

# 自动化与信息化工程 解决方案

AUTOMATION AND INFORMATION ENGINEERING  
TECHNOLOGY SOLUTIONS



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深耕行业KNOW-HOW  
助力企业数字化转型

DEEPLY ROOTED IN INDUSTRY-SPECIFIC KNOW-HOW  
EMPOWERING THE ENTERPRISE A DIGITAL MAKEOVER

## 智周万物

02

天俱时集团  
自动化与信息化工程

### Intelligence for All Things

TIANS Group  
Automation and Information Engineering

## 智慧未来

04

我们的能力

### Intelligence for the Future

Our Ability

## 智圆行方

22

技术优势

### Intelligence with Ability & Integrity

Technology Advantages

## 智者见智

26

项目案例

### Intelligence for the Intelligent

Typical Cases

## 智慧共创

36

我们的客户

### Innovation under Intelligence

Our Clients

技驭未来

TECH THE FUTURE

CONTENTS



# Intelligence for All Things

## 智周万物

天俱时集团  
TIANS Group



工艺技术服务  
Process and Technology  
Services



工程咨询与设计  
Engineering Consulting  
and Design



工程总承包  
T-EPC



自动化与信息化  
Automation and  
Informatization



智能装备  
Intelligent Equipment



### 26+年

始创于1998年，是一家赋能新技术产业化的工程设计集团。总部位于石家庄，青岛、天津设分公司及办事处；瑞士设生物医药咨询创新中心。

Founded in 1998, TIANS is an engineering design group empowering industrialization of new technologies. Headquartered in Shijiazhuang, with branches and offices in Qingdao, Tianjin and Jinan; and a biomedical consulting and innovation center in Switzerland.

### 60+百强

中国医药工业百强企业战略合作伙伴，已为60多家医药百强企业提供服务。

We are a strategic partner of top 100 enterprises in China's pharmaceutical industry, and has provided services to more than 60 top 100 pharmaceutical enterprises.

### 500+客户

涉及精细化工、合成生物、生物医药、化学制药、冶金矿山、食品健康、医疗器械等行业领域。

We serve 500+ clients involved in the fields of fine chemical, synthetic biology, biomedicine, chemical pharmaceutical, metallurgical mining, food health, medical devices, etc..

### 2000+项目

覆盖全国20多个省、市、自治区，数十项国家级、省级优质工程。

The projects cover more than 20 provinces, cities and autonomous regions, and dozens of national and provincial quality projects.

## 自动化与信息化工程 Automation and Information Engineering

化学合成工艺过程自动化工程中国领先  
自动化工程单合同规模制药行业领先

Leading in China:  
Automation Engineering of Chemical Synthesis Process  
Leading in Pharmaceutical Industry:  
Single Contract Scale of Automation Engineering

天俱时自动化与信息化拥有电子与智能化工程专业承包壹级等30余项资质，坚持以自动化、信息化技术为核心，精通生产过程中核心生产工艺及生产辅助过程的自动化关键技术，结合行业属性为客户提供满足工艺需求的从系统设计、集成开发、工程实施到项目管理的一站式数字化工程解决方案，助力企业数字化转型，实现智能制造。

TIANS have more than 30 qualifications in automation and information technology, such as class A contract for electronic and intelligent engineering. Based on automatic key technologies in core production process and production support process, combining with industry attributes, we focused on supplying various industries' clients with one-stop Digital Engineering Solutions, which satisfying clients with process requirements from system design, integrated development, project implementation to project management, empowering enterprises' digital industrialization and realizing intelligent manufacturing.

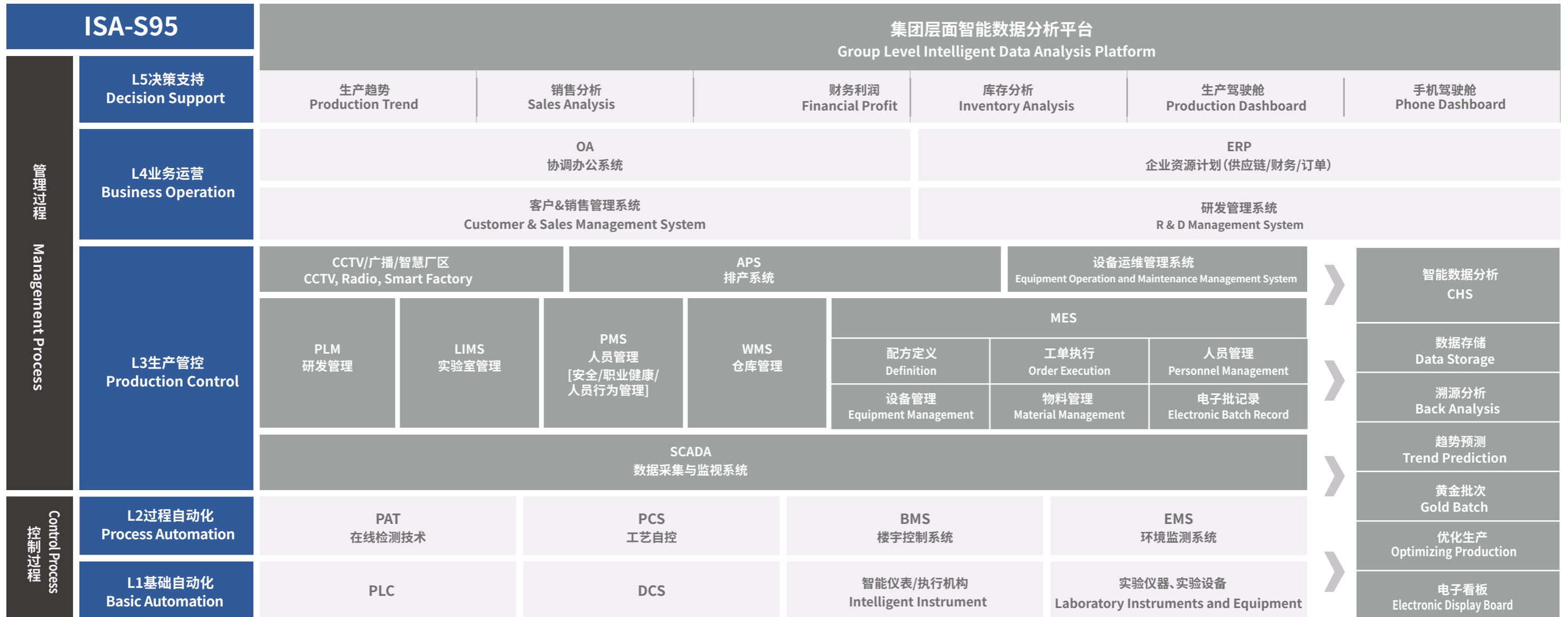




# Intelligence for the Future

## 智慧未来

### 我们的能力 Our Ability





# 2.1

## 化学合成自动化解决方案 Chemicals Synthesis Automation Solution

化学合成通常伴随剧烈的反应过程，对反应的控制精度要求极高，同时控制精度的高低直接影响产品质量与收率，甚至导致安全事故。良好的自动化解决方案对于保证生产安全、提高生产效率、稳定产品质量、降低生产成本至关重要。天俱时自动化与信息化团队致力于化学合成领域近20年，深耕行业Know-How，可提供涵盖反应器控制、萃取分相、减压蒸馏、结晶、液体罐区等典型控制单元的定制化解决方案，可广泛应用于化学制药、精细化工等领域。

### 关键控制技术 Critical Control Technologies

#### 液体加料 Liquid Feeding

- 针对反应特点及进料精度需求，提供前端进料计量、末端进料计量形式。
- 前端高位罐计量，提供不同计量精度的液位控制方案。
- 前端流量计量，针对单一物料、多种物料、一对一、一对多等情形，提供不同型式流量计控制方案。
- 多种溶剂计量可选用末端计量方式。

#### 滴加控制 Dripping Control

- 根据反应剧烈程度及工艺特点，提供占空比滴加控制、匀速滴加控制等控制形式。
- 结合反应釜背压，提供常压滴加、加压滴加等方案。
- 根据GMP验证需求，制定无残留滴加方案。
- 根据滴加特点，对滴加调节阀进行精准计算选型，满足高精度滴加控制。

#### 氮气控制 Nitrogen Control

- 针对容器设备易燃易爆气相空间，可选择一键氮气置换方案，实现真空、氮气惰化、氧含量检测整个过程自动控制，保障工艺的本质安全。
- 根据接收罐的位置，可选择氮封转料控制、氮气加压转料控制等方案。

#### 温度控制 Temperature Control

- 结合反应控温精度需求及投资性价比，可选择±1°C常规温度控制系统、±0.5°C精准控温系统。
- 根据反应剧烈程度选择不同类型夹套媒介，满足反应换热需求。
- 根据反应放热曲线结合程序控制、串级控制、温差控制、模糊控制策略，建立精准控温模型。
- 根据安全联锁要求，合理设置紧急冷却系统。

#### 反应釜综合控制 Reactor Comprehensive Control

- 为反应釜定制综合控制方案，采用模块化控制策略，确保各个模块间的协同与高效运行。
- 多模块之间实现顺序控制，交叉模块之间定制专用控制方案，大幅提升反应釜操作效率的同时，实现全流程自动化。

#### 重点危险化工工艺安全控制 Safety Control of key Hazardous Chemical Processes

- 为确保“两重点一重大”危险化工工艺的安全运行，结合现行法规及应急管理部文件，可选择紧急切断控制、紧急冷却控制、紧急泄压控制等一系列安全措施，迅速响应并降低潜在风险。
- 根据HAZOP分析和SIL定级结果，确保控制回路满足SIF验算要求，实现化工工艺的本质安全。

#### 萃取分层控制 Extraction Stratification Control

- 针对轻相重相介质的物理特性（如电导率、密度、颜色、电容及乳化层现象），设置不同原理的分层检测仪。
- 结合实际放料速度需求，设计灵活的流量控制策略，大流量放料与小流量调节结合，有效防止轻重相之间二次混合；制定合适的分层控制模型，可实现一键自动分层，显著提高人工操作的需求，提高产品收率。

#### pH调节控制 pH Adjustment Control

- 针对多样化的pH调节场景，提供一系列精心设计的pH计配置型式，如沉入式、侧插式、外循环式、在线取样器式及提拉护套式。
- 针对不同工艺控制需求及各类复杂工艺，可选择占空比调节控制、比值调节控制以及连续调节控制。

#### 减压蒸馏控制 Vacuum Distillation Control

- 为满足不同蒸馏工艺的需求，制定多样化的蒸馏终点控制方案。
- 在减压蒸馏过程中，通过准确的控制真空度和冷凝回流温度，提高溶剂回收速率，实现全自动减压蒸馏，使蒸馏过程更加稳定、高效。

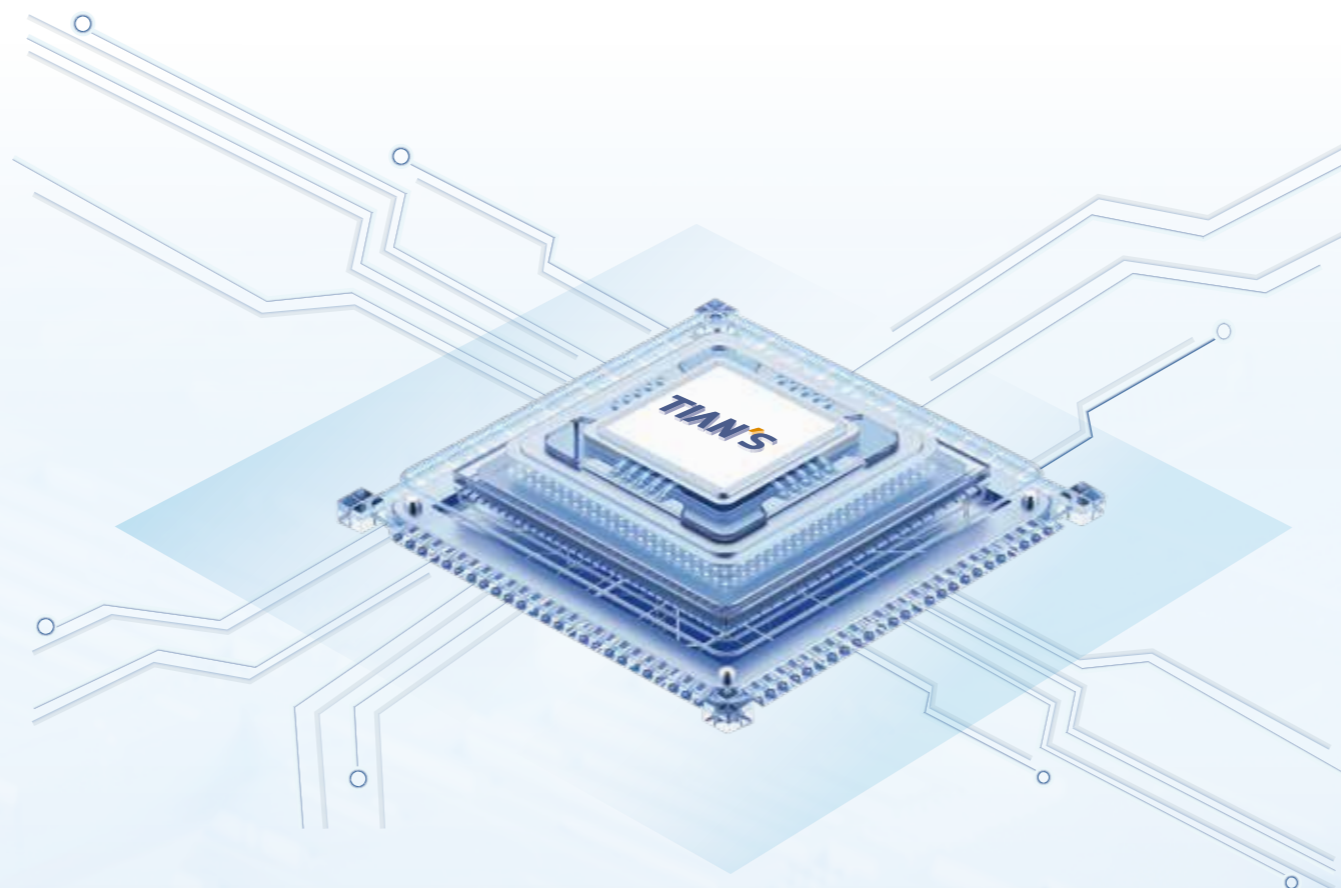
#### 结晶控制 Crystallization Control

- 结合产品结晶特点，可选择梯度降温结晶控制、加热蒸发溶剂析晶控制、投晶种静态结晶控制、投晶种动态结晶控制等方案。
- 提供西门子PSE机理混合模型结合密度、粘度等数据库，自动计算粒径分布，动态指导生产，确保结晶过程的稳定性，提高产品质量和收率。



扫码观看化学合成原料药工艺过程自动化3D演示

Scan the code and watch chemical synthetic API process 3D demonstration of process automation



## 特色技术 Specific Technologies

### 1 滴加控制系统 Dripping Control System

自主开发了适用于多种场合的滴加功能,在保证滴加过程的稳定及安全性的情况下,滴加重精度控制在 $\pm 0.5\text{kg}$ 以内。  
Independently developed dripping function for a variety of occasions, in the case of ensuring the stability and safety of the drip process, the drip weight accuracy is controlled within  $\pm 0.5\text{kg}$ .

根据滴加物料数量,提供单滴加、双滴加可选。  
According to the quantity of dripping material, single or double drop adding are available.

根据控制对象,提供恒比例滴加、恒温滴加、恒压滴加、恒温恒pH滴加等功能。  
According to the control object, provide different dripping types.

针对合成多功能反应釜同类物料滴加,自主开发了滴加小车控制模块,实现了滴加罐的移动操作。  
Independently developed the control module of drip feeding car, with the moving operation of drip feeding tank is realized.

### 2 分层控制系统 Hierarchical Control System

通过溶剂萃取电导率数值的单位自动换算,实现控制精度 $\pm 50\mu\text{s}/\text{cm}$ ,保证了分层的准确性,简化了生产操作。

Through the automatic conversion of the unit value of the solvent extraction conductivity, the control accuracy of  $\pm 50\mu\text{s}/\text{cm}$  is achieved, which ensures the accuracy of stratification and simplifies the production operation.

### 3 全自动回收控制系统 Automatic Recycling Control System

实现了精馏塔的一键启停操作,操作便捷安全,通过自平衡调节保证精馏系统的稳定性,有效提升回收产品的质量。

Realized the one-click start-stop, convenient and safe operation of rectification tower, and guaranteed the stability of the rectification system through self-balancing adjustment, with the quality of recovered products is effectively improved.

### 4 全自动酸碱中和控制系统 Automatic Acid-base Neutralization Control System

实现了酸碱配比的自动整定、酸碱中和的全自动控制,以及生产废水pH稳定控制。

It realizes automatic setting of acid-base ratio, automatic control of acid-base neutralization and pH stabilization of production wastewater.

### 5 TCU温度控制系统 TCU Temperature Control System

通过对夹套介质的高精度控制,实现釜内控温、夹套控温、梯度控温等控制精度均在 $\pm 0.5^\circ\text{C}$ 以内。

Through high precision control of jacket medium, the temperature in the kettle, jacket and gradient are all controlled within  $\pm 0.5^\circ\text{C}$ .

### 6 高精度加料控制系统 High Precision Feeding Control System

基于对反应物、加料速率、输送泵频率及进料中后阶段的偏差线性计算等精准控制,实现了加料量及滴加速度精度 $\pm 0.5\text{kg}$ 之内。

Based on accurate control of reactants, feed rate, pump frequency and linear calculation of deviation during and after feeding, the accuracy of feed amount and drop acceleration is achieved within  $\pm 0.5\text{kg}$ .

### 7 反应釜温度控制系统 Reactor Temperature Control System

保证反应温度能够迅速且稳定地达到预设反应温度,并维持在 $\pm 0.5^\circ\text{C}$ 的极窄温差范围内。

Ensuring that the reaction temperature can quickly and stably reach the preset reaction temperature, and maintain within a very narrow temperature range of  $\pm 0.5^\circ\text{C}$ .

## 轻量化T-MES系统 Simplified T-MES

天俱时支持基于客户实际需求,为客户设计、定制简洁、零代码、低成本的轻量化智能制造执行系统。系统独具核心功能、功能灵活敏捷、操作方便快捷、信息传达高效快速,通过工单一键下发、实时数据监控、自动化工作流程和智能分析,提供即时的决策支持。

Based on the actual needs of clients, TIANS advocate for design and customize concise, zero-code, low-cost lightweight intelligent manufacturing execution system for clients. The system has unique core functions, flexible and agile, convenient operation and efficient and fast information release, providing instant decision support through one-click delivery of work orders, real-time data monitoring, automated workflows and intelligent analysis.



## 人员定位管理系统 Personnel Positioning Management System





## 2.2

# 全流程自动化发酵技术解决方案 Full Process Automation Fermentation Technology Solution

面对发酵工业产业结构升级的要求,双碳背景下节能减排的压力,以及智能化发酵的需求,天俱时提供从发酵配料、物料连续灭菌、发酵罐实消/空消、无菌管路灭菌、菌株培养到系统清洗的全流程自动化发酵技术解决方案,可广泛应用于生物医药、生物材料、食品健康、医美、天然健康产物、农兽药等领域,有效降低染菌率、节能降耗、减少人员操作、提高生产效率、提高发酵水平。

Facing the requirements of industrial structure upgrading of the fermentation industry, the pressure of energy saving and emission reduction under the background of double carbon, as well as the needs of intelligent fermentation, TIANS has been committed to providing automatic fermentation technology solutions for the whole process from fermentation ingredients, continuous sterilization of materials, fermenter elimination/empty elimination, sterile pipeline sterilization, strain culture to system cleaning. It can be widely used in biomedicine, biological materials, food health, medical beauty, natural health products, agricultural and veterinary drugs and other fields, which effectively reduce the rate of bacterial contamination, energy saving, reduce personnel operation, improve production efficiency, improve fermentation level.

 <p>降低染菌率 Effective Reduction in Infection Rate</p>	 <p>蒸汽消耗降低50%以上 More Than 50% Reduction in Steam Consumption</p>	 <p>减少操作人员20% 20% Reduction in Operators</p>	 <p>提升生产效率 Improve Production Efficiency</p>	 <p>提高发酵水平 Increase Fermentation Levels</p>
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## 关键控制技术 Core Technologies

### 1 发酵配料过程控制 Fermentation Ingredient Process Control

天俱时拥有技术成熟及功能完善的自动配料系统,系统结合智能称重技术、无人小车技术、自动投料装备、DCS系统控制技术等,实现了全流程无人控制,减轻劳动强度,提高生产效率,实现精准计量。

TIANS has an automatic batching system with perfect technology and functions, which combines intelligent weighing technology, unmanned car technology, automatic feeding equipment, DCS system control technology, etc.

### 2 发酵生产自动灭菌过程控制 Automatic Sterilization Process Control for Fermentation Production

根据发酵罐消毒工艺和路线设计,实现消毒过程的罐体排空、夹套排空、预热、升温、保压、计时、通气、降温等过程的自动化精准控制,保证无菌率、节约蒸汽消耗的同时减少人员操作,为微生物发酵生产提供可靠环境,实现节能减排。

Combined with the fermentation tank disinfection process and route design, it realizes the automatic precise control of tank emptying, jacket emptying, preheating, heating, pressure holding, timing, aeration, cooling and other processes in the disinfection process.

### 3 物料连续灭菌过程控制 Material Continuous Sterilization Process Control

实消毒时间长对培养基成份破坏较大,蒸汽用量大,天俱时基于阿伦尼乌斯公式和等效灭菌理论,应用智能瞬时连消技术将配制好的培养基向发酵罐等培养装置输送的同时进行加热、保温灭菌和冷却等操作过程,从而有效提高生产效率,节约能源。

While the disinfection time of sterilization in real tanks is long, which destroys the components of the culture medium and the amount of steam is large, based on Arrhenius equation and equivalent sterilization principle, TIANS applies intelligent instantaneous disinfection technology to deliver the prepared medium to the fermenter and other cultivation devices while heating, heat preservation and sterilization, cooling and other operations.

### 4 移种站全自动过程控制 Seed Transfer Station Automation Process Control

根据工艺设定,自动匹配移种路线,对移种管路进行自动清洗、排空、升温、保温消毒、降温、移种等操作,实现移种过程全自动控制。

According to process design, automatically select the seeding line, and carry out automatic cleaning, emptying, heating, heat preservation and disinfection, cooling, transplantation and other operations on the transplantation pipeline.

### 5 发酵培养过程控制 Fermentation Culture Process Control

根据微生物生长特性,结合生产经验和专家数据库,建立控制模型,对发酵过程的补料、温度、pH、DO、进气流量、罐压、消泡实现培养过程精准控制,从而保证生产稳定,提高发酵单位,提升产品品质。

Based on the microbial growth characteristics, combined with production experience and expert database, a cultivation control model is established to achieve precise control of feeding, temperature, pH, DO, inlet air flow, tank pressure and defoaming of the fermentation process.

### 6 分离纯化工艺过程控制 Separation and Purification Process Control

分离纯化一键式全自动控制系统高度集成,包含自动萃取分相、pH控制、温度控制、流量控制、全流程自动膜过滤系统、全流程自动离交系统等。简化了操作过程,优化了生产流程,保证最终产品的质量及一致性,同时提升生产运维的安全性能。

TIANS One-button Automation Control System for Separation and Purification is highly integrated, including automatic extraction phase separation, pH control, temperature control, flow control, automatic membrane filtration system and automatic separation system for the whole process, etc.

# 发酵工厂数字化管理平台

## Digital Management Platform of Fermentation Factory

天俱时发酵工厂数字化管理平台将发酵企业整个数字化系统数据进行采集、分析,采用数字孪生技术对车间生产情况实时展示,为发酵企业数字化转型赋能。

With digital twinning technology showing the production situation of workshops in real time, TIANS Digital Management Platform collects and analyzes the data of digital systems of the whole fermentation enterprise, which empowering the digital transformation of fermentation enterprises.



提高效率

Improve Effectiveness



实时监测

Monitoring in Real Time



灵活适配

Flexible Adaptation



定制设计

Customized Design



【发酵工厂数字化管理平台】

### 平台特色

#### Platform Advantages

#### 1 工厂总览

Factory Overview

可对发酵工厂的重点参数集中展示,使得发酵工艺重要参数一眼可见,保证发酵过程的稳定性。

Factory overview: The key parameters are displayed in a centralized manner, ensuring the stability of fermentation process as the important process parameters are visible at one time.

- 发酵罐状态参数
- 物料流向三维显示
- 仪表数据三维显示
- 空压系统数据监测
- 蒸汽系统数据监测
- 循环水系统温度及流量监测
- 年度生产计划&生产进度动态展示
- 报警事件提示记录
- Fermenter Status Parameters
- Material Flow 3D Display
- Instrument Data 3D Display
- Air Pressure System Data Monitoring
- Steam System Data Monitoring
- Circulating Water System Temperature and Flow Monitoring
- Dynamic Display Annual Production Plan & Production Progress
- Alarm Records

#### 2 楼层分布

Different Floors Monitoring

可详细查看各楼层设备信息,涵盖设备名称以及运行状态,提高生产透明度。

Different Floors Monitoring: the equipment information of each floor could be viewed in detail, including the name and operation status.

#### 3 运行参数

Operation Parameters Display

直观展示各设备真实具体的数据参数,包括物料流向信息、批次号、发酵时长、运行参数、控制阀数据等信息,显著提升操作效率,降低故障风险,优化生产调度。

Operation Parameters: visually display the real and specific parameters of each equipment, including material flow information, batch number, fermentation duration, operation parameters, valve data, etc.

#### 4 视频监控

Video Surveillance

可监测相关区域的现场情况,让管理无死角。

Video Surveillance: monitoring the whole factory without blind corners.

#### 5 对接能源管理系统

Docking Energy Management System

实时掌握能源消耗情况,直观分析并展示数据,找到生产工艺能源消耗更匹配的工艺数据,从而提高能源系统的运行及管理效率。

Docking Energy Management System: monitor energy consumption in real-time, analysis and display data directly, find more matching process data for energy consumption control.

#### 6 对接T-MES系统—生产看板

Docking T-MES System

对当月工单、班组产量,年度/月生产总量对比,车间计划与实际产量统计等信息可视化呈现,实现生产过程信息化、数字化。

Docking T-MES System to Realize Visual Board: visual presentation of the monthly work order, team output, annual/monthly total production, workshop planning and actual production statistics, etc.

#### 7 对接DCS系统—运行批记录

Docking DCS System

对每一批生产的电子批记录进行详细展示批次、设备名称、产量等信息,增强可追溯性与质量控制,并显著提高灵活性与可扩展性。

Docking DCS to Run Batch Records: display the electronic batch records for each batch, including production batch, equipment, output and other information.



# 2.3

## 公用工程节能自动化解决方案 Energy Saving Utility Automation Solution

全球范围内, 各国政府和企业正积极响应实现碳中和的双重目标, 将节能减排作为推动产业升级的重要战略。天俱时公用工程致力于提供全面的节能自动化解决方案, 方案涵盖楼宇管理系统 (BMS)、环境监测系统 (EMS)、动力节能群控系统以及能源管理系统等, 通过智能化控制系统达到节能减排的目标, 通过优化能源使用降低生产运营成本, 通过高效创新的自动化技术落实精细化能源管理, 助力生物制药、无菌制剂和化学原料药等行业客户实现可持续发展。

Governments and enterprises are actively responding to the dual goal of carbon neutrality all around the world, viewing energy conservation and emission reduction as an important strategy to promote industrial upgrading. TIANS utility engineering has been committed to providing a full range of energy efficient automation solutions, which including building management systems (BMS), environmental monitoring systems (EMS), power efficient group control systems and energy management systems, achieving energy conservation and emission reduction through intelligent control systems, reducing production and operating costs through optimizing energy use, and implementing refined energy management through efficient and innovative automation, to assist the biopharmaceutical, aseptic pharmaceutical and chemical raw materials industry clients to achieve sustainable development.

楼宇管理系统 (BMS) Building Management System	环境监测系统 (EMS) Environmental Monitoring System	动力节能群控 Utility Energy Saving	能源管理系统 Energy Management System
系统模式 System module	温湿度监测 (洁净区、库区) HVAC and warehouses temperature and humidity monitoring	设备数据监测和控制 Equipment data monitoring and control	能源监测 Energy monitoring
系统安全连锁 System interlock	压差监测 Pressure difference monitoring	设备负载管理 Device load management	能源控制 Energy control
风量平衡 Air volume balance	悬浮粒子检测 Suspended particles monitoring	设备故障管理 Equipment operation breakdown Management	能源成本 Energy cost
温湿度控制 H&T control	浮游菌采样 Plankton monitoring	高效节能运行策略 Efficient and energy-saving operation strategy	能源预测 Energy calculate
房间变风量控制 Variable air volume control	冰箱/培养箱关键参数检测 Refrigerator and incubator temperature monitoring		能效评估 Efficient evaluation
报警管理 Alarm management	报警管理 Alarm management		能效报告 Efficient report

## 关键控制技术 Core Technologies



灵活的系统管理  
Flexible System Management

- 参数管理  
Parameter Management
- 导入/导出  
Import/Export Function
- 数据备份/恢复  
Data Backup/Restore
- 文件管理  
Document Management
- 脚本管理  
Script Management
- 电子秤配置  
Scale Configuration
- 打印机配置  
Printer Configuration

高效的人员管理  
Efficient Personnel Management

- 用户管理  
User Management
- 权限管理  
User Rights Management
- 角色管理  
Role Setting
- 人员档案  
Personnel Profile
- 人脸识别  
Biometrics
- 电子签名  
Electric Signature

智能的物料管理  
Intelligent Material Management

- 物料档案  
Material Archive
- 收料管理  
Receiving Management
- 发料管理  
Issuing Management
- 库存台账  
Inventory Ledger
- 效期管理  
Validity Management
- 批次管理  
Batch Management
- 标签管理  
Label Management
- 物料追溯  
Material Traceability

7 Core Functions  
核心功能



精准的配方管理  
Precise Recipe Management

- 配方创建  
Recipe Creation
- 配方审核  
Recipe Review
- 配方升级  
Recipe Upgrade
- 工艺参数  
Process Parameters Setting

可视化设备管理  
Visualize Equipment Management

- 设备档案  
Equipment Archive
- 点巡检  
Point Inspection
- 维修管理  
Maintenance Management
- 验证管理  
Validation Management
- 校准管理  
Calibration Management
- 容器管理  
Container Management
- 设备状态  
Device Status Monitoring

系统集成的生产管理  
Production Management for System Integration

- 计划排产  
Plan Scheduling
- 生产批指令  
Production Batch Instructions Setting
- 备料计划  
Material Preparation Plan
- 批记录设计  
Batch Record Design
- 数据采集  
Data Acquisition
- 作业跟踪  
Job Tracking
- 物料称量  
Material Weighing
- 物料投料  
Material Feeding
- 操作SOP  
Manipulate SOP
- 设备清洁  
Equipment Clean
- 房间清场  
Room Clearance
- 辅助记录  
Secondary Record
- 生产报表  
Production Reports

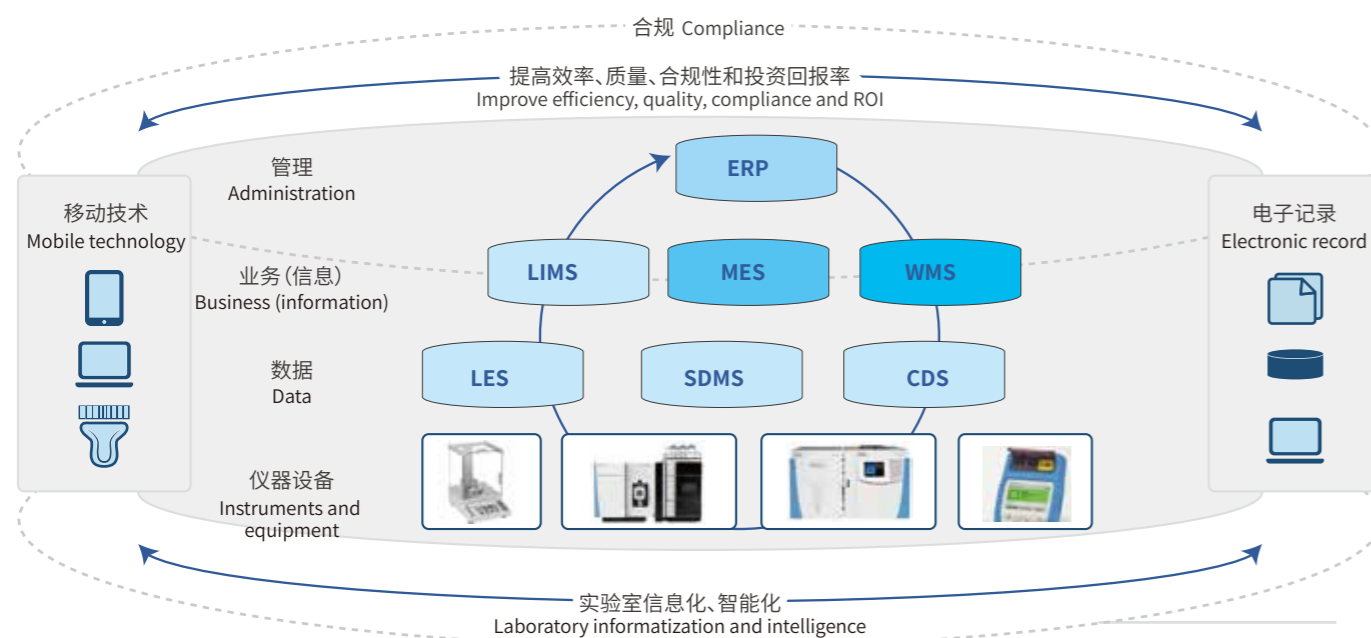
合规高效的质量管理  
Compliant & Efficient Quality Management

- 取样管理  
Sampling Management
- 来料检验  
Incoming Inspection
- 过程检验  
Process Inspection
- 完工检验  
Completion Inspection
- 放行管理  
Release Management
- 偏差和事件  
Deviations Dispose & Record
- 不合格品处理  
Non-conforming Products Handling
- 审计管理  
Audit Management

## 实验室信息管理系统 (LIMS) Laboratory Information Management System



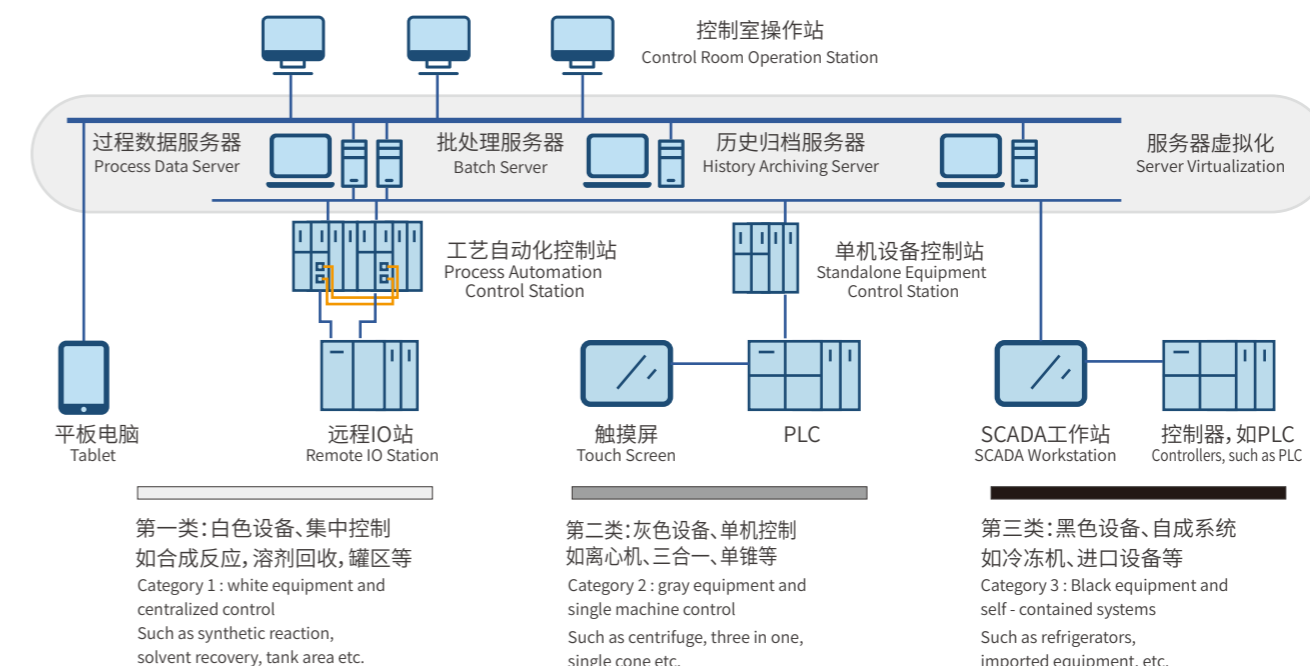
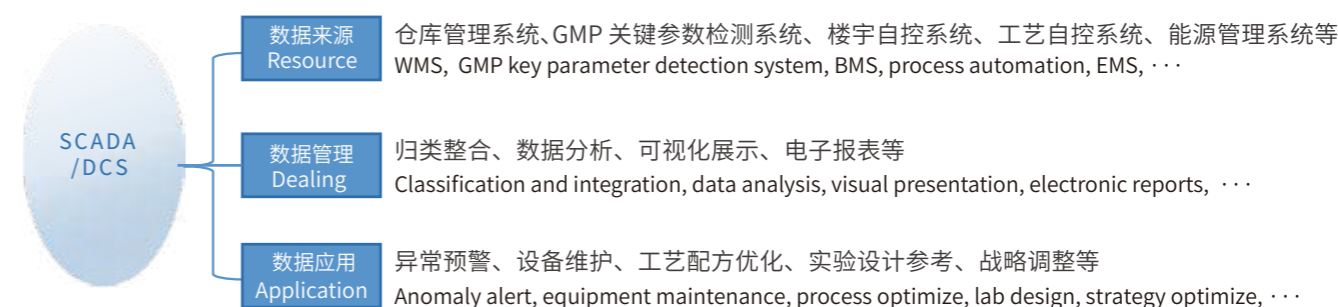
- 符合FDA 21 CFR Part11, NMPA, ISO 17025等法规要求
  - 使实验室样品监测业务流程“精细化”
  - 按顺序指导用户完成SOP规定的每个实验步骤
  - 与仪器集成, 实时抓取数据
  - 支持法规要求的电子签名
  - 审计追踪记录整个执行过程
  - 灵活移动端简便日常操作
- Comply with regulatory requirements such as FDA 21 CFR Part11, NMPA, ISO 17025, etc.
  - “Refined” process of laboratory sample monitoring
  - Instruct users completing experimental steps specified by SOP
  - Real time data collection via integrated instruments
  - Legitimate electronic signature supported
  - Every step recorded through the audit trail process
  - Mobile app supported for portability



## 数据采集监控系统 (SCADA) Supervisory Control and Data Acquisition System

实现数据实时采集、实时存储、实时管控、及时预警以及零散数据收集整合、数据综合分析、数据三维呈现等, 为综合管理人员、科研人员、工程师等提供可靠、详实的高质量数据, 为企业运营效率提升、实验室设计、生产工艺优化、产品安全、风险防控等提供支持。

The supervisory control and data acquisition system realizes real-time data collection, real-time storage, real-time control, timely warning, various data collection, comprehensive analysis of data, three-dimensional presentation, etc., providing support for the improvement of enterprise operation efficiency, laboratory design, production process optimization, product safety and risk control for the general management personnel, scientific research personnel, engineers and so on.





## 生产可视化平台 (BI) Production Visualization Platform

医药、化工企业数字化转型日益深入,企业转型过程中面临信息断层、数据加工难、安全防控薄弱、自动化和信息化技术不足等问题,天俱时生产可视化平台通过先进的数据采集与处理技术、标准化三维建模、可靠的数据统计分析模型、及时高效的异常预警功能、三维数据可视化界面等,为客户构建精益管理、安全生产、高效运营、可持续发展的智能化工厂。

The digitalization transformation of pharmaceutical and chemical enterprises is deepening day by day, enterprises are faced with problems such as information fault, data processing difficulty, weak security prevention and control, and insufficient automation and information technology, TIANS production visualization platform build a lean management, safe production, efficient operation, and sustainable development intelligent plant for clients through advanced data acquisition and processing technology, standardized 3D modeling, reliable data statistical analysis model, timely and efficient anomaly warning function, 3D data visualization interface, etc..

- 基于数字化BIM设计构建可视化工厂 · Build a visual factory based on digital BIM design
- B/S架构设计, 无需安装 · B/S architecture design, no installation required
- 标准API接口, 灵活适配多数数据源 · Standard API interface, flexible adaptation to multiple data sources
- 灵活生成可视化图表, 快速产生数据3D可视化界面 · Flexibly generate visual charts and 3D visualization interfaces
- 支持数据在线预览及多元转换 · Support online data review and multiform conversions
- 支持数据报表定向分享, 灵活设定有效期及密码 · Support report targeted sharing and validity period and password setting flexibly



## 2.5 计算机化系统验证 Computer System Validation

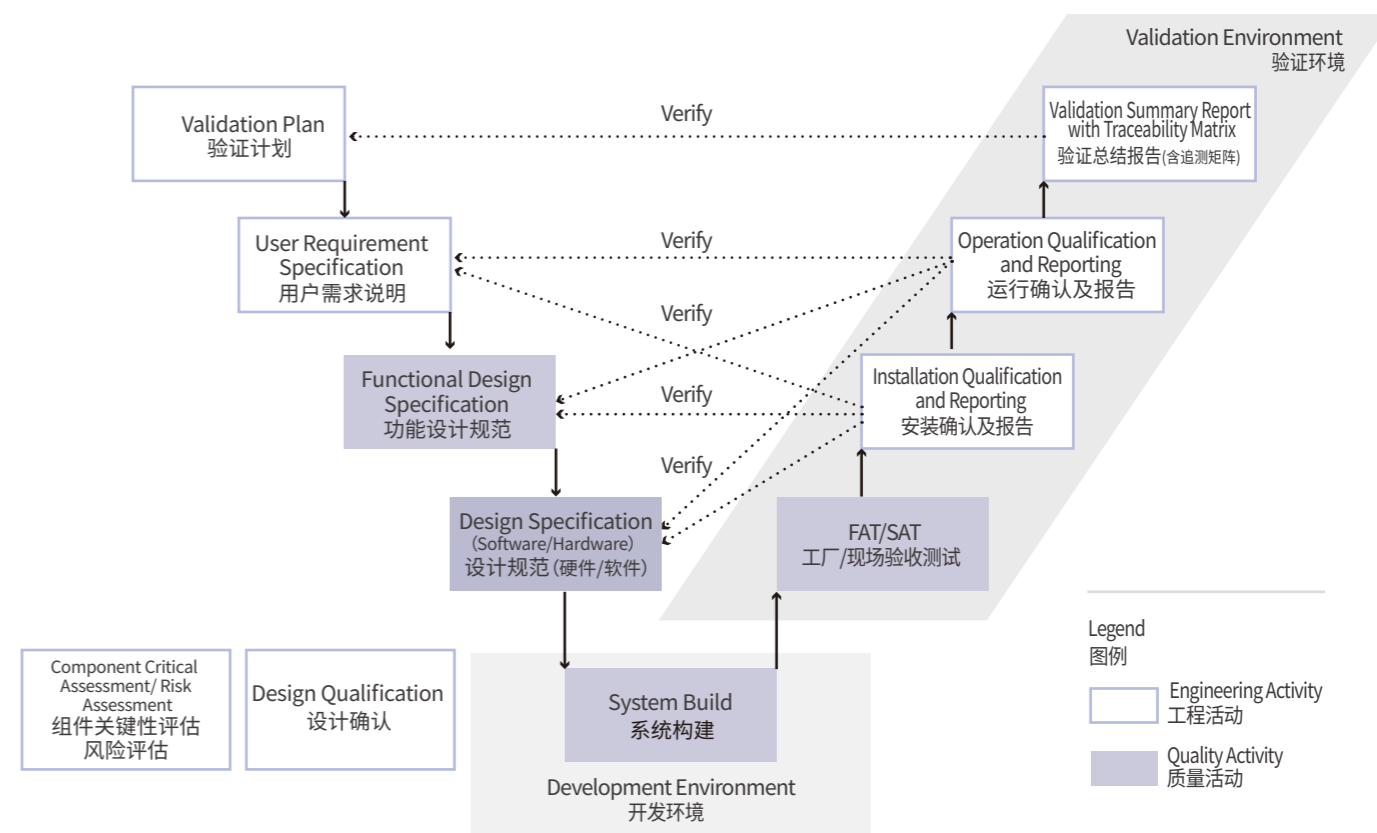
计算机化系统的生命周期活动将按照ISPE GAMP5 V-model的方法进行实施。

在整个项目生命周期活动中将按照GAMP中软、硬件类别及确认方法对系统内的软、硬件采取不同的验证策略,在系统整个生命周期实施质量风险管理方法,遵循文档管理、偏差管理和变更控制等支持流程,保证系统法规符合性。

The life cycle activities of the computerized system will be implemented in accordance with the ISPE GAMP5 V-Model methodology.

In the whole project life cycle activities, different verification strategies will be adopted for the software and hardware in the system according to the categories and confirmation methods of software and hardware in GAMP, quality risk management methods will be implemented during the whole life cycle of the system, in accordance with support processes such as document management, deviation management and change control, ensuring the compliance of system regulations.

## 项目执行及验证生命周期模型 Project Execution and Validation Lifecycle Model



# 3

## Intelligence with Ability & Integrity 智圆行方

01

全流程定制化服务

Customized Service for Whole Process

用户需求分析 URS	二次优化设计 QOD	功能描述 FS	硬件设计说明 HDS	软件设计说明 SDS	设计确认 DQ
<p>与客户详细交流对URS进行澄清把需求说明量化</p> <p>Communicate with customer in detail to clarify URS</p> <p>Quantify the requirements statement</p>	<p>工艺工程师、软件设计经理、车间主任针对控制逻辑进行梳理、优化</p> <p>仪表阀门工程师、工艺人员、业主自控工程师针对仪表选型进行梳理优化</p> <p>Process engineer, software design manager and workshop director sort out and optimize the control logic</p> <p>Instrumentation and valve engineers, process personnel and owner control engineers comb and optimize the instrument selection</p>	<p>根据URS缩写功能说明文件用更清晰更准确的语言响应URS</p> <p>用户管理 数据归档 报警功能</p> <p>According to the URS abbreviation function specification file</p> <p>Use clearer and more accurate language to respond to URS</p> <p>User management Data archiving Alarm function</p>	<p>控制柜布局 硬件选型描述 网络架构 系统通信接口</p> <p>Layout of control cabinet Description of hardware selection The network architecture System communication interface</p>	<p>程序结构 程序功能块介绍 HMI界面介绍</p> <p>Program structure Program function block introduction HMI interface introduction</p>	<p>双方根据URS要求对设计文件进行审核确认</p> <p>确认后开始进行详细设计和项目具体执行</p> <p>The design documents were reviewed and confirmed by both parties according to URS requirements</p> <p>After confirmation, detailed design and project execution will begin</p>
系统构建 System Build	工厂测试 FAT	安装确认 IQ	功能测试 OQ	用户培训 User Training	
<p>DQ确认后进行程序编写、控制柜组装、设备采购、现场安装</p> <p>After DQ confirmation, program preparation, control cabinet assembly, equipment procurement and on-site installation will be carried out</p>	<p>控制柜外观检测 根据图纸校验接线 元器件标签检查 软件打点测试 硬件安装测试 软件功能测试</p> <p>Control cabinet appearance inspection Verify wiring according to drawing Component Label Inspection The software is tested Hardware installation test Software functional testing</p>	<p>计算机软硬件安装确认 现场接线及仪表安装确认 根据IQ清单及电路图进行现场打点测试</p> <p>Computer hardware and software installation confirmation Confirm field wiring and instrument installation Conduct on-site test according to IQ checklist and circuit diagram</p>	<p>程序功能测试 控制功能测试 报警测试 数据测试(报表、历史趋势、操作记录) HMI界面测试 用户管理功能测试等</p> <p>Program function test Control function test Alarm test Data testing (reports, historical trends, operational records) HMI interface testing User management functional tests, etc</p>	<p>编写用户操作手册 组织操作人员培训维护人员 直到用户熟练运用此系统</p> <p>Compile user operation manual Organize operation personnel training and maintenance personnel training until users are proficient in using the system</p>	

## 02

### 懂工艺的自控专家



依托集团工艺技术中心及近20年行业经验积累,自控团队工艺基础扎实、现场经验丰富,无论是控制方案设计还是仪表阀门选型,均结合生产工艺特点,为客户提供针对性解决方案。

#### Teamwork of Experts from All Fields

Relying on the group's process technical center and industry experience accumulated in recent 20 years, the automatic control team has a solid process foundation and rich field experience. Both control scheme design and instrument valve selections are combined with production process characteristics to provide targeted solutions for customers.

## 03

### 专业设计团队二次优化



二次优化设计的能力及深度直接决定了自动化、信息化解决方案的成败;

设置专职优化设计团队,充分结合项目特点,从数字化工厂整体规划、IT网络架构、工艺梳理、控制逻辑功能梳理、仪表阀门选型、仪表安装等方面进行专业的深度优化设计。

#### Secondary Optimization of Professional Design Team

Whether or not automation and informatization proposal success is directly determined by the capability of secondary optimization during design.

Full-time optimization design team responsible for project optimization, based on the characteristics of the project, from all aspects ranging from overall planning of digital factory, IT network architecture, processes sorting, control logic functions sorting, instrument valve selections, instrument installations, etc.

## 04

### 方案落地、可实施性强



从生产实际出发,结合医药生产工艺特性、生产特点、使用习惯,为客户提供针对性自动化、信息化解决方案;

方案实用性强、性价比高、减少人力成本、提高生产效率、提高产品质量。

#### Highly Implementable Proposal

Provide customers with targeted automation and information solutions which is designed based on the vision of actual production, combined with the characteristics of the pharmaceutical production process, production characteristics, and usage habits;

The proposals are highly practical, cost-effective, labor-saving, and focus on the improvement of production efficiency and product quality.

## 05

### 专业验证团队保障



验证团队服务过多家通过美国cGMP、欧盟GMP、中国GMP 2010版认证的大型医药企业,计算机系统验证经验丰富。

#### Verification Support from Professional Team

The verification team has served many large pharmaceutical enterprises passing the verifications such as cGMP in the United States, GMP in the European Union, and GMP 2010 in China, with rich experience in computer system verification.

## 06

### 团队理念国际领先



与国际主流合作商深度战略合作,并通过引进、消化、吸收、再创新,掌握前沿技术,始终在行业中保持技术领先地位。

#### Leading in the World: Idea of Automatic Control

Tian's Group maintains a leading position in the industry through in-depth strategic cooperation with our core partners from all over the world and possesses a batch of cutting-edge core technologies via introduction, digestion, absorption, re-innovation.



# 4

## Intelligence for the Intelligent 智者见智

蓝晶微生物·江苏蓝素生物材料有限公司  
年产25000吨生物降解新材料(PHA)产业化  
项目一期工程

Bluepha · Jiangsu Lansu Biomaterials Co., Ltd.  
The First Phase of The Biodegradable New Material  
Polyhydroxyalkanoates (PHA) Industrialization Project  
With an Annual Output of 25,000 Tons

国内同行业发酵生产车间自动化程度领先

Leading automation of fermentation production  
workshops in China

项目类型:生物降解新材料

**Project Type:** New Biodegradable Materials

服务范围:发酵车间仪表及DCS系统、提取车间仪表及DCS系统、  
动力车间仪表及DCS系统、环保车间仪表及DCS系统、  
BMS空调仪表及PLC系统

**Service Scope:**Instrument and DCS system for fermentation  
workshop, instrument and DCS system for extraction  
workshop, instrument and DCS system for power house,  
instrument and DCS system for environmental protection  
workshop, BMS air conditioning instrument and PLC system

项目规模:I/O点约2400点

**Project Scale:** I/O points around 2400

项目标准:EMA

**Project Standard:** EMA



秦皇岛华恒生物工程有限公司  
氨基酸发酵自动化工程

Qinhuangdao Huaheng Biotechnology Co. Ltd.  
Amino Acid Fermentation Automation Engineering



项目类型:发酵、提取车间

服务范围:DCS系统、自控设备采购、系统集成及编程调试等

项目规模:IO点约5000点

项目标准:EMA、FDA

**Project Type:** Fermentation & Extraction Workshop

**Service Scope:** DCS system, automation device procure-  
ment, System integration and programming debugging, etc.

**Project Scale:** I/O points around 5000

**Project Standard:** EMA, FDA

内蒙古溢多利生物科技有限公司  
年产2万吨生物酶制剂项目

Mongolia Yidouli Biotechnology Co., Ltd.  
Enzyme Project with 20,000 Tons Annual Output



亚洲最大的生物酶制剂企业

Asia's largest bio-enzyme preparation company.

项目类别:酶制剂

服务范围:机电安装

项目规模:占地100亩,建设规模为1,200立方主发酵系统,年产  
2万吨食品级生物酶制剂

**Project Type:** Enzymes

**Service Scope:** Electronic and mechanical construction

**Project Scale:** Covering an area of 100 acres, the construction  
scale is 1,200 cubic meters of main fermentation system, with  
an annual output of 20,000 tons of food-grade biological  
enzyme preparations

山东安舜制药有限公司  
乐陵医药产业园二期自动化工程

Shandong Anshun Pharmaceutical Co., Ltd.  
Automation Project in Laoling Pharmaceutical Industrial  
(Park Phase II)



国内化学制药行业多功能合成车间自动化、信息化程度领先

Leading in domestic chemical and pharmaceutical industry for  
automation and informationization level of multi-functional synthesis  
workshop

项目类型:抗肿瘤多功能合成车间

服务范围:DCS+Batch系统、SIS系统、SCADA系统、

人员信息管理系统、计算机化系统验证

项目规模:IO点约12000点

项目标准:EMA、FDA

**Project Type:** Anti-tumor drug Multi-functional Synthesis  
Workshop

**Service Scope:** DCS + Batch system, SIS system, SCADA  
system,staff information management system, computer system  
verification

**Project Scale:** I/O points around 12,000

**Project Standards:** EMA, FDA

联邦制药·珠海联邦制药股份有限公司  
高栏港原料药项目自控系统工程

United Laboratories·Zhuhai United Laboratories Ltd.  
Automatic control system engineering of Gaolan Port  
API Project



项目类型:合成原料药

服务范围:DCS系统、SCADA系统、计算机化系统验证

项目规模:IO点16000

项目标准:EMA、FDA

**Project Type:** Synthetic APIs

**Service Scope:** DCS system, SCADA, computerized  
system verification

**Project Scale:** I/O points around 16000

**Project Standard:** EMA, FDA

天科(荆州)制药有限公司  
绿色制药产业基地自控项目

Tianke (Jingzhou) Pharmaceutical Co., Ltd  
Automatic Control Project of Green Pharmaceutical  
Industry Base



化学制药智能工厂优秀示范项目

Excellent demonstration project of chemical pharmaceutical  
intelligent factory

项目类型:高端创新原料药

服务范围:合成一车间(含溶媒回收)、罐区、动力车间、原料库、成  
品库、质检楼、环保中心,涵盖DCS系统、BMS/EMS系  
统、SCADA系统、能源管理系统、人员信息管理系统、人  
员定位系统、计算机化系统验证

项目规模:IO点约13000点

项目标准:EMA、FDA

**Project Type:** High-end Innovative APIs

**Service Scope:**Synthesis workshop I, tank area, power workshop,  
API material warehouse, finished product warehouse, quality  
inspection building, environmental protection center, including  
DCS system, BMS/EMS system, SCADA system, energy manage-  
ment system, personnel information management system,per-  
sonnel position system, computer system verification

**Project Scale:** I/O points around 13000

**Project Standard:** EMA, FDA

人福医药·黄冈人福药业有限责任公司  
国际高端新型特色原料药产业化生产基地  
8#、12#厂房工艺自控系统

Humanwell Healthcare·Huanggang Humanwell  
Pharmaceutical Co., Ltd.  
Automatic Process Control system for 8#, 12# Plant at  
International High-end New-type Characteristic API  
Industrialization Production Base



项目类型:高端新型特色原料药

服务范围:DCS系统、计算机化系统验证

项目规模:IO约2000点

项目标准:EMA、FDA

**Project Type:** High-end New-type Characteristic APIs

**Service Scope:** DCS system, computerized system verification

**Project Scale:** I/O points around 2000

**Project Standard:** EMA, FDA



康龙化成(绍兴)药业有限公司  
一期项目自动化工程

Pharmaron (Shaoxing) Pharmaceutical Co., Ltd.  
Automation Project (Phase I)



项目类型:高级医药中间体  
服务范围:DCS系统、SIS系统、SCADA系统、  
计算机化系统验证  
项目规模:IO点约7000点  
项目标准:EMA、FDA

**Project Type:** Advanced Pharmaceutical Intermediates  
**Service Scope:** DCS system, SIS system, SCADA system,  
computer system verification  
**Project Standards:** EMA, FDA  
**Project Scale:** I/O points around 7000

金城医药·山东汇海医药化工有限公司  
培南类高端医药中间体项目自动化工程

Jincheng Pharma • Shandong Huihai Pharmaceutical  
Chemical Co., Ltd.  
Meropenem High-end Pharmaceutical Intermediates  
Project Automation Engineering



项目类型:医药中间体  
服务范围:DCS系统、SIS系统  
项目规模:IO点约8500点

**Project Type:** Pharmaceutical Intermediates  
**Service Scope:** DCS system, SIS system  
**Project Scale:** I/O points around 8500

中节能万润化工园区  
一期&二期项目自动化工程

China Energy Conservation and Environmental Protection  
Group Co.,Ltd.  
Automation Project of Valiant Chemical Park (Phase I &  
Phase II)



项目类型:原料药、液晶材料  
服务范围:DCS+Batch系统、SCADA系统、  
人员信息管理系统、计算机化系统验证  
项目规模:IO点约10000点  
项目标准:EMA、FDA

**Project Type:** APIs, Liquid Crystal Materials  
**Service Scope:** DCS + Batch system, SCADA system,  
staff information management system and computer  
system verification.  
**Project Scale:** I/O points around 10000  
**Project Standards:** EMA, FDA

浙江研一新能源科技有限公司  
AONE&SONE自动化工程

Zhejiang Yanyi New Energy Technology Co., Ltd.  
AONE & SONE Automation Engineering



项目类型:新能源特种粘结剂  
服务范围:DCS系统  
项目规模:IO点共约3000点

**Project Type:** New Energy Special Binder  
**Service Scope:** DCS system  
**Project Scale:** I/O points around 3000



广州百济神州生物制药有限公司  
三期&四期项目BMS&EMS系统

BeiGene (Guangzhou) Biopharmaceutical Co. Ltd.  
Phase III & Phase IV Project BMS&EMS System



国内同行业洁净厂房自动化、信息化程度领先

Leading in the degree of automation and informatization of clean workshops in the same industry in China

项目类型: 抗体偶联药物

服务范围: BMS空调自控系统、EMS环境监测系统、PLC系统、SCADA系统、计算机化系统验证

项目规模: IO点约8000点

项目标准: EMA、FDA

**Project Type:** Antibody-drug Conjugate

**Service Scope:** BMS system, EMS system, PLC system, SCADA system, computer system verification

**Project Scale:** I/O points around 8000

**Project Standard:** EMA, FDA

深圳市海普瑞药业集团股份有限公司  
坪山工厂新建预灌充制剂线项目BMS&EMS工程

Shenzhen Hepalink Pharmaceutical Group Co., Ltd.  
The New pre-filling Preparation Line Project BMS & EMS Project at Pingshan plant



项目类型: 无菌注射剂

服务范围: BMS&EMS系统、计算机化系统验证

项目标准: EMA、FDA

**Project Type:** Sterile Injection

**Service Scope:** BMS & EMS system, computerized system verification

**Project Standard:** EMA, FDA

广东华生元基因工程发展有限公司  
重组人表皮生长因子喷剂、滴眼剂智能化信息化项目

Guangdong Watsin GeneTech Ltd.  
Recombinant Human Epidermal Growth Factor Spray and Eye Drops Intelligent and Informatization Project



项目类型: 生物制药

服务范围: BMS&EMS系统、动力群控系统、计算机化系统验证、MES、SCADA、能源管理系统、人员行为识别系统、生产可视化看板

项目规模: IO点1148

项目标准: GMP

**Project Type:** Biopharmaceutical

**Service Scope:** BMS & EMS system, group control system for power energy-saving, computerized system verification, MES, SCADA, EMS, personnel behavior recognition system, production visualization platform

**Project Scale:** I/O points around 1148

**Project Standard:** GMP

绿叶制药·绿叶嘉奥制药石家庄有限公司  
CNS重组及药物研发生产基地A区项目  
BMS&EMS工程

Luye Pharma · Luye Jiaao Pharma Shijiazhuang Co., Ltd.  
Phase I Project CNS Recombinant and Drug Development Production Base Zone A BMS & EMS



项目类型: API车间、微球车间

服务范围: BMS&EMS系统、动力节能群控系统、SCADA、特气系统、能源计量系统、计算机化系统验证

项目规模: IO点3260

项目标准: GMP、FDA

**Project Type:** API workshop, microspheres workshop

**Service Scope:** BMS & EMS system, group control system for power energy-saving, SCADA, special gas system, energy metering system, computerized system verification

**Project Scale:** I/O points around 3260

**Project Standard:** GMP, FDA

远大医药·武汉武药制药有限公司  
小品种(短缺药)药品原料药生产基地建设项目  
(二期工程) 自控工程

Grand Pharmaceutical • Wuhan Wuyao Pharmaceutical Co., Ltd.  
Small Variety Drugs (shortage drugs) API Production base Construction Project (phase II) Automatic Control Project



项目类型: 原料药合成车间  
服务范围: DCS系统、SIS系统、群控系统、BMS&EMS、  
计算机化系统验证  
项目规模: IO点约3500点  
项目标准: FDA

**Project Type:** API Synthesis Workshop  
**Service Scope:** DCS system, SIS system, group control system, BMS & EMS, computerized system verification  
**Project Scale:** I/O points around 3500  
**Project Standard:** FDA

上海君实生物工程有限公司  
临港基地中试车间新建项目

New Project of Pilot Plant of Lingang Base for Shanghai Jun Shi Biological Engineering Technology Co., Ltd.



国内生物制药行业洁净厂房自动化、  
信息化程度领先  
**Leading in domestic biopharmaceutical industry for the automation and informationization level of clean workshop**

项目类型: 单克隆抗体  
服务范围: BMS空调自控系统、EMS环境监测系统、  
DCS系统、SCADA系统、AGV自动移动  
小车系统、弱电系统、计算机化系统验证  
项目标准: EMA、FDA

**Project Type:** Monoclonal Antibody  
**Service Scope:** BMS air conditioning automatic control system, EMS environmental monitoring system, DCS system, SCADA system, AGV automatic mobile trolley system, weak current system, computer system verification  
**Project Standards:** EMA, FDA

北京诺诚健华医药科技有限公司  
药物研发平台升级项目BMS&EMS工程

Beijing InnoCare Pharma Tech Co., Ltd.  
Drug Research and Development Platform Upgraded Project BMS&EMS System



项目类型: 抗癌药物  
服务范围: BMS&EMS系统、动力节能群控系统、  
计算机化系统验证  
项目标准: EMA、FDA

**Project Type:** Anticancer Medicine  
**Service Scope:** BMS & EMS system, group control system for power energy-saving, computerized system verification  
**Project Standards:** EMA, FDA

江苏金斯瑞蓬勃生物科技有限公司  
53#BMS&EMS工程

Jiangsu GenScript ProBio Biotech Co., Ltd.  
53#BMS&EMS Project



项目类型: 生物制药  
服务范围: BMS&EMS系统、动力节能群控系统、  
计算机化系统验证  
项目标准: EMA、FDA

**Project Type:** Biopharmaceutical  
**Service Scope:** BMS & EMS system, group control system for power energy-saving, computerized system verification  
**Project Standard:** EMA, FDA



# 5

## Innovation under Intelligence

### 智慧共创

超越客户预期						EXCEED CLIENT EXPECTATIONS							