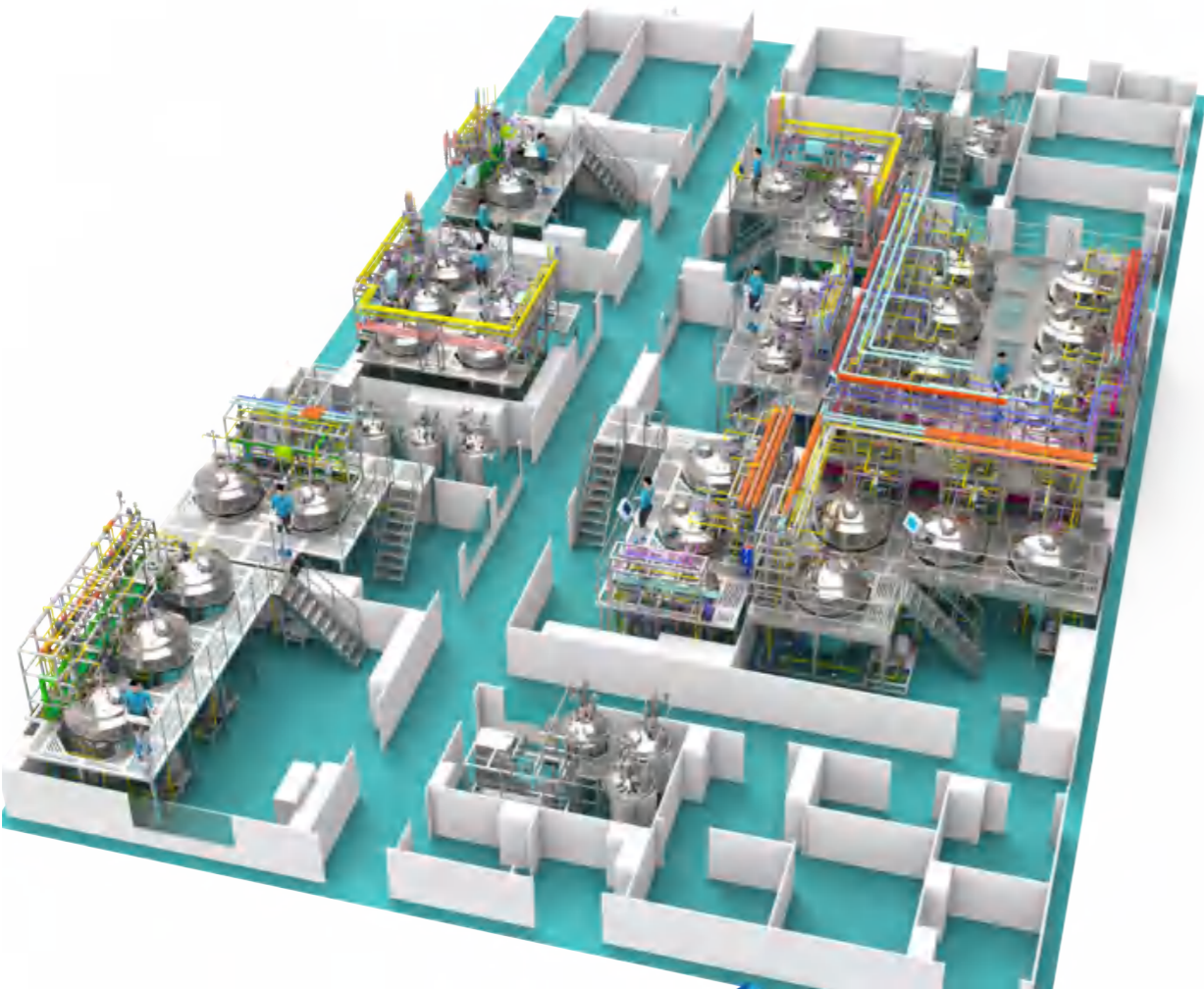
中药注射剂板块 Traditional Chinese Medicine Preparation

中药注射剂系统功能模块

- ◎ 提取、浓缩系统
- ◎ 一次冷沉系统
- ◎ 浓配系统
- ◎ 超滤系统
- ◎ 二次冷沉系统
- ◎ 稀配系统
- ◎ 成品过滤系统
- ◎ CIP/SIP 系统

TCM injection system function module

- Extraction and concentration system
- First cold sinking system
- Concentrated system
- Ultrafiltration system
- Secondary cold sinking system
- Dilute distribution system
- Finished product filtration system
- CIP/SIP system



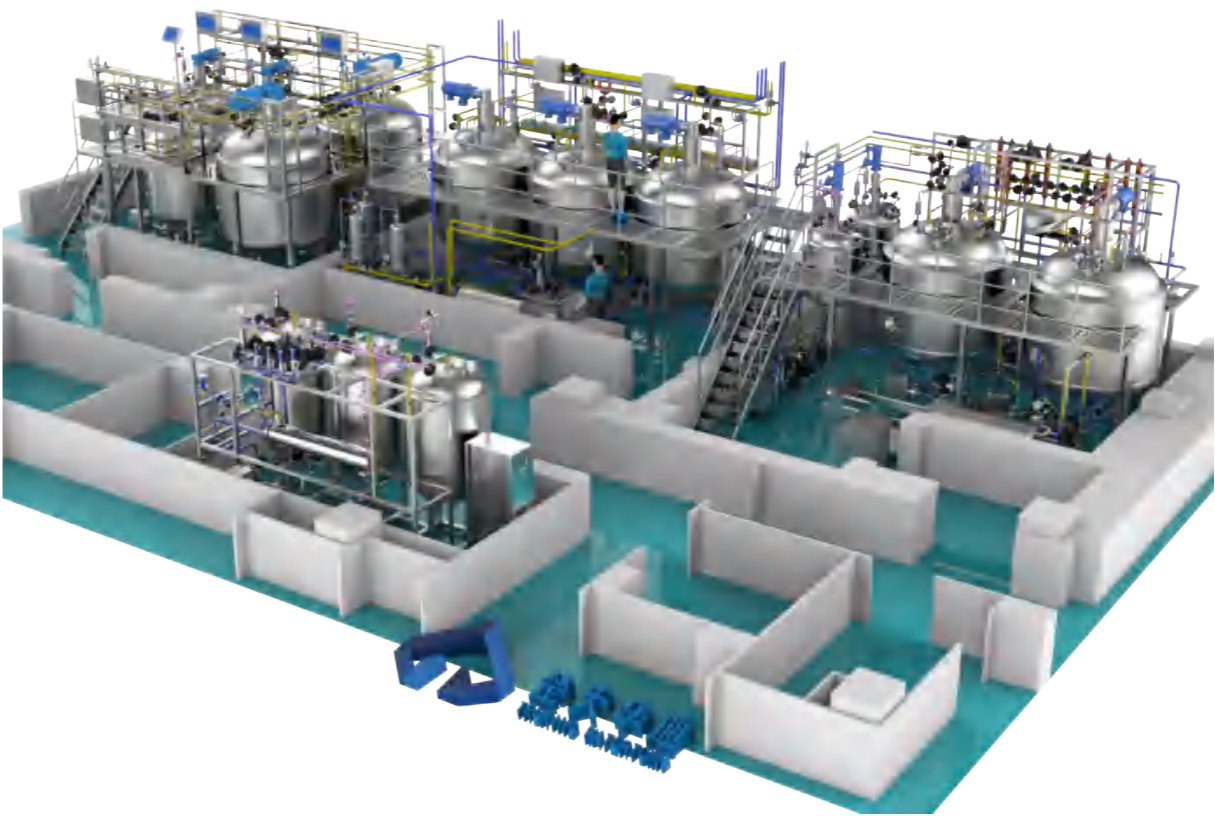
医美板块 Cosmetic Medicine

医美产品系统功能模块

- ◎ 溶解吸附系统
- ◎ 过滤系统
- ◎ 醇沉系统
- ◎ 洗涤脱水系统
- ◎ 干燥系统
- ◎ 精制系统
- ◎ CIP/SIP 系统

Cosmetic medicine product system function module

- Dissolving adsorption system
- Filtration system
- Alcohol sedimentation system
- Washing and dehydration system
- Drying system
- Refining system
- CIP/SIP system



CIP 工作站 CIP Station

- ◎ 单罐、双罐、多罐固定式 cip 系统
 - Single tank, double tank, tanks fixed cip system
- ◎ 移动式 cip 系统
 - Mobile cip system
- ◎ 规格包括 50L、200L、100L、500L、1000L、2000L、4000L、5000L
 - Specifications including 50L, 200 L 100L, 500L, 1000L, 2000L, 4000L, 5000L
- ◎ 参数化控制流速、温度、PH 值、电导率、时间等
 - Parameterized control of velocity, temperature, PH value, conductivity, time, etc.
- ◎ 特殊流程设计，无交叉污染风险
 - Special process design, without risk of cross contamination
- ◎ 优化的清洗程序省时、节水
 - Optimization of cleaning procedures to save time, water

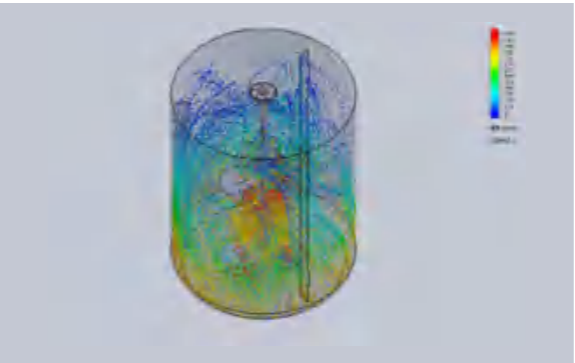


CIP 移动加药车 CIP moveable cart

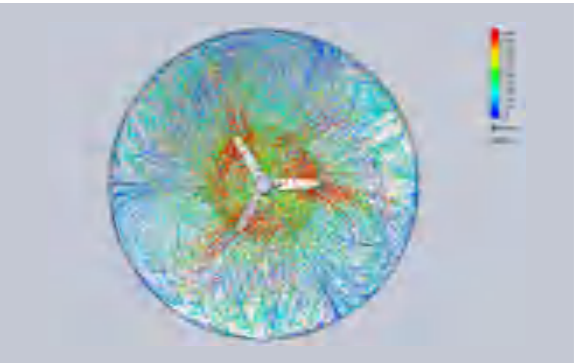
工艺技术服务 Service

搅拌 CFD 模拟、搅拌实验、带料测试、工艺放大、产品研发等
Mixing CFD simulation, mixing experiment, material testing, process amplification, product development, etc.

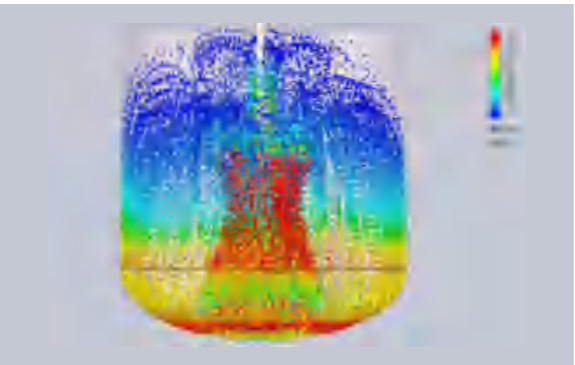
- ◎ 搅拌 CFD 模拟：采用 CFD 模拟反应器内流动、混合、传热等过程，实现对非理想反应器的准确数值提供参考依据。
- ◎ 产品研发：客户新产品开发过程中，辅助用户进行产品开发、产品升级迭代、工艺验证等，解决用户测试设备不足的痛点。
- ◎ 工艺放大：辅助用户，将药品的生产从实验室规模放大到工业规模，以验证、复审和完善实验室工艺所研究确定的反应条件，为正式生产提供数据、物质和消耗，达到降低产业化风险的措施，提高生产效率、降低成本、提升产品质量。
- ◎ 带料测试：将用户实际物料与 CFD 模拟桨叶形式，通过测试设备进行物料试验，保障用户达到物料最终混合状态，验证桨叶的合理性，提供搅拌数据推荐，辅助用户调整搅拌参数保证药品性状。
- Mixing CFD simulation: using CFD to simulate the flow in the reactor, mixing, heat transfer process, such as implementation of non-ideal reactor provided a reference for accurate numerical.
- Product research and development: the customer in the process of new product development, assist the user in terms of product development, product upgrading iteration, process validation, etc., to solve the user pain points by the lack of test equipment.
- Process amplification: user assistance, drug production from laboratory scale to the industrial scale, to verify, review and improvement of laboratory technology research to determine the reaction conditions, provide data for formal production, material and consumption, to reduce the risk of industrialization measures, improve the production efficiency, reduce costs, improve product quality.
- Material testing: the user actual material and CFD simulation of blade forms, material experiment was carried out by testing equipment, guarantee the user to achieve material mixed state, eventually to verify the rationality of the blade, mixing data provided recommendations, auxiliary users adjust mixing parameters ensure pharmaceutical properties.



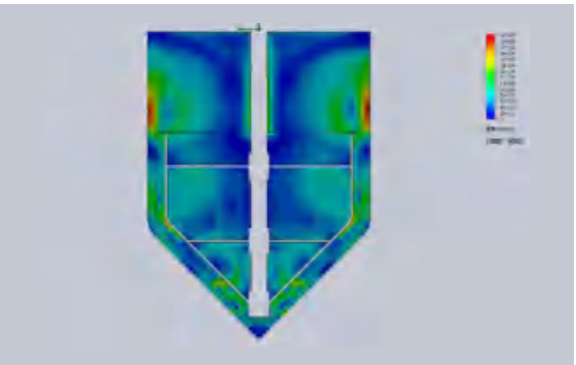
推进式桨叶 CFD 模拟分析
CFD simulation analysis of propulsion blade



弧形桨叶 CFD 模拟分析
CFD simulation analysis of arc blade



六叶圆盘涡轮式桨叶 CFD 模拟分析
CFD simulation of six - blade disc turbine blade



高粘度框式桨叶 CFD 模拟分析
CFD simulation analysis of high viscosity frame blade

自动化控制系统解决方案 Automation Control System

法规符合 Regulatory Compliance

- ◎ 符合美国 FDA、欧盟、WHO 标准
- ◎ cGMP、欧盟认证检查
- ◎ GAMP5 良好自动化生产实践指南
- ◎ FDA 21 CFR part11 相关要求
- Conform to FDA, EU and WHO standards
- cGMP and EU certification inspection
- Good Automated Manufacturing Practice
- Relevant requirements of FDA 21 CFR part 11

设计功能 Design Function

- ◎ 数据完整性
- ◎ 权限管理 / 集中用户管理
- ◎ 审计追踪 / 电子签名
- ◎ 移动监控 / 微信推送报警
- ◎ 灾难恢复 / 智能无人值守
- ◎ 易损件智能维护功能
- ◎ 能源管理 / 报表开发
- Data integrity
- Rights management/Centralized user management
- Audit trail/Electronic signature
- Mobile monitoring/Wechat alarm push
- Disaster recovery/Intelligent unattended
- Intelligent maintenance function of wearing parts
- Energy management/Report development

全新一代人机交互系统，所见即所得 A new generation of HMI system



可检索审计跟踪日志 Retrievable audit trail log

程序控制 / Program Control

- ◎ CIP/SIP 程序一键式启动，全自动执行
- ◎ 可根据清洗介质、清洗对象进行自由搭配
- ◎ 程序可进行暂停、跳转控制
- ◎ 具有自动气密性检测功能，判断系统漏点
- ◎ 可在线仿真运行程序
- ◎ 具备 PLC 自诊断功能
- CIP/SIP program is started with one key and automatically executed
- It can be freely matched according to the cleaning medium and cleaning object
- The program can be paused and Jumped
- automatic air tightness detection to judge the leakage point of the system
- Online simulation running program
- With PLC self diagnosis function
- ◎ 工艺步骤、工艺参数使用配方化管理
- ◎ 执行步序动态可视
- ◎ 记录历史步序信息，便于异常情况跳转
- Formulated management of process steps and parameters
- Dynamic visualization of execution steps
- Record historical step sequence information to facilitate abnormal situation jump

清洗方式选择

F2:PW>碱洗>PW>WFI

清洗对象选择

☒

罐

☒

脱碳循环管路

☐

送液管路

清洗控制

启动暂停继续停止

跳转控制

待机状态

步骤

阶段	1	2	3	4	5	6	7	8	9	10
加水										
加辅料										
接液										
调pH										
降温										
转移										
溶解										
投料										

步骤: 1 阶段: 加水

启用

加水重量至	100.0	Kg
定容后搅拌时间	30	s
定容后搅拌频率	35	Hz
冷点降温上限	40.0	℃
冷点降温下限	35.0	℃

配方编辑

记录名: xp001

数据已完成

配制控制

启动暂停继续停止

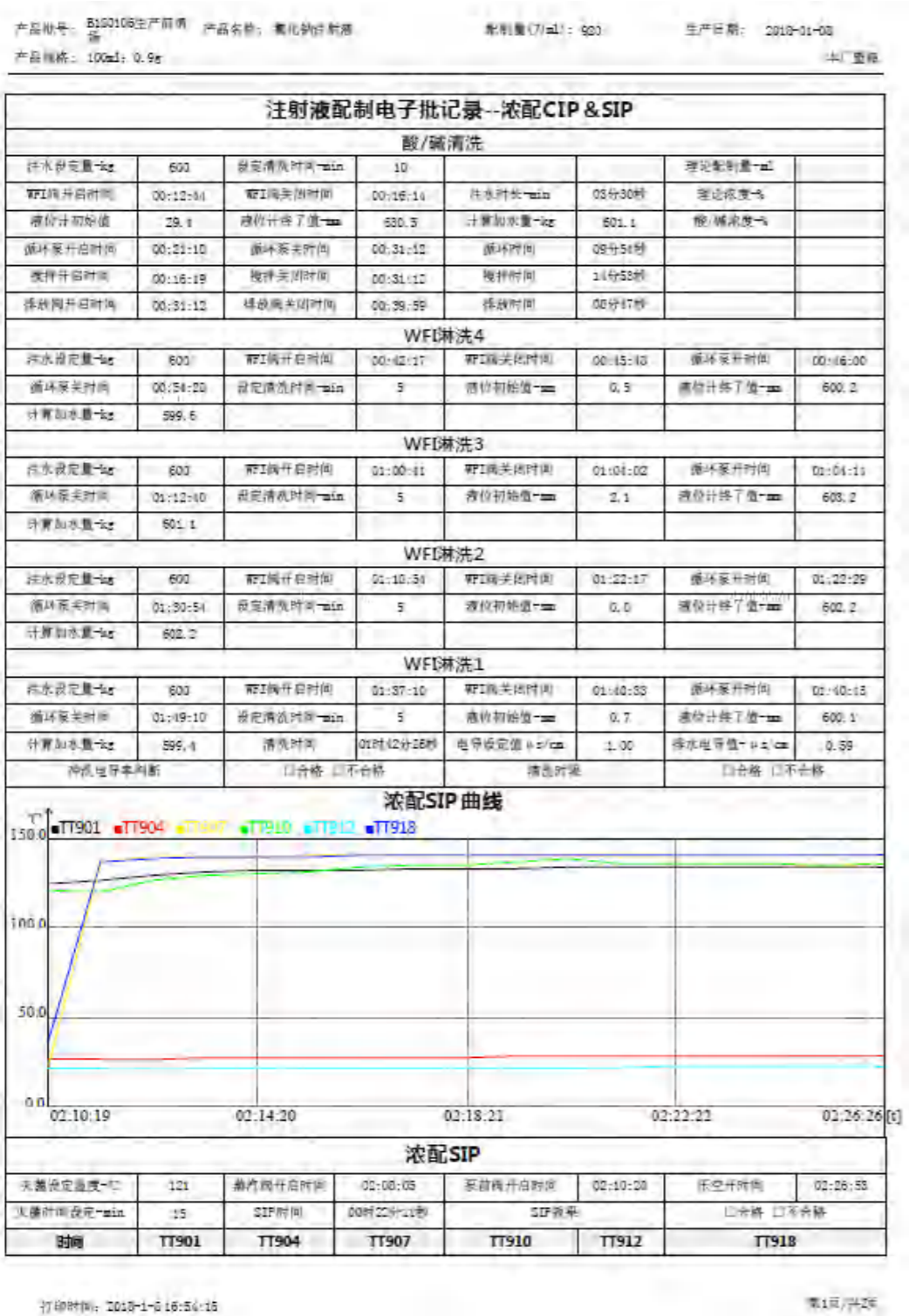
配方信息

运行配方xp001

步骤信息

历史步骤0

报表开发 / Report Development



- 定制化批次报表

○ 根据需要按区域、设备、批次检索报表

○ 数据报表、趋势报表可进行显示编辑
- Customized batch report

- Search by area, equipment or batch as required

- Data report and trend report can be edited to display

工业互联网远程运维平台
Industrial Internet Remote Operation and Maintenance Platform



- 传统被动维护转为主动智能维护

○ 远程解决设备故障

○ 程序升级与调整

○ 支持深度定制, 数据上云

○ 短信 / 微信自动推送报警

○ 经安全认证, 带操作追踪
- Switching from passive maintenance to active maintenance

- Troubleshoot device faults remotely

- Program upgrade and adjustment

- Support deep customization, data on the cloud

- SMS/WeChat automatic push alarm

- Safety certified and operation tracking

报警产生推送 - 微信
Alarm generation push - WeChat

报警消失推送 - 微信
Alarm disappearance push - WeChat

告警通知

您好,尊敬的用户您所负责维护监控的设备

告警内容: 液位低低, 请注意

告警场所: 天津市滨海新区新环东路与新业街交叉路口

告警设备: DS22178

告警级别: 严重

告警时间: 2022-09-19 19:05:14

备注: SBJ202209190003

告警通知

您好,尊敬的用户您所负责维护监控的设备

告警内容: 液位低低, 请注意已结束. 持续时间: 2秒

告警场所: 天津市滨海新区新环东路与新业街交叉路口

告警设备: DS22178

告警级别: 严重

告警时间: 2022-09-19 19:05:14

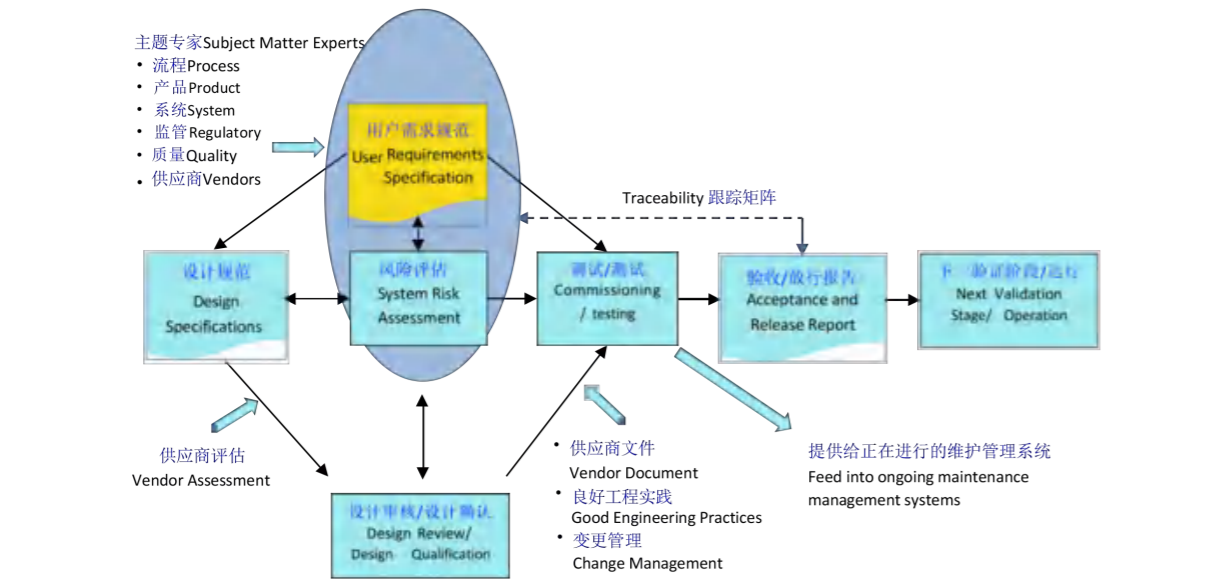
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验证咨询与服务解决方案 Validation Consulting and Service

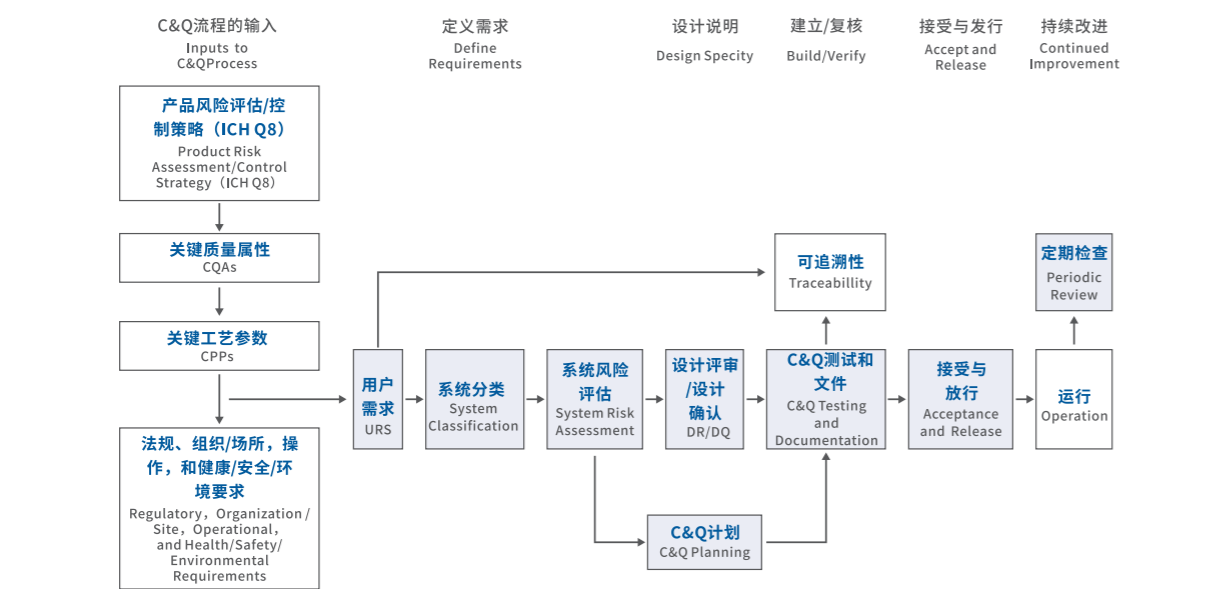
我们建立了应对不同客户需求的验证文件执行体系，提供的验证服务包括验证咨询服务、验证测试服务及有关 GMP 合规风险管理的培训服务，验证文件体系符合 FDA、EUGMP、WHO、cGMP 等规范和标准要求。

We have established a validation document execution system to meet different customer needs. The validation services we provide include validation consulting services, validation testing services and training services related to GMP compliance risk management. The validation document system complies with FDA, EUGMP, WHO, cGMP and other specifications and standards.

C&Q 活动和文档的关系图 - 用户需求规范 Relational Diagram for C&Q Activities and Documents - User Requirements Specification



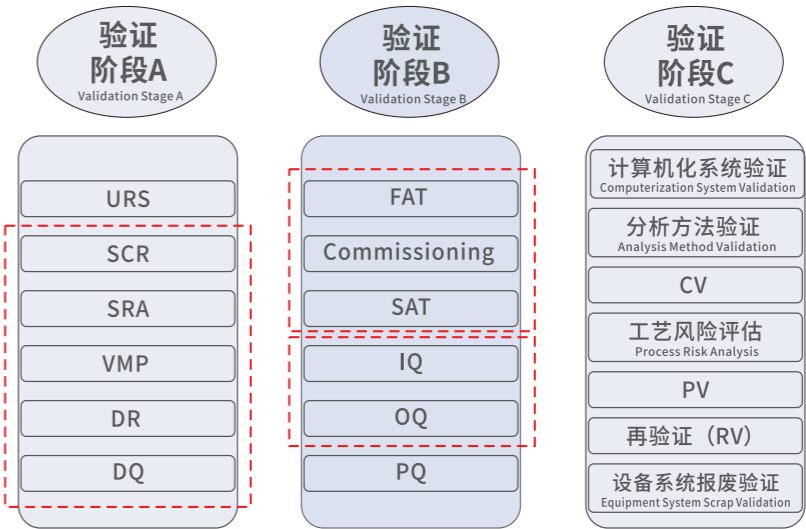
基于科学和风险的 C&Q 的流程图 / C&Q Process Flow based on Science and Risk



验证工作分属 / Validation Allocation

红色虚线部分是我们提交与客户的文件，客户对其进行批准；其他部分是以客户为主，我们可以提供相应的协助工作。

The dashed red line is the document we submit to the customer, and the customer approve it. Other parts are customer-oriented, and we can provide corresponding assistance.



验证咨询业务 / Validation Consulting Services

我们拥有 30 余位药企生产和质量工作经验的验证工程师，可为用户提供制药流体工艺系统验证服务，如制药用水分配与管网系统、制药用气管网系统、配液系统、CIP/SIP 系统、工艺罐等。产品应用范围涉及生物制品（如疫苗、血液制品、重组产品等）、药品制剂（如小容量注射剂、粉针剂、冻干粉针剂、大容量注射剂、固体制剂、口服液等）原料药等多种剂型。根据用户的需求，提供符合现行版中国 GMP、欧盟 GMP、美国 FDA、WHO 等规范和标准要求的完善的确认与验证咨询服务。

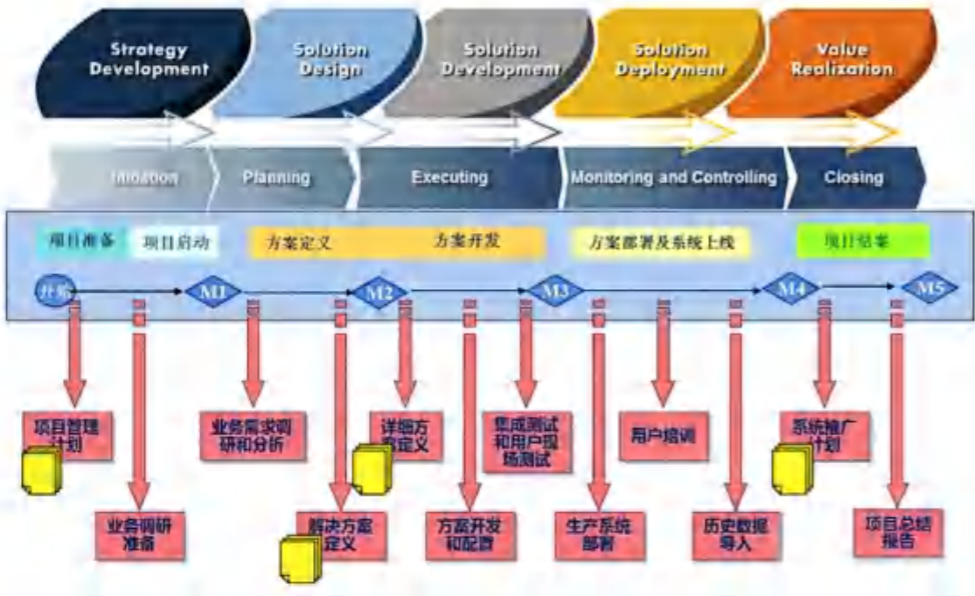
We have more than 30 validation engineers with production and quality work experience in pharmaceutical companies. We can provide customers with validation services for pharmaceutical fluid process system, such as pharmaceutical water distribution and pipeline system, pharmaceutical gas pipeline system, liquid dispensing system, CIP/SIP system, process tank, etc. The product application scope involves biological products (such as vaccines, blood products, recombinant products, etc.), pharmaceutical preparations (such as small volume injection, powder injection, lyophilized powder injection, large volume injection, solid preparations, oral liquid, etc.), bulk drugs and other dosage forms. According to the needs of users, we provide perfect confirmation and validation consulting services in line with the current version of Chinese GMP, EU GMP, FDA, WHO and other norms and standards.



工程项目管理解决方案 Engineering Project Management

我们建立了端到端的项目化管理协作平台，动态、高效调配项目所需资源，全流程管控项目执行过程，并拥有一支深耕制药行业、高度专业化、职业化的项目管理团队，通过组织和体系保障，利用自身经验优化项目设计、BIM空间设计、项目实施方案，合理统筹规划，提升总体项投资效益，确保每一个用户具有良好的项目体验，促进项目高质量交付。

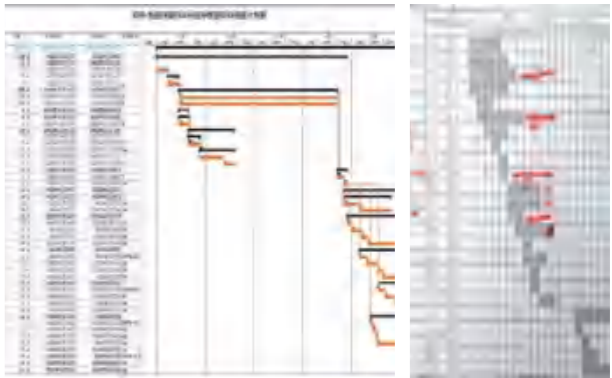
We established the end-to-end project management collaboration platform, dynamic, efficient deployment project resources required, whole process control project implementation process, and has a highly specialized and professional project management team deeply explore in pharmaceutical industry, through the organization and system security, use its experience to optimize project design, BIM space design, project implementation plan, and reasonable overall planning. Improve overall project investment benefits, ensure that every user has a good project experience, and promote high-quality project delivery.



需求管理	Requirement	进度计划管理	Schedule
URS输入 技术方案DQ确认 工程造价 质量&进度需求	URS input DQ Project cost Quality & schedule requirements	项目进度主计划 工厂制造 现场安装 调试&验证	Schedule master plan Factory On-site installation Commissioning & Validation
资源管理	Resource	风险管理	Risk
原材料供应链 制造平台 物流运输 现场人、机、料	Raw material supply chain Manufacturing Logistics People, machine and materials on site	技术风险 供应链风险 运输风险 安装风险	Technical risk Supply chain risk Transport risk Installation risk
质量管理	Quality	沟通管理	Communication
品质控制 制造质量 安装质量 调试&测试质量	Quality control Manufacturing quality Installation quality Commissioning & test quality	项目启动会 技术交底 变更管理 过程问题关闭	Project start meeting Technical clarification Change management Process problem closure



需求管理 Requirement Management



进度计划管理 Schedule Management



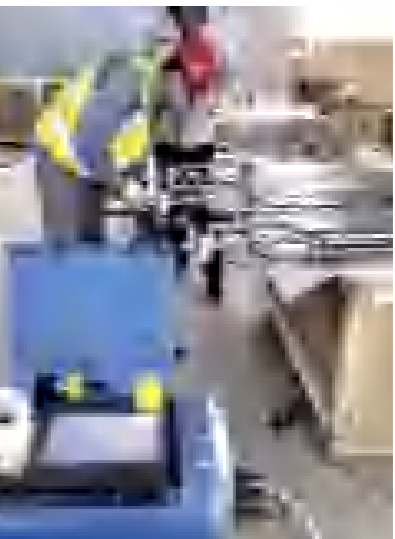
资源管理 Resource Management



风险管理 Risk Management



沟通管理 Communication Management



质量管理 Quality Management

服务理念

0431-81989135



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

0431-81989135



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