

Biopharmaceutical Engineering SOLUTION

Driven by Both International and Local Factors

国际+本土双驱动下的生物医药工程解决方案

| Build a Better Bio-world



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BUILD A BETTER BIO-WORLD

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TIANS

走进天俱时

ABOUT TIANS

25^{+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，上海、天津、济南、武汉设分公司及办事处；瑞士设生物医药咨询创新中心。

Founded in 1998, is an engineering design group empowering industrialization of new technologies. Headquartered in Shijiazhuang, with branches and offices in Shanghai, Tianjin, Jinan and Wuhan; 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。

It is 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}

涉及生物制品、药物制剂、化学原料药、中成药、医疗器械等工程科技领域。

Clients are involved in the fields of engineering science and technology, such as biological products, pharmaceutical preparations, chemical APIs, proprietary Chinese medicines, medical apparatus and instruments engineering.

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.

天俱时主营业务

Major Business Activities



工艺技术服务

Process Technical Services



工程咨询与设计

Engineering Consulting and Design



工程总承包

T - EPC



智能装备

Intelligent Equipment



自动化与信息化

Automation & Digitalization

生物医药事业部

BIOPHARMACEUTICAL DIVISION

天俱时生物医药事业部拥有国际视野与先进理念，与国际知名咨询公司CB Consultancy AG 保持战略合作，并成立瑞士生物医药咨询创新中心，致力于为生物医药企业提供专业咨询、设计、采购、施工及GMP合规性服务的一站式工程总承包解决方案，帮助生物医药企业加速实现从产品研发到工业化生产的项目建设。

The Biopharmaceutical Division of TIANS Group has international vision and advanced ideas, maintaining strategic cooperation with CB consultancy AG, an international well-known consulting company, and sets up a biomedical consulting & innovation center in Switzerland. The business unit is dedicated to providing biopharmaceutical enterprises with one-stop general contracting solutions including professional consulting, design, purchasing, construction and GMP regulation services, helping biopharmaceutical enterprises accelerate the project construction from product research to industrial production.

行业应用

Industry Application

抗体偶联药物 Antibody-drug Conjugate

疫苗 Vaccine

抗体药物 Antibody Drugs

细胞与基因治疗 Cell & Gene Therapy

胰岛素 Insulin

注射剂 Injection

无菌制剂 Sterilization Drugs

口服固体制剂 Oral Solid Drugs

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EPC工程总承包

EPC GENERAL ENGINEERING CONTRACT

天俱时交付 超越客户预期



天俱时集团是EPC模式的首创者和践行者,致力于为客户提供项目建设全过程各阶段的整体解决方案,以工艺技术与设计为核心,以系统集成优化为特色,以一次性试生产成功为目标,帮助客户应对创新技术产业化的复杂挑战,实现From Lab to Fab 的信仰之跃。

As the pioneer and practitioner of the EPC model, TIANS Group is committed to providing clients with overall solutions for all stages of the whole process of project construction, with process technology and design as the core, system integration optimization as the feature, and one-time trial production success as the goal, helping clients cope with the complex challenges of innovative technology industrialization and realizing the leap of faith from Lab to Fab.



天俱时交付 TIANS Delivery

EPC工程总承包

EPC GENERAL ENGINEERING CONTRACT

TIANS Delivery, Exceed Client Expectations

节省业主精力

Save Time

只需对接天俱时一个总承包商
一站式代业主管理模式,整体控制项目的安全、进度、质量、成本
项目运作与施工组织的风险由工程总承包商承担

Clients just need to communication with TIANS.
All-inclusive agent model, providing overall project control with regard to safety, progress, quality and cost.
The general contractor bears the risks in project operation and construction organization.

利于投资控制

Investment Control

业主可规避费用风险,工程投资可控
总承包商利用自身经验优化项目设计、实施方案,总体提升项目投资效益
由总承包商承担因组织协调不到位产生的费用风险

The clients could avoid cost risks and make the investment controllable.
Benefiting from its own experiences, the general contractor helps optimize the project design and implementation, so as to improve the overall investment returns.
The general contractor bears the costs arising from the lack of organizational coordination.

缩短建设周期

Shorten Period

可实现统筹规划、合理安排,使各环节有序衔接,大大缩短建设工期,帮助业主抢占市场先机
Interconnect all steps in good order to achieve overall planning, which significantly shortens the construction cycle and helps clients seize the market opportunity.

保证工程质量

Quality Assurance

从设计源头开始,项目全流程管理,难点痛点问题一并解决,全方位把控工程质量
通过设计优化、建议反馈、高效沟通、避免脱节、设计全程服务等方面,综合提升工程质量

Execute all-process management from the beginning of the design, provide solutions to difficulties and control project quality from all aspects.
Overall improvement on project quality through design optimization, timely suggestions and feedbacks, effective communication, avoid disconnections and provide full services design, etc.

工程咨询

ENGINEERING CONSULTING

国际化视野

Service With Global Vision

天俱时瑞士生物医药咨询创新中心拥有全球视野的专家团队,核心成员深耕生物医药行业超过20年,拥有全球前十的制药企业工厂设计经验。

秉承能源的高效利用、成本优化、资源的合理使用、保护环境和气候的可持续性服务理念,在设计中充分考虑项目的功能性、灵活性和可视性,并充分关注节能、环保和智能制造,为客户建设国际化的生物工厂。

TIANS Swiss Biomedical Consulting and Innovation Center has a team of experts with a global vision, core members who have been deeply engaged in the biomedical industry for more than 20 years, and have experience in factory design for the world's top ten pharmaceutical companies.

Adhering to the sustainable service concept of efficient use of energy, cost optimization, rational use of resources, environmental protection and climate protection, we fully consider the functionality, flexibility and visibility of the project in design, and pay full attention to energy saving, environmental protection and intelligent manufacturing, so as to build an international biofactory for clients.



天俱时瑞士生物医药咨询创新中心团队

工程设计

ENGINEERING DESIGN

EPC设计理念

EPC Design Concept

双行甲 Double A Qualification
资质

BIM BIM Center
中心

160+ Design Team
设计团队

300+ Design Project Cases
项目案例

天俱时设计是天俱时实施EPC战略、完成“天俱时交付”的核心与龙头。以20余年服务于制药行业的工程总承包经验为基础,设计成员兼备丰富的生产管理经验、工程设计经验和工程建设经验,在设计过程中,能将生产工艺、建造工艺与环保节能工艺并行考虑,帮助客户实现方案、投资、进度和项目品质的全方位保证,提供最具落地性、符合项目需求的设计服务。

TIANS design is the core to implement the EPC strategy and complete the "TIANS delivery". Based on more than 20 years of engineering general contract experience in the pharmaceutical industry, the design members have rich experience in production management, engineering design and engineering construction, they will consider the production process, construction process, environmental protection and energy-saving technology in parallel in the design process, helping clients achieve all-round guarantee of scheme, investment, progress and project quality, and provide the most practical design services that meet the project needs.

设计服务

- 项目建议书
- 项目可行性研究报告
- 概念设计
- 基础设计
- 详细设计
- 消防设计专篇
- 安全设施设计专篇
- 职业卫生专篇

Design Services

- Project Proposal
- Project Feasibility Study Report
- Concept Design
- Basic Design
- Detailed Design
- Fire Protection Special Design
- Safety Facility Special Design
- Occupational Health Special Design

工程管理 ENGINEERING MANAGEMENT

打造精品项目

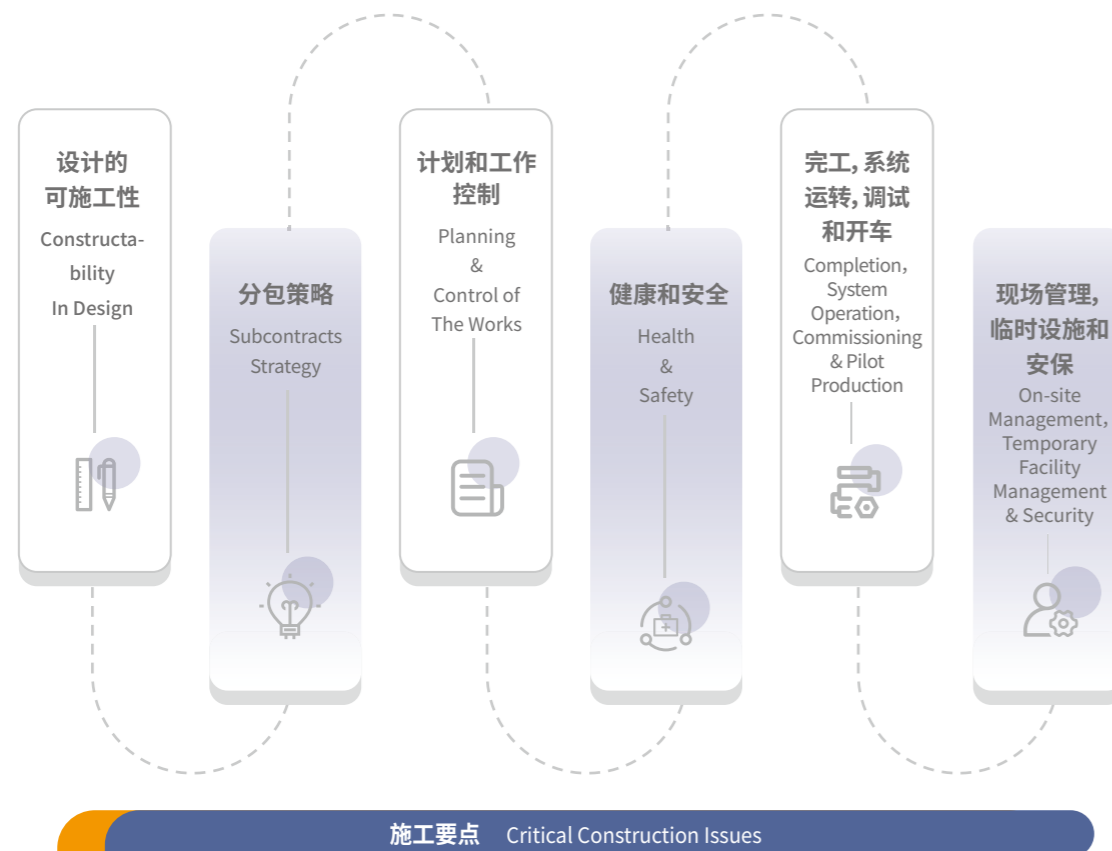
Create Typical Projects

以 20 余年制药行业经验为基础，拥有专业的工程师团队，遵循良好的工程质量管理规范(GEP)，有效控制工程的进度、质量、安全、成本、文明施工等，并有调试、检测中心为工程质量保驾护航，帮助生物医药企业打造精品工程。

Based on more than 20 years of experience in the pharmaceutical industry, we have a professional team of engineers. Following Good Engineering Practices (GEP), we can effectively control the construction process, quality, safety, costs and civilized construction of the project, and have a commissioning and testing center to escort the project quality, helping biopharmaceutical enterprises build high-quality projects.

组织工艺、设计、施工人员、造价工程师等有关人员进行二次优化设计，对图纸认真分析和理解，发现问题，优化工艺。

Organize process, designer, construction personnel, cost engineers and other relevant personnel to carry out secondary optimization design, carefully analyze and understand the drawings with the real situations, correct the problems, and optimize the process.



工程管理 ENGINEERING MANAGEMENT

用技术打造洁净室建设新高度

Create A New Height of Clean Room Construction with Technology

天俱时洁净工程致力于为制药行业提供最专业的，满足 FDA、EMA、GMP 要求的洁净技术一站式服务，包括 GMP 厂房围护结构、洁净通风系统、洁净管道工程、生物安全实验室等。

TIANS clean room engineering is committed to providing the most professional one-stop service of cleaning technology for the pharmaceutical industry, which can comply with FDA, EU GMP, GMP certification. It coverage GMP factory building envelope, clean room ventilation system, clean room pipeline engineering, biosafety laboratory, etc.

此外，天俱时已先后参编多项洁净室领域的国标，还获得全国洁净室及相关受控环境标准化技术委员会 (SAC/TC319) 委员单位称号，矗立起净化领域的行业标杆。

In addition, TIANS has successively participated in the compilation of a number of national standards in the field of clean room, and has also won the title of member unit of the National Technical Committee for standardization of clean room and related controlled environments (sac/tc319), standing as an industry benchmark in the field of purification.



自动化与信息化

AUTOMATION & INFORMATIONIZE ENGINEERING

自动化工程单合同规模制药行业领先

Leading In Single Contract Scale Of Automation Engineering

天俱时自动化与信息化工程以自动化、信息化技术为核心,专注于生物医药领域,掌握生物医药生产过程中主要生产工艺、公辅工程等自动化与信息化核心技术,结合行业特点和生产需求为客户提供从系统规划设计、工程实施、调试维保到计算机化系统验证的全生命周期的一站式解决方案,助力医药企业实现数字化工厂。

TIANS Group automation and information engineering takes automation and information technologies as the core, focuses on the field of biomedicine, masters the main production processes in the biomedical production process, public auxiliary engineering and other automation and information core technologies, combines industrial characteristics and production needs to provide clients with one-stop solutions in the whole life cycle from system planning and design, engineering implementation, commissioning and maintenance to computerized system validation, helping pharmaceutical enterprises realize digital factories.

公用工程自动化(BMS/EMS系统)

Utility Automation (BMS/EMS System)

空调机组开机顺序控制	Start-up Sequence Control of Air Conditioning Unit
温湿度自动控制、送风风量/风压自动控制、房间压差自动控制	Automatic control of Temperature and Humidity, Air Supply Volume/Air Pressure, and Room Pressure Difference
模式控制(生产模式、非生产模式、消毒模式)	Mode Control (production mode, non-production mode,sterilization mode)
系统连锁	System Interlocking
关键房间温湿度、压差、尘埃粒子、浮游菌监测	Monitoring of Temperature and Humidity, Pressure Difference, Dust Particles and Planktonic Bacteria in Critical Rooms
报警、趋势、报表	Alerts, Trends, Reports
用户管理	User Management
电子记录及签名	Electronic Records and Signatures

GMP验证

GMP VALIDATION

遵从GMP

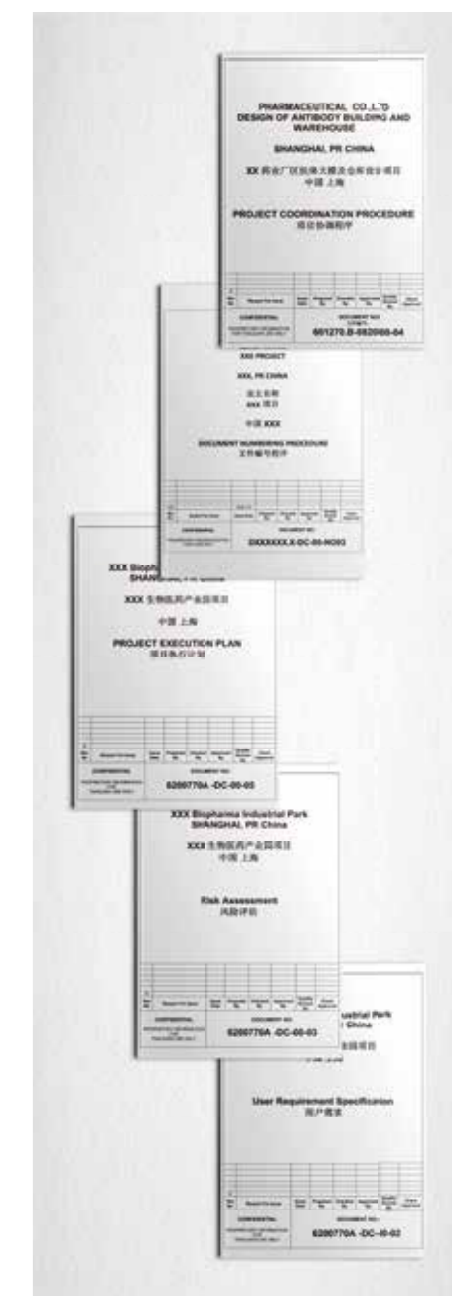
Compliance With GMP

天俱时验证中心基于科学和风险的C&Q的流程图,可以在项目建设全生命周期内提供符合中国GMP、EMA、FDA、WHO等法规要求的验证服务,涵盖的服务范围包括:验证体系、空调/厂房设施、设备、计算机化系统、仓储、辅助类设备等。

Based on science and risk control C & Q process, TIANS provides validation services that meet the compliance requirements of Chinese GMP, EMA, FDA, WHO, etc. during the whole project construction life cycle, covering the scope of services including validation system, air conditioning/plant facilities, equipment,computerized system, warehousing, auxiliary equipment, etc.

验证服务 Validation Services

系统验证SOP的咨询或搭建	Consultation or Construction of SOPs for System Validation
设计文件/图纸的GMP符合性审核	GMP Compliance Audit of Design Documents/Drawings
URS审核	URS Audits
初步风险评估(IRA)	Preliminary Risk Assessment
验证计划(VP)	Validation Program
风险评估(RA/SRA)	Risk Assessment
追溯矩阵(TM)	Traceability Matrix
工厂验收测试/现场验收测试(FAT/SAT)	Factory Acceptance Test / Site Acceptance Test
设计/安装/运行/性能确认(DQ/IQ/OQ/PQ)	Design/Installation/Operation/Performance Qualification
验证总结报告(VSR)	Validation Summary Report
GMP检查的现场支持	On-site Support for GMP Inspections



专家团队

EXPERTS TEAM



Christian Bachofen

国际知名生物医药设计规划专家

天俱时集团生物医药首席技术官
CB Consultancy AG创始人兼首席设计师

Christian Bachofen

Internationally Famous Expert in Biopharmaceutical Design and Planning

Chief Technology Officer of Biopharmaceutical of TIAN'S Group
Founder and Chief Designer of CB Consultancy AG



贺利雄

医药化工工艺设计专家
注册化工工程师

Louis He

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Registered chemical engineer



周兰霞

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Linda Zhou

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Lecturer in Project Management of Zurich University of Applied Science and Technology



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生物工艺技术专家
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Expert in Bioprocess and Technology
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Biotechnology and Industrial Planning Expert

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Vice President of China Pharmaceutical Intelligent Manufacturing Industry Alliance
Expert of China Chemical Enterprise Management Association



Pascal Huber

国际知名医药工艺设计专家

高级工程师
CB Consultancy AG管理团队

Pascal Huber

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Senior Engineer
Member of CB Consultancy AG Management Team



侯佳

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Hardy Hou

Clean Room Technology Expert
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Member of CPAPE Pharmaceutical Environmental Engineering Committee



汪生宝

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中国医药工程设计协会专家委员会专家

Wede Wang

Pharmaceutical and Chemical HVAC Design Expert

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Expert of China Pharmaceutical Engineering Design Association



甄兴航

制药行业GMP验证咨询专家
高级工程师
河北省建筑工程质量安全专家

Eden Zhen

GMP Validation Consulting Expert In Pharmaceutical Industry
Senior Engineer
Hebei Construction Engineering Quality and Safety Expert

全体系资质

QUALIFICATIONS

咨询与设计资质 / CONSULTING AND DESIGN QUALIFICATION

■ 化工石化医药行业工程设计甲级	Class A for engineering design in chemical, petrochemical and pharmaceutical industry
■ 建筑行业工程设计建筑工程甲级	Class A for engineering design in construction industry (construction engineering)
■ 工程咨询单位甲级资信	Class A for engineering consulting company
■ 环境工程设计专项水污染防治工程甲级	Class A for environmental engineering design in special water pollution prevention and control project
■ 环境工程(固体废物处理处置工程、大气污染防治工程)专项乙级	Class B for special environmental engineering (solid waste treatment and disposal engineering, air pollution prevention and treatment)
■ 特种设备固定式压力容器设计	Design of fixed pressure vessel for special equipment
■ 特种设备压力管道设计GC1	GC1 for pressure pipeline design of special equipment
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施工资质 / CONSTRUCTION QUALIFICATION

■ 机电工程施工总承包壹级	General contracting level I for mechanical and electrical engineering construction
■ 电子与智能化工程专业承包壹级	Professional contracting level I for electronic and intelligent engineering
■ 防水防腐保温工程专业承包壹级	Professional contracting level I for waterproof and anti-corrosion insulation engineering
■ 建筑装修装饰工程专业承包壹级	Professional contracting level I for building furnishing and decoration engineering
■ 建筑工程施工总承包贰级	General contracting level II for construction engineering
■ 市政公用工程施工总承包贰级	General contracting level II for municipal public works construction
■ 环保工程专业承包贰级	Professional contracting level II for environmental engineering
■ 钢结构工程专业承包贰级	Professional contracting level II for steel structure engineering
■ 消防设施工程专业承包贰级	Professional contracting level II for fire fighting facilities engineering
■ 电力工程施工总承包叁级	General contracting level III for power engineering construction
■ 输变电工程专业承包叁级	Professional contracting level III for power transmission and transformation engineering
■ 特种设备压力管道安装GC2级	Special equipment pressure pipe installation GC2
.....	...

科技创新

SCIENCE & TECHNOLOGY INNOVATION

参与国家标准编写

Participation In The Formulation Of National Standards

天俱时集团致力于参与在相关领域的标准和规范建设,健全和完善标准体系,为行业提供智力支持

- 《洁净室及相关受控环境 第1部分:根据粒子浓度划分空气洁净度等级》
- 《洁净室及相关受控环境 第2部分:用粒子浓度监测提供洁净空气洁净度的证据》
- 《医药工业洁净厂房施工与验收标准》
- 《洁净室及受控环境中细胞培养操作技术规范》
- 《细胞制备洁净室运行规范》
-

TIANS is currently involved in the formulation of the following standards and is determined to be engaged in the making of more national standards. A sound and complete standard system provides industry with intelligent support.

- Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
- Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
- Standard for construction and acceptance of pharmaceutical industry cleanroom
- Manufacturing practices for cell culture in clean room and relevant controlled environment
- Cell preparation standard for cleanroom operation
-

专利

Patents

182 项

知识产权
163 Intellectual Properties

151 项

授权专利
135 Authorized Patents

31 项

软件著作权
28 Software Copyrights



代表性生物医药业绩 EXEMPLARY PHARMACEUTICAL PERFORMANCES

生物医药团队成员已参与主导了近百座符合中国新版GMP、FDA及EMA要求的制药厂设施建设,将持续帮助中国生物医药企业不断建设里程碑式项目。

The biopharmaceutical team has participated and led the set-up and construction of over 100 pharmaceutical factories in accordance with the latest Chinese GMP, FDA and EMA requirements. The team will sustain to help Chinese biopharmaceutical companies build milestone projects.



广州百济神州生物制药有限公司

BeiGene(Guangzhou) Biopharmaceutical Co., Ltd.

三期及四期项目车间BMS&EMS系统
Phase III & Phase IV of Project BMS & EMS System

生物制药
Biopharmaceutical



广州百济神州生物制药有限公司

BeiGene(Guangzhou) Biopharmaceutical Co., Ltd.

ADC及DS4生产车间机电安装及洁净装修工程
Mechanical Electrical and Clean Room Installation Engineering of ADC & DS4 Workshops

抗体偶联药物
Antibody-drug Conjugate



广州百济神州生物制药有限公司

BeiGene(Guangzhou) Biopharmaceutical Co., Ltd.

1PQ实验室扩建项目机电安装工程
Mechanical and Electrical Installation Works of 1PQ Laboratory Expansion Project

单克隆抗体
Monoclonal Antibody

深圳市海普瑞药业集团股份有限公司

Shenzhen Hepalink Pharmaceutical Group Co.,LTD

坪山工厂新建制剂线EPC工程
EPC Engeering of Pingshan Project New Preparation Line

无菌注射剂
Sterile Injection





上海君实生物工程有限公司

Shanghai TopAlliance Biosciences Co., Ltd.

君实生物科技产业化临港项目(二期)
TopAlliance Biotech Industrialisation Port Project (Phase II)
单克隆抗体
Monoclonal Antibody



正大天晴药业集团股份有限公司

VTTQ Pharmaceutical Group Co., Ltd.

高端综合制剂车间净化机电安装工程
High-end Comprehensive Preparation Workshop
Purification Mechanical and Electrical
Installation Engineering
抗癌创新药
Anti-cancer Innovative Drugs



苏州君盟生物医药科技有限公司

Suzhou Junmeng Biopharm Co., Ltd.

创新性治疗用单克隆抗体产业化项目
Innovative Monoclonal Antibody for Treatment
Industrialization Project
单克隆抗体
Monoclonal Antibody



北京诺诚健华医药科技有限公司

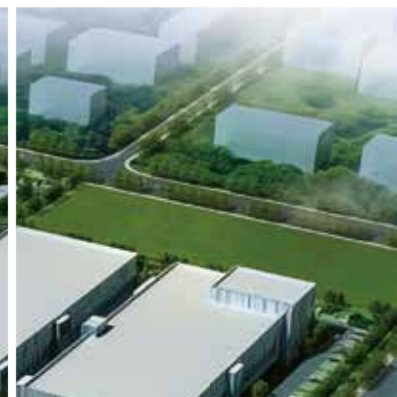
Beijing INNOCARE Pharmaceutical Technology Co., Ltd.

药物研发平台升级项目净化机电安装工程
Drug R&D Platform Upgrade Project Purification Mechanical and Electrical
Installation Engineering
抗癌药物
Anticancer Medicine

金斯瑞蓬勃生物科技有限公司

GenScript Biotech Corporation

BMS&EMS工程
BMS & EMS Engineering
细胞与基因治疗
Cell and Gene Therapy





杭州多禧生物科技有限公司

Hangzhou DAC Biotechnology Co., Ltd.

抗体偶联药物厂房工程净化项目
ADC Preparation Workshop Clean Room Engineering

抗体偶联药物
Antibody-drug Conjugate

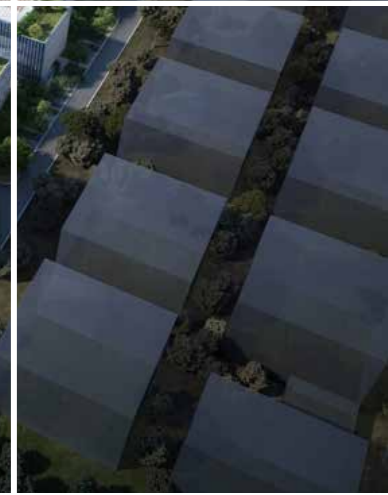


上海乐土生命科技有限公司

Shanghai CHEERLAND Biomedical Co., Ltd.

CDMO项目设计
CDMO Project Design

生物制药
Biopharmaceutical



杭州复因生物科技有限公司

Hangzhou EXEGENESIS Bio Co., Ltd.

基因治疗药物项目二期机电净化工程
Phase II Project of Gene Therapy Medicine

基因治疗药物
Gene Therapy Medicine



深圳市乐土生命科技投资有限公司

Shenzhen CHEERLAND Life Technology Investment Co., Ltd.

CDMO项目设计
CDMO Project Design

单克隆抗体
Monoclonal Antibody



深圳市华生元基因工程发展有限公司

Shenzhen Watsin GeneTech Ltd.

重组人表皮生长因子喷剂、滴眼剂搬迁项目 (EGF生产项目)
净化装修工程
Relocation Project of Recombinant Human Epidermal Growth Factor Spray and Eye Drops (EGF Production Project) Purification Engineering

重组蛋白制品
Recombinant Protein Products

上海上药康希诺生物制药有限公司

CanSino Biologics Inc. (Shanghai)

疫苗生产基地改造项目设计
Renovation Project Design of Vaccine Production Base

腺病毒载体疫苗
Adenovirus Vector Vaccines





上海联合赛尔生物工程有限公司

Shanghai United Cell Biotechnology Co. Ltd.

霍乱疫苗扩产暨四期生产厂房新建项目设计
Cholera Vaccine Expansion & New Construction of phase IV Production Plant

霍乱疫苗
Cholera Vaccine



江苏泰康生物制药有限公司

Jiangsu T-mab BioPharma Co. Ltd.

抗体药物中试产业化项目设计
Antibody Drug Pilot Industrialization Project Design

单克隆抗体及抗体偶联药物
Monoclonal Antibodies & Antibody-drug Conjugate

乐普生物科技有限公司

Lepu Biotechnology Co., Ltd.

生物单克隆PD-1、PDL-1产业化项目设计
Industrialization Project Design of Biological Monoclonal PD-1 and PDL-1

单克隆抗体
Monoclonal Antibody



和元智造(上海)基因技术有限公司

OBIO Intelli-M (Shanghai) Gene Technology Co., Ltd.

精准医疗产业基地建设项目设计
Precision Medicine Industry Base Construction Project Design

基因治疗药物
Gene Therapy Drugs

复星安特金(成都)生物制药有限公司

Fosun AdgenVax (Chengdu) Biopharma Co. Ltd.

复星医药创新疫苗总部及产业化基地项目设计
Project Design of Fosunpharma Innovative Vaccine Headquarters & Industrialization Base

疫苗
Vaccines



成大生物(本溪)有限公司

Chengda Biology (Benxi) Co., Ltd.

质量控制部(QC)扩建项目安装工程
Quality Control Department (QC) Expansion Project Installation Engineering

疫苗
Vaccines



我们的客户 OUR CLIENTS

	<p>超越客户预期 EXCEED CLIENT EXPECTATIONS</p>													

*以上仅列出部分客户
*The above list of clients is not exhaustive