Integrity | Expertise | Innovation | Efficiency

Globally cGMP Compliant Contract Quality and Contract Testing Services Specialized in Biologics

JADE Biomedical™

Bio-CQO™

Jade Biomedical 苏州驾玉生物
& Shanghai Bio-Pacific 上海玉咏生物

Company History

- Established in May 2017 in Suzhou Industrial Park (SIP), China
- GMP testing center in Shanghai operational in Q3, 2019
- GMP testing center in Shanghai expansion operational in Q4, 2020
- 30+ customers to date & impressive pipeline
- Innovative business model
- Strategic Collaboration with Charles River Laboratories in Q4, 2020

驾玉品牌和业绩 – 4年来稳定成长，为中国高端生物药产业化做贡献

FEATURED STORY

Feb 18 2021

国际CXO股权投资及战略合作

Partnership with Jade Biomedical Fuels CMC Support in Asia

Clients in the APAC region will have access to greater regulatory support and capacity for a broad range of analytical services for the development of their biologic drugs, including comprehensive quality testing for cell and gene therapies, thanks to our new partnership with **Jade Biomedical**. As a premiere contract quality organization (CQO) based in Shanghai and Suzhou, China, Jade offers end-to-end GMP testing services built upon an in-depth understanding of quality systems that comply with the Chinese health authorities and global regulatory standards. In addition to analytical testing, Jade offers support for regulatory submissions, quality assurance, cold chain management, and facility design.

charles river

客户涵盖30+中国及国际生物制药领军企业

2018/2017: 初创期

2019/2018: Bio-CQO成长期

2020/2019: CTL建设期

2021/2020: 快速成长期

Business Highlights

World's First Contract Quality Organization –"CQO^{R}"

JADE is the premiere international standard GMP quality service company based in China providing contract quality services (BioCQO^{R}) in manufacturing and Quality systems, operations, product testing, regulatory filing of clinical and commercial-stage biopharmaceutical products during product realization.


商标注册证

第 32401161 号

BioCQO

核定使用商品/服务项目（国际分类：42）

第42类：技术研究；替他人研究和开发新产品；科学实验室服务；质量控制；质量检测；质量评估；质量体系认证；化学研究；生物学研究；临床试验（截止）

注 册 人 苏州驾玉生物医药有限公司

注册人地址 苏州工业园区星湖街218号A1北座2楼B08单元

注册日期 2019年04月07日 有效期至 2029年04月06日

局 长 发证机关

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

FDA

ICH harmonisation for better health

World Health Organization

CNAS

Ingrain Quality into Making Complex Medicine

Recognized & Strengthened by Global Partnership

FEATURED STORY

Feb 18 2021

Partnership with Jade Biomedical Fuels CMC Support in Asia

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驾玉生物
JADE BIOMEDICAL

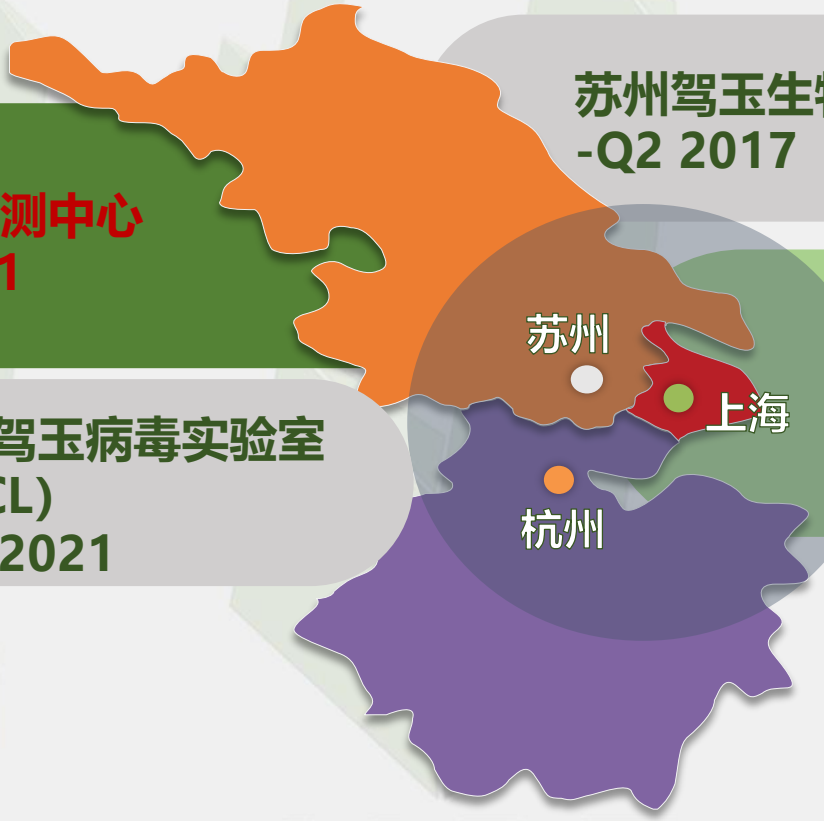
charles river

Jade Business Location: Yangtze River Delta Region

~52% of Biopharmaceutical companies in China located here

苏州驾玉生物（商务总部）
-Q2 2017

苏州驾玉生物安全检测中心
计划启动于Q3 2021



上海张江玉咏生物（微生物，细胞等）
检测中心
-Q4 2019

苏州驾玉病毒实验室
（RCL）
-Q1 2021

Claudia Lin 林巧博士 – Founder & CEO

Shanghai Native

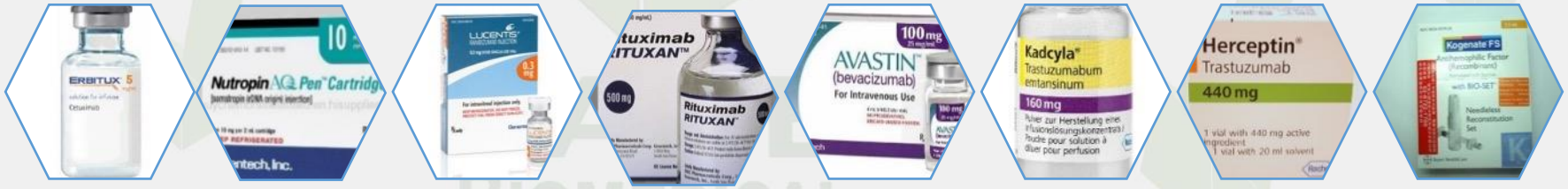
Career Highlights

- PhD in Cell and Molecular Biology, University of California, Berkeley
- Senior Quality Executive, Genentech/ROCHE & Bayer Healthcare, USA
- CMC expert with experience in product development and commercialization for 20+ products in US, China, & EU
- Global leadership reputation, strategic vision, and achievements in organizational development and business management
- “China National Expert” Innovation Expert awardee 2016
- Former Vice President of Quality and CMC of China‘s well-known Biopharmaceutical Enterprises Innovent Biologics （信达生物）
- Founded Jade Biomedical in 2017

David Kapitula, CTO – 20+ Years Manufacturing & Quality Experience

Career Highlights

- MD, Albert Einstein College of Medicine
- MBA, Uni of Penn, Wharton School of Business - Engineering and Business Management
- QC Manager, VI Technologies, Inc, New York
- Director, Quality Control, Imclone Systems Inc, New Jersey
- Director, Contract Manufacturing, Imclone Systems Inc, New Jersey
- Sr. Director, Quality Control, Cell Genesys Inc, Hayward, California
- Director, Quality Assurance, Bayer Healthcare, Berkeley, California
- Director, Quality, ROCHE/Genentech, Singapore
- VP, SVP of Quality and Operations, JHL, Taiwan and China
- Founder/VP of Quality and Regulatory Affairs, CMAB, Suzhou, China
- Chief Operating Officer, Jade Biomedical - Responsible for the technical and financial operations at Jade



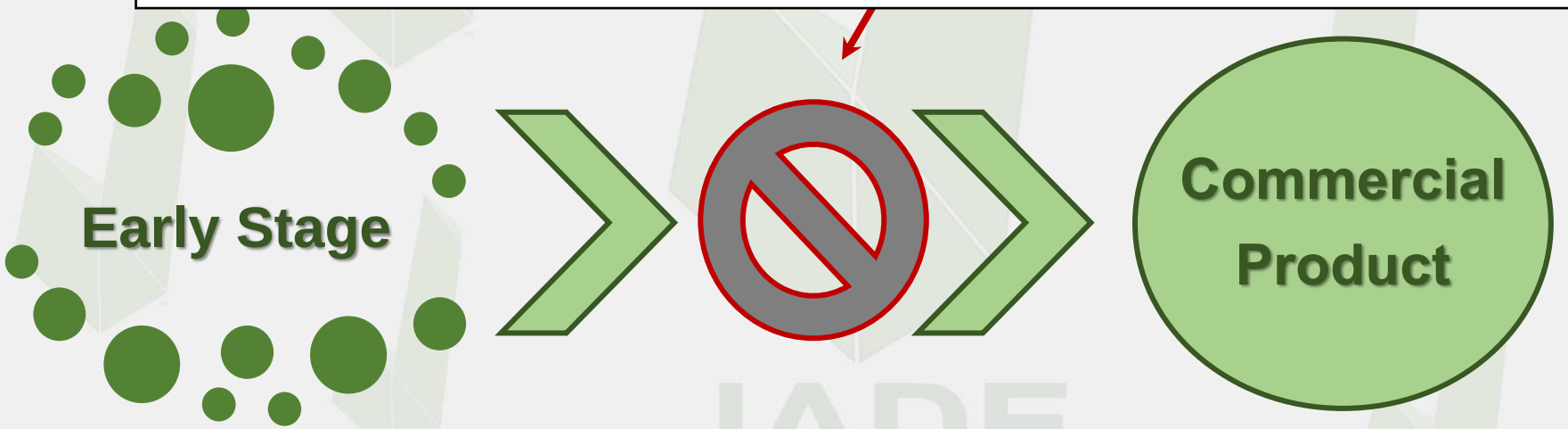
John Zhang, COO – 23+ Years In R&D, clinical, registration, manufacturing, government affairs management

More than 23 YEARS EXPERIENCE In R&D, clinical, registration, manufacturing, government affairs management, among them, more than 10 years of overall management experience in the upper, middle and lower reaches of biological product development (antibody, cell therapy, vaccine) , more than 8 years of research and development experience in the upper and middle reaches of biological drugs, and more than 4 years of clinical experience in macromolecular drugs, familiar with domestic and foreign GMP regulations and policies; at least 10 years experience in biopharmaceutical process development and commercialization; at least 8 year experience in R & D, Production Technology, commercialization and strategic management, in the field of macromolecular biological products, antibodies, stem cells, tumor vaccines, etc. . Upstream Research and development, downstream technology, chief engineer, responsible for the United States and China FDA clinical applications, project, GMP Plant Engineering Design and construction; not only understand the United States GMP high-quality and production, but also successfully integrated into China's work model.

Market Needs: Challenges in Biologics Drug Product Realization

- Biologics (biopharmaceuticals + cell and gene therapies) market is a "goldmine", especially for China
- China's central government policy defines biologics therapy industry as a "National Strategic Focus" - huge policy benefits and monetary incentives granted since 2011
- Most of the progress in the past 8 years resulted in strong R&D pipelines, and an abundance of early stage drug candidates
- How Quality
  expe otential

Manufacturing and Quality



Abundant

Rare, only 1 Approved In US or EU

Compliance: Drug Regulation Globalizing at Remarkable Speed

2016-2021

- Modernize drug regulatory review process
- Enforce the law
- Prioritize innovation and critically needed drugs
- Intellectual property protection

- Join ICH and begin implementation of ICH guidelines
- Allow open competition with global pharma industry
- Encourage only good quality drug to move forward

New Chinese Pharmaceutical Law – Implemented in Dec., 2020

GMP Quality Is Recognized as a Core Competitive Edge for Product Success in China

Bio-CQO Services – "A to Z GMP Quality for Bio"

Quality Systems, GMP Compliance

- ✓ **Phase Appropriate**
- ✓ **Product Appropriate**
- ✓ **Build vs. gap assessment (GMP audits) & remediation**
- ✓ **PAI preparation**

Control Strategy

- ✓ QbD programs
- ✓ Process control reviews
- ✓ QC strategy
- ✓ Material control
- ✓ Overall control strategy

Regulatory Filing Support

- ✓ IND-filing US, China, EU (IMPD, CTA)
- ✓ BLA NDA filing globally, CMC focus
- ✓ All supplemental Filings

QA Services

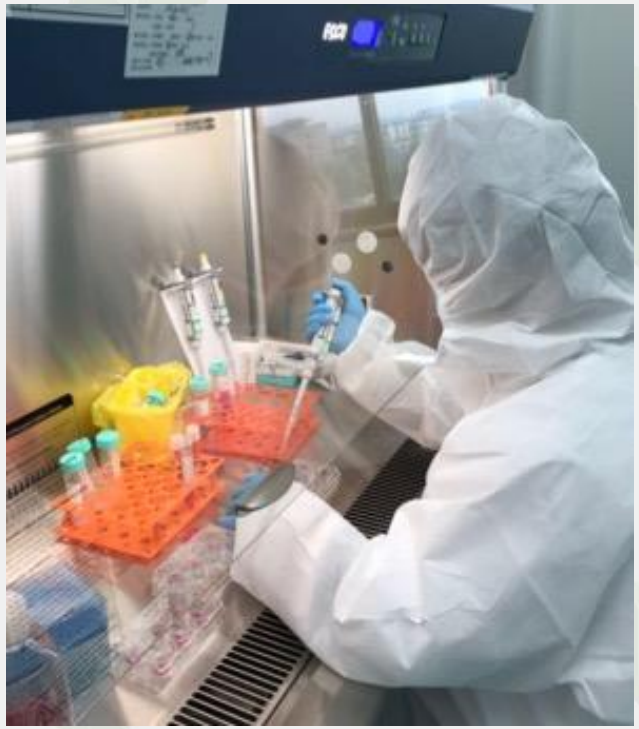
- ✓ Material/vendor management
- ✓ Deviation, Change Control management
- ✓ CDMO Quality Agreement
- ✓ Lot release support
- ✓ CAPA

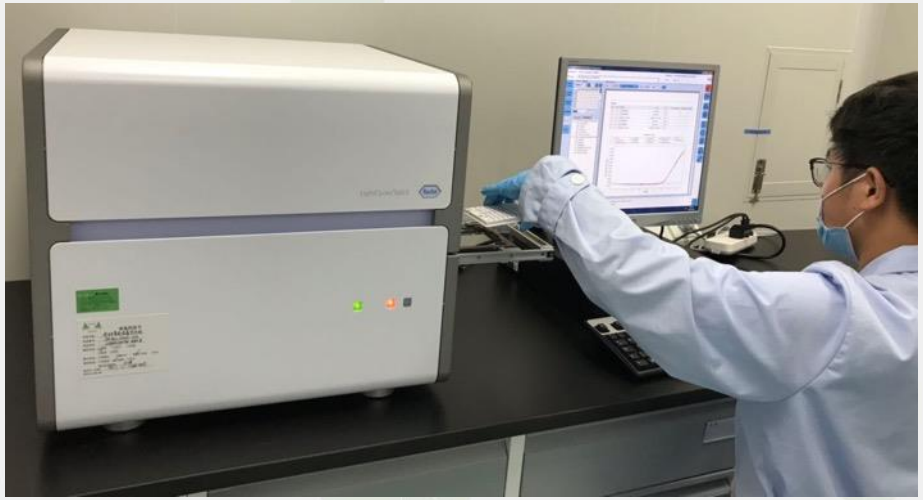
GMP Facility Projects

- ✓ **Design review**
- ✓ **Validation of facility/utilities**
- ✓ **Validation of equipment/instrument/CSV**

Contract Testing Services (CTL) – Jade Bio-Pacific Laboratories

Lab 1&2, 上海张江
2019,4Q已成功运行
2020,4Q第二期运行





Biologics CTL Testing Services – Type of Services Being Offered

Environment

- Cleanroom Validation
- Regular Monitoring
- Cleaning Validation
- Disinfectant Validation

Critical Biologics Starting Material

- Plasmid
- MCB
- WCB
- EOPC
- Virus

In Process & Final Product Testing

- DS
- DP
- UPB
- Apheresis
- Transduced T cells
- iPSC
- RNA

More Future:

- GMP Cell Banking
- Viral Clearance
- Cold Chain/Logistics

Global GMP Standards, Charles River Lab Partnership Support

Partial List of Testing Services (Cell Gene Therapy)

JADE BIOMEDICAL

Safety Testing

Mycoplasma Culture (EP/USP/JP)
Mycoplasma Culture (CHP)
Mycoplasma qPCR
TEM
Co-Culture adventitious Virus
qPCR adventitious Virus (Specific)
Human infectious virus
RCL
RCA
RCR

Microbiology/EM

Traditional Sterility
Rapid Sterility
Bioburden
Endotoxin (Gel Clot)
Endotoxin (Kinetic)
Growth Promotion Media/Reagents
Media Hold Study
Clean Utilities Testing (Water, Gas, Steam)
Environmental Monitoring

General

Appearance
Color and Clarity
pH
Osmolality
Sub Visible Particulate
Volume in Container
UV (Conc.)
Cell Count & Viability
Magnetic beads

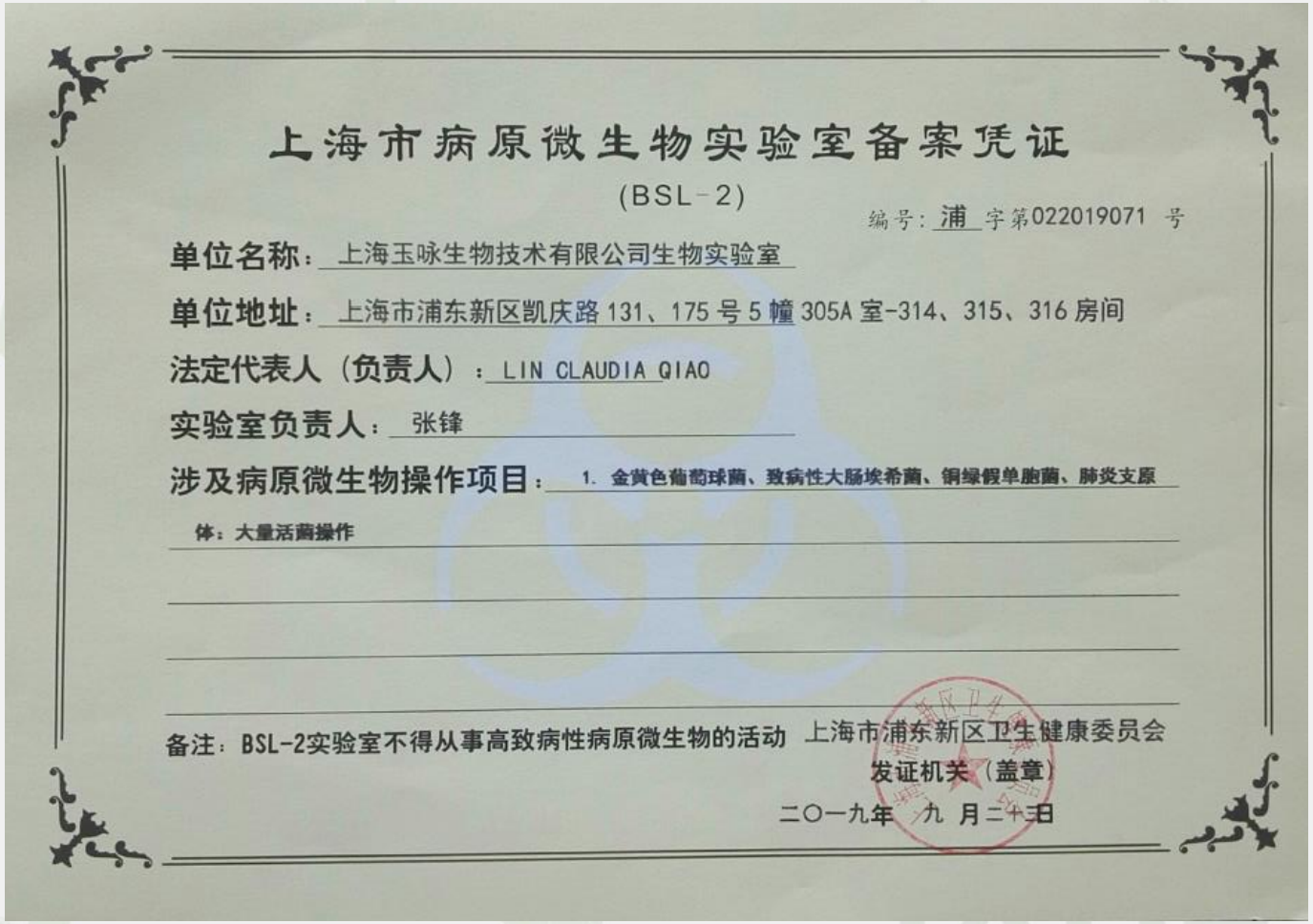
Molecular

Residual ProA
Host Cell Protein/DNA
Cell Based (Potency)
ELISA (for Potency or Cytokine)
FACS of immune cells
Telomerase Activity
Copy no
SEC
IEC
cIEF
CE SDS (reduced)
CE SDS (non-reduced)

Characterization

Identity (Cell)
Construct Copy No.
Sequence
Determination of virus particle count
Virus titer determination
Restriction map
Deamidation
CDC
ADCC
PBRT
C-Term AA
Free Sulfhydryl
Glycan Profile
Oligosaccharide Comp./Dist.

Jade Bio-pacific Laboratories - Qualifications



上海市病原微生物实验室备案凭证

(BSL-2)

编号：浦 字第022019071 号

单位名称：上海玉咏生物技术有限公司生物实验室

单位地址：上海市浦东新区凯庆路131、175号5幢305A室-314、315、316房间

法定代表人（负责人）：LIN CLAUDIA QIAO

实验室负责人：张锋

涉及病原微生物操作项目：1. 金黄色葡萄球菌、致病性大肠埃希菌、铜绿假单胞菌、肺炎支原体：大量活菌操作

备注：BSL-2实验室不得从事高致病性病原微生物的活动

上海市浦东新区卫生健康委员会

发证机关（盖章）

二〇一九年 九 月二十三日

- 国际生物大分子安全性检测大头 Charles River Laboratories 战略合作
- 国际大公司审计成功签约
- 中国领军细胞治疗公司审计成功签约
- 检测报告用于IND及BLA申报

Global GMP Systems, BSL-2 Certified, CNAS CMA Expected by Q2

JADE Biomedical, Inc.™

Jade Biomedical – Bio-Pacific Lab 2 Suzhou

BSL-2 Fully capable of RCL testing

Jade Biomedical – Bio-Pacific Lab 3 Suzhou

One stop solution

Global GMP

Cell bank testing

Safety Testing

Product Testing

Etc.

Protection of Client Intellectual Information

- JADE adheres to strict confidentiality agreements which are signed by each of its employees
- JADE provides data room space to each of its clients with strict level access and permissions
- JADE does not have its own products therefore has no conflict of interest with its clients
- JADE internal information is distributed according to fixed members in project teams

Your
GMP
Quality
Partner

JADE
BIOMEDICAL

Visit our website
jade.bio
Contact
info@jadebiomedical.com

Example Client Service Bio-CQO Project

China's well-known biopharmaceutical company, first market product

JADE Service Content

- Lead quality system verification and correction
- Provide technical guidance on key BLA quality issues before CMC declaration
- Review related BLA sections
- Assist pre-listing regulators to prepare GMP audit including mock audit for NMPA and EMA

Example Client Service Bio-CQO Project

China's well-known CAR-T enterprises, IND filing, clinical production

JADE Service Content

- Lead quality system verification and correction
- Complete and appropriate plant facilities and equipment verification, process control strategy, and product quality standard formulation
- IND CMC section review
- Preside over and lead on-site audit of regulatory agencies
- As quality leader, QC QA responsible for clinical sample production supervision, testing, quality problem resolution and product release

Example Client Service – Bio–CQO Project

MAH innovative biopharmaceutical enterprises in China

JADE Service Content

- Fully responsible for company's compliance and quality work, leading CMC decisions including:
  - Management of production and product release of CDMO
  - Management of technology transfer for product internationalization
  - Establish quality system of MAH
  - Make final decisions on GMP quality issues as a quality attorney including release
  - Responsible for QC to determine formulation and revision of product quality standards, validity period, etc.
  - Write comparable experiments, quality risk assessment, etc.
  - Assist clinical CRO to develop clinical supply chain plan
  - Perform final lot release for clinical supply to the world

Example Client Service – Contract Testing Project

Leading China CAR-T Company with Global Partnership

JADE Service Content

- Mycoplasma tests that meet requirements of pharmacopoeia and GMP in China, United States and Europe including:
  - Method verification
  - Comparison of Pharmacopoeia methods in different regions
  - Detection of clinical samples and key materials

Example Client Service – Contract Testing Project

Leading Nasdaq Innovative Cell Therapy Company

JADE Service Content

- Mycoplasma tests that meet USP/CP
- Production cell bank testing that meet global GMP requirement
- RCL testing that meet global GMP requirement
- Testing cell bank release testings