PHARMAC
珐成浩鑫 ●●●

不锈钢
STAINLESS STEEL
BIOREACTOR SYSTEM
生物反应器系统

XBioR
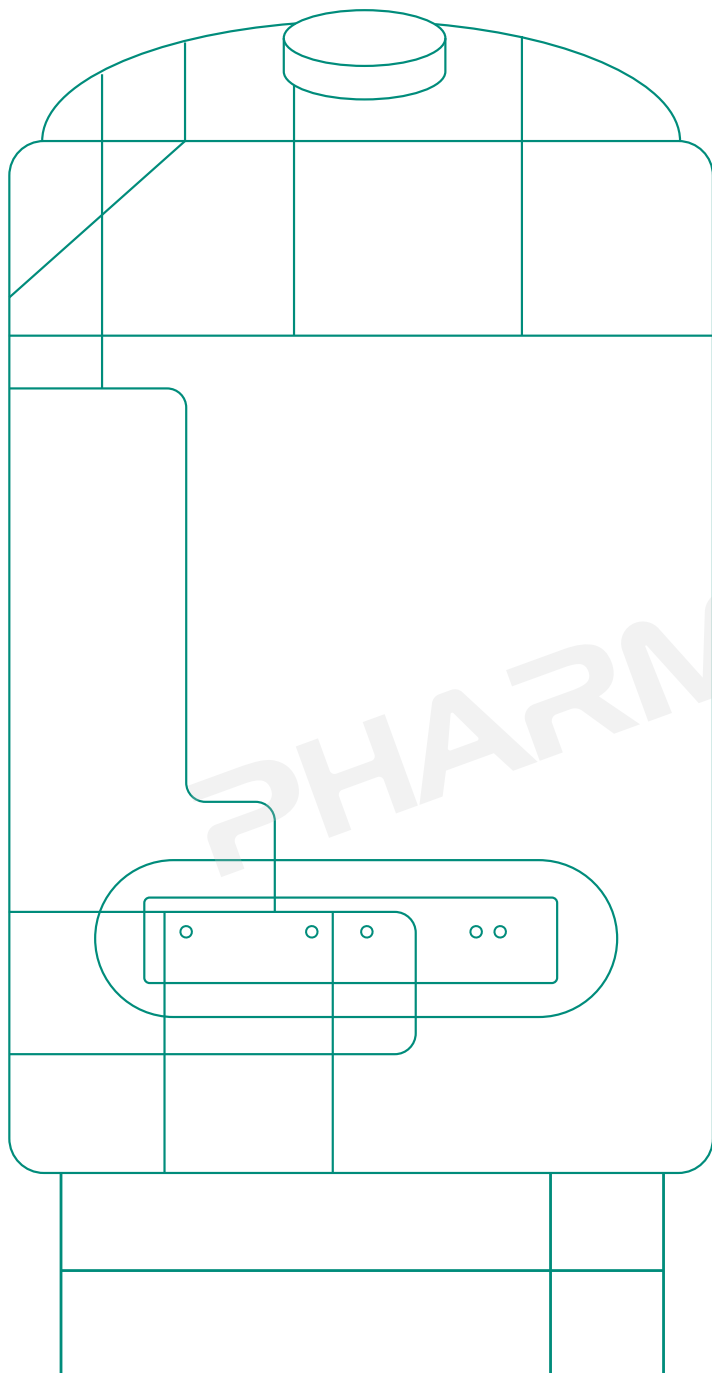
全悬浮
高定制
自动化

SUSPENSION SOLUTIONS
HIGHLY CUSTOMISED
AUTOMATED

PHARMAC
珐成浩鑫 ●●●

关于我们
ABOUT US

珐成浩鑫致力于为生物制药、日用化工、合成生物及相关行业提供**专业的洁净流体系统工程服务**。专注于推动**流体工艺技术突破和自主知识产权工艺装备**的打造，实现高质量、可持续的洁净流体设备**本土化制造之路**。

PHARMAC is committed to providing professional clean liquid system engineering services for the pharmaceutical, daily chemicals, food, synthetic biology and related industries.We have been dedicated to driving breakthroughs in fluid process technology and the development of proprietary process equipment in order to achieve high-quality and sustainable localized manufacturing of clean fluid equipment.

能为客户提供包括：**生物反应器、配液系统、生物发酵系统、水机及分配系统**等专业流体工艺设备。

We are capable of providing customers with professional fluid process equipment such as bioreactors, formulation systems, fermentation systems, PW & WFI genertion & distribution systems.

PHARMAC，**引领洁净流体系统新方向，助力生命科学领域前行**。

Leading the way in the clean liquid system, making contributions in the advancement of life sciences.

谁更需要我们
WHO NEEDS THIS SYSTEM

人源（化）抗体生产	人用/兽用疫苗的生产	哺乳动物细胞培养表达重组蛋白	昆虫细胞生产
Humanized antibody production	Human / animal vaccines production	Recombinant protein production in mammalian cell culture expression	Insect cell production

我们提供什么
WHAT DO WE OFFER

珐成浩鑫的 **XBioR** 系列不锈钢生物反应器系统，规模涵盖从实验室规模到工业生产超大规模**(5L-15KL)**。通过 **CFD 仿真模拟技术**优化了罐内气液、液液和固液的混合效果，具备**低剪切、强混合**的搅拌设计，支持多种气体组合通气策略和精准的温度控制，配备丰富的**在线监测技术**，有效提升了细胞培养密度和表达性能。

Pharmac's XBioR series stainless steel bioreactor systems, with scales ranging from laboratory-scale to industrial-scale (5L-15KL). Using CFD simulation technology, we optimize gas-liquid, liquid-liquid, and solid-liquid mixing effects, featuring low shear, high mixing intensity agitation design. We support various gas combination aeration strategies and precise temperature control, equipped with comprehensive online monitoring technologies to effectively enhance cell culture density and expression performance.

此外，我们提供以生物反应器为核心的工艺设备三维设计，针对大型设备，可进行**黑白分区设计**，降低项目工程建设风险，减少运维成本。公司还与国内知名高校合作，可为客户提供部分**细胞培养基及工艺验证服务**。

In addition, we offer three-dimensional design of process equipment centered around bioreactors. For large-scale equipment, we can implement black-and-white partition designs to mitigate project construction risks and reduce operational costs. Our company also collaborates with renowned domestic universities to provide customers with certain cell culture media and process validation services.

经典项目案例
CLASSIC PROJECT CASES

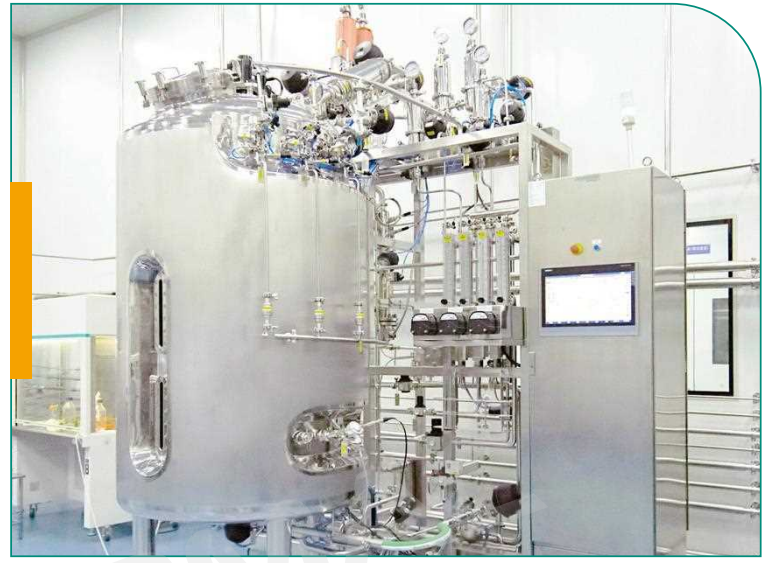### XB-15000

15,000L超大规模不锈钢生物反应器

15,000L Ultra Large Scale Stainless Steel
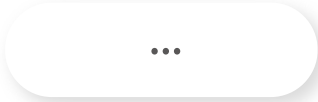Bioreactor

XB-100/500/1000/3000/5000

**100L/500L/1,000L/3,000L/5,000L
不锈钢生物反应器**

100L/500L/1,000L/3,000L/5,000L
Stainless Steel Bioreactor

已服务客户
SERVED CUSTOMERS

兰州生物制品研究所有限责任公司
SINOPHARM LANZHOU INSTITUTE OF BIOLOGICAL PRODUCTS CO.,LTD.

HPBG 华派
HUAPAI BIOLOGICAL GROUP 生物集团

华晟
HUASHENG

大华农
DAHUANONG

Hanvet

YEBIO 易邦生物

CENTREBIO

美兰生物
MEILAN SHENGWU

MEBOLO SWINE BREEDING

ringpu 瑞普生物

中岸生物
SINOLAND

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XBioR 系列已实现：
5L-5000L标准不锈钢生物发酵反应器系统
5L-15,000L定制生物反应器系统
上游成套设备解决方案

XBioR series has achieved:
5L-5000L standard stainless steel bioreactor system
5L-15,000L customized bioreactor system
Upstream complete equipment solution

设备功能
EQUIPMENT FUNCTIONS

关键质量属性 / 关键工艺参数监控

- pH
- 压力
- 细胞传感器 (选项配置)
- (自动)控压功能
- (自动/关联)pH控制
- 防止培养基返流功能
- 自动放料功能
- 气体流量 (自动)控制

- DO
- 尾气分析仪(选项配置)
- (自动)CIP/SIP功能
- (自动)消泡功能
- (自动/关联)补料控制
- 防止尾气过滤器堵塞功能
- 自动提升功能

- 温度
- 拉曼光谱(选项配置)
- 自动控温功能
- (自动/关联)溶氧控制
- 多种补料策略
- 自动移种功能
- 防错防呆功能

CQA / CPP

- pH
- Pressure
- Cell sensor (option configuration)
- Automatic temperature control function
- (Automatic) Defoaming function
- (Automatic /Associated) pH Control
- Multiple feeding strategies
- Prevent clogging function of exhaust filter
- Automatic feeding function
- Minimised risk of operator

- DO
- Exhaust gas analyzer
- Raman spectra(option configuration)
- (Automatic) CIP/SIP function
- (Automatic) Pressure control function
- (Automatic/Associated) DO control
- (Automatic/Associated) Feeding Control
- Prevent medium reflux function
- Automatic seed transfer function
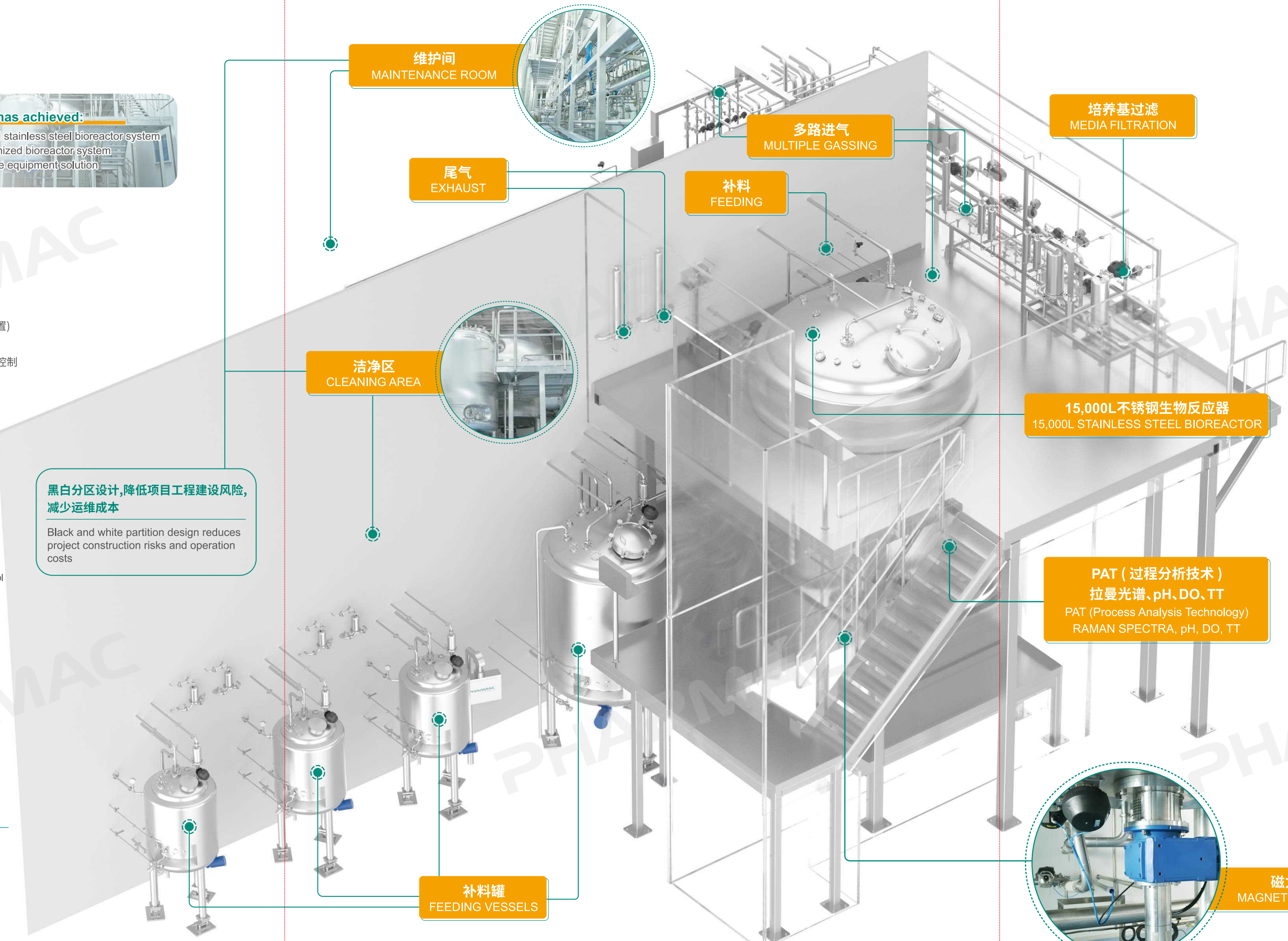- Automatic lifting function
- Gas flowrate (automatic) control

- Temperature

控制系统功能
CONTROL SYSTEM FUNCTIONS

- PLC或DCS
- 上位机(选项配置)
- GAMP5
- ISA S88
- 多级权限管理功能

- 配方管理功能
- 审计追踪功能
- 自动报警功能
- 实时/历史曲线查询功能
- 趋势曲线

- 补料数据记录
- 批报表自动生成功能

- PLC or DCS
- SCADA (option)
- GAMP5
- ISA S88
- Multi level permission

- Recipe management function
- Audit tracking function
- Automatic alarm function
- Real time/historical curve query function
- Trend curve

- Feeding data record
- Batch report function

维护间
MAINTENANCE ROOM

多路进气
MULTIPLE GASSING

尾气
EXHAUST

补料
FEEDING

培养基过滤
MEDIA FILTRATION

洁净区
CLEANING AREA

黑白分区设计,降低项目工程建设风险,减少运维成本

Black and white partition design reduces project construction risks and operation costs

15,000L不锈钢生物反应器
15,000L STAINLESS STEEL BIOREACTOR

PAT (过程分析技术)
拉曼光谱、pH、DO、TT
PAT (Process Analysis Technology)
RAMAN SPECTRA, pH, DO, TT

补料罐
FEEDING VESSELS

磁力搅拌
MAGNETIC AGITATOR

www.pharmachamp.com

工程设计方面：

- 模块化设计
- 标准化设计
- 关键部件冗余设计
- 黑白分区设计

设备特点：

- 合理的3D设计减少培养基的管道残留,减少生产成本
- 过程开发,流程优化,高低档不同配置
- 满足ISPE/ASME BPE等要求
- 尾气过滤冗余设计
- 可更换的气体分布器,满足客户对生产工艺的探索和优化
- 拓展接口丰富

搅拌可选择：

- 上机搅拌
- 上磁力搅拌
- 下机械搅拌
- 下磁力搅拌

浆叶可选择：

- 象耳浆
- 水翼浆
- 四宽叶推进浆等
- 多种浆叶形式和组合

In terms of engineering design:

- Modular design
- Standardized design
- Redundancy design of key components
- Black and white partition design

Equipment features:

- Reasonable 3D design reduces culture media pipeline residue and production costs
- Process development, process optimization, high and low grade different configuration
- Comply with ISPE / ASME BPE and other requirements
- Dual exhaust gas filtration
- Replaceable gas sparger to satisfy customer 's exploration and optimization of the production process
- Various expansion possibilities

Agitator options:

- Mixing machine
- Magnetic stirring on top
- Mechanical mixing
- Magnetic stirring

Impeller blades options:

- Elephant ear blade
- Hydrofoil blade
- Four wide blade propulsion blade, etc
- Multiple blade forms and combinations

从设计到落地,助力客户商业化进程
From design to implementation, supporting clients in commercialization

拉曼光谱
Raman Spectra

产品视频
Product Video

3

4

5

我们的最优解
OUR OPTIMAL SOLUTION

标准化
STANDARDIZATION

设计与制造符合cGMP指南和ASME BPE标准

The design and manufacture complies with cGMP guidelines and ASME BPE standards

备件的通用性

The versatility of spare parts

便于维护及快速安装的撬装模块化设计

Skid-mounted modular design for easy maintenance and rapid installation

基于ISA 88批次控制系统的自动化设计

Automation design based on ISA 88 batch control system

DQ/IQ/OQ/FAT/SAT符合GEP, GMP规范

DQ/IQ/OQ/FAT/SAT complies with GEP and GMP Standards

定制化
CUSTOMIZATION

根据客户的需求定制生物反应器

Customized bioreactors according to client's requirements

自动SIP（原位灭菌）/CIP（原位清洗）

Automatic SIP (Sterilization in place) CIP (Cleaning in place)

多路进料/补料, 收获和无菌采样系统

Multi-feeding line, harvesting and aseptic sampling system

温度、压力、pH、DO、拉曼光谱等多种PAT技术的应用

The application of various PAT techniques, such as temperature, pressure, pH, DO, and Raman Spectra.

滤壳提升设计

Filter housing lifting design

双尾气处理系统（加热/冷却）

Dual exhaust gas treatment system (heating / cooling)

早期设计阶段运用CFD（计算流体力学）模拟

Utilization of CFD（Computational Fluid Dynamics）simulations in the early design phase.

高度灵活的进气系统

High flexible gassing strategy

稳定的温控

Stable temperature control

低剪切, 强混合的搅拌系统

Low shear, high mixing intensity agitation system

XBioR 系列参数表
XBIOR SERIES PARAMETER TABLE

容器 Vessel	• 工作体积 Working volume • 全容积 Total volume • 最小工作容积 Minmum liquid working volume • 容器高径比 Overall geometry H:D ratio • 设计压力 Design pressure • 设计温度 Design temperature	• 5L-30KL • 7L-40KL • ~30% • 1.1:1~2:1 • -1~3 barg • 5-150℃
搅拌 Agitator	• 桨叶形式 Impeller type • 桨叶数量 Impeller quantity • 搅拌电机 Agitation motor drive • 电机功率 Motor power • 搅拌器类型 Agitator type	• 象耳桨或莱宁水翼桨 Elephant ear or lightning impellers • 2 • 380 V AC 3/220 V AC • 根据应用条件 According to the application condition • 上/下机械或磁力 Top / bottom mechanical or magnetic
夹套 Jacket	• 夹套类型 Jacket type • 温度控制 Temperature control	• 全夹套/蜂窝夹套/半管夹套 Full/ Dimple/ half-pipe jacket • 冷/热板换循环控温或电加热控温 Closed loop system with recirculation pump and heat exchanger for heating and cooling or electical heating
过程监控仪表 Process monitoring instrument	• pH Probes • DO Probes • MFC • 泡沫电极 Foam probes • 压力传感器 Pressure transmitter • 液位/重量监测Level/Weight • 温度监测Temp. • 可选 Option	• 2（可选备用接口）(Spare nozzle is optional) • 2（可选备用接口）(Spare nozzle is optional) • 流量计+控制阀或MFC Flowmeter+control valves or MFC • 1(可选备用接口)(Spare nozzle is optional) • 1(可选备用接口)（Spare nozzle is optional) • 差压液位计或称重模块 Differential pressure level transmitter or load cell • 单支双芯(可选备用接口）Single with double core (Spare nozzle is optional) • CO₂ 电极/细胞密度电极/拉曼电极 CO₂ Probes / Cell density Probes / Raman Probes
通气 Gassing strategy	• 表层通气 Surface • 深层通气 Deep • 空气 Air • 氧气 O₂ • 二氧化碳 CO₂ • 氮气 N₂ • 过滤器 Filter	• 管道直通 Open pipe • 环形分布器 Ring sparger 微泡管 Microsparger • 按需求配置Configure as required • 按需求配置Configure as required • 按需求配置Configure as required • 按需求配置Configure as required • 0.2um 除菌过滤器 Microbial filter
尾气 Exhaust	• 换热器 Heat-exchanger • 过滤器 Vent Filter • 尾气分析 Vent gas analysis	• 排气冷却器和加热器可选配 Exhaust cooler and heater for option • 0.2um 除菌过滤器（一用一备可选） Dual 0.2um microbial filter (One use, one prepare for option) • 预留备用接口 Spare nozzle for reservation
取样 Sampling	• 取样阀手动/自动 Sampling valve Manual/Automatic • CIP/SIP	• 手动/自动 Manual/Automatic • CIP/SIP
进/补料 Feeding	• 进料1 Feeding line 1 • 进料2 Feeding line 2 • 进料3 Feeding line 3 • 进料4 Feeding line 4 • 进料5 Feeding line 5 • 进料6 Feeding line 6 • 进料7 Feeding line 7 • 进料8 Feeding line 8 • 灌流 Perfusion	• 接种 Seed Feeding • 培养基进料 Medium Feeding • 蠕动泵/流量计可供选择 Peristaltic pumps / Flowmeter for option • 蠕动泵/流量计可供选择 Peristaltic pumps / Flowmeter for option • 蠕动泵/流量计/备用口可选 Peristaltic pumps/ Flowmeter / Spare nozzle for option • 蠕动泵/流量计/备用口可选 Peristaltic pumps/ Flowmeter /Spare nozzle for option • 可选备用接口 Spare nozzle for option • 可选备用接口 Spare nozzle for option • 可选备用接口 Spare nozzle for option
控制系统 Control system	• 系统 system • 显示 Display • 编程 Programming	• Simens Wincc or PCS7+batch • 触摸屏或电脑 Touch screen or IPC • ISA-88 GAMP5

我们的制造能力
WHAT WE OFFER

● 制造始于1995年
  Our history of manufacturing can be traced back to 1995

● 20年+, 洁净容器/换热器/模块设计及加工制造历史
  20+ years' experience in clean vessel/heat exchanger/module design and manufacturing

● 容器及模块制造工艺流程的过程控制
  Process control of vessel and module manufacturing process flow

● 国内少有可生产钛材/哈氏合金等特材压力容器的厂家
  One of the few domestic manufacturers with the capacity to produce pressure vessels made of special materials such as titanium and Hastelloy

认证
AUTHENTICATION

* 压力容器特种设备生产许可证
* ASME（美国机械工程师协会)U钢印授权证书
* 压力设备(PED) 认证
* 可提供满足
  GMP、CFDA、FDA、EMA、WHO等体系的文件

* Pressure Vessel as Special Equipment Production License
* "U" Steel Seal Certificate of Authorization from ASME
* Pressure Equipment Directive (PED) Certification
* We can provide documents that meet the requirements of GMP, CFDA, FDA, EMA, WHO and other systems

珐成制药系统工程(上海)有限公司

Pharma Champ Pharmaceutical Engineering (ShangHai) Co., LTD.

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广州市浩鑫洁净工程技术有限公司

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珐成制药设备(浙江)有限公司

Pharma Champ Pharmaceutical Equipment (Zhejiang) Co., LTD.

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