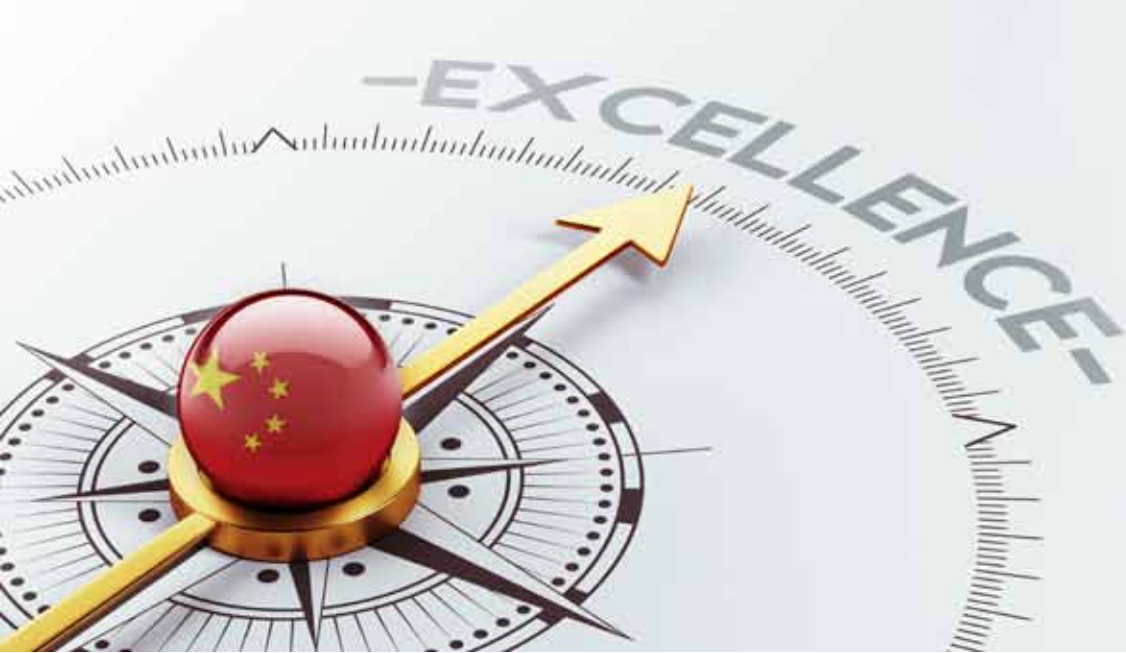




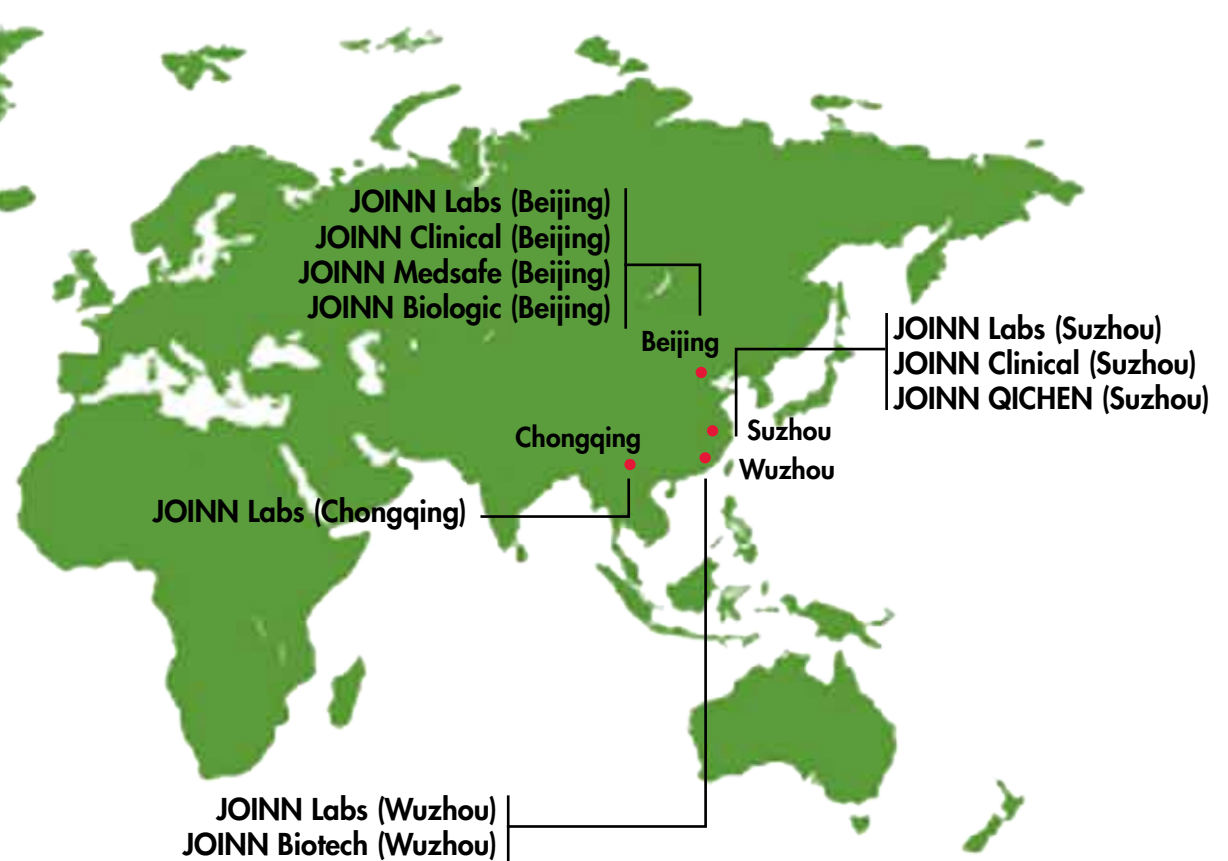
JOINN CAPABILITIES



**December 2019 – JOINN Laboratories (China) Co., Ltd and Biomere merged to form a new premier, global nonclinical contract research organization (CRO). The Joinn - Biomere merger creates a new and expanded North American business subsidiary greatly enhancing our global scale and international footprint, while complementing and expanding on a scientific portfolio in great demand. With locations on the east and west coast and China, we are ideally suited to support our clients' needs.**

### **WHAT SETS JOINN APART FROM OTHER CHINESE CROs?**

- First private preclinical CRO in China
- Preclinical evaluation of the first gene therapy product marketed in China
- Leading CRO in new drug preclinical safety evaluations in China
- Leading CRO in biological product evaluations in China
- JOINN possesses the largest animal facilities and the most employees among all certified GLP Laboratories in China
- Provides support for the global regulatory filing of investigational new drugs







## HISTORY

### JOINN (Beijing)

1995	Founded: Committed to Drug R&D Services
2005	China GLP Certified, 2010, 2013 Recertified
2008	AALAC Accredited, 2011, 2014 Reaccredited
2009	US FDA GLP Inspection, 2013 Reinspected
2016	Korean MFDS GLP Inspection

### JOINN (Suzhou)

2011	Started Operation
2011	AALAC Accredited, 2014 Reaccredited
2013	China GLP Certified, 2017 Recertified
2015	OECD GLP Certified
2016	US FDA GLP Inspection
2018	CNAS Certified
2019	US FDA GLP Inspection

CMO/CDMO  
(Protein/Antibody/Cell)

- Protein/antibody/cell manufacturing
- Preclinical/clinical sample/commercial batches manufacturing
- Cell line construction
- Process development
- GMP manufacturing
- Quality control
- Tech-transfer

Drug Screening

- Early-stage safety assessment
- Efficacy
- Pharmacokinetics
- Ophthalmology

Preclinical Safety Assessment

- Pharmacology & pharmacodynamics
- Pharmacokinetics
- General toxicology
- Genotoxicity
- Safety pharmacology
- DART - Seg I, II, III
- Carcinogenicity
- Stem cells/CAR-T
- Inhalation toxicity
- Supporting global IND filing

Clinical Trials  
Phase I-IV

- Site and patient services
- Clinical trial monitoring
- Bioanalysis (small molecule, large molecule, cell/gene therapy)
- Data management & Biostatistics
- Medical writing

Post-market  
Re-evaluation

- Consistency evaluation (BE studies)
- Pharmacovigilance
- Improving and revising package inserts
- Re-evaluation of injections
- Pharmacovigilance

JOINN Biologics Inc.  
JOINN Biologics US Inc.

JOINNJOINN Laboratories (CHINA) Co., Ltd.  
JOINN Laboratories (Suzhou) Inc.  
JOINN Laboratories (Chongqing) Inc.  
Laboratories (Wuzhou) Inc. (under construction)

JOINN Clinical  
(Suzhou) Co., Ltd.  
JOINN MedSafe Co., Ltd.





## PHARMACOLOGY & PHARMACODYNAMICS

- **Tumors:** Heterotopically/Orthotopically (Lung, Liver, Brain) Implanted Tumors, PTX (Animal imported from Jackson Lab), Immune Reconstruction
- **Hematological Diseases:** Coagulation Diseases, Thrombopenia, Granulocytopenia, Anaemia
- **Metabolic Diseases:** Diabetes, Insulin Resistance, Adiposis, Hyperlipemia
- **Neuropsychiatric Diseases:** Drug Addiction, Withdrawal, Cerebral ischemia, Dementia
- **Cardiovascular & Cerebrovascular Diseases:** Atherosclerosis, Myocardial Infarction, Cerebral Embolism, Pulmonary Embolism
- **Urologic Diseases:** Drug Induced Renal Injury, Surgery Induced Renal Injury, Renal Failure
- **Immunity Related Diseases:** Arthritis (CIA, AIA), Multiple Sclerosis, *In vivo* Neutralization Testing of TNF- $\alpha$  Drugs, GVHD
- **Hepatic Disease:** Alcoholic and Nonalcoholic Fatty Liver, Hepatic Fibrosis, Liver Cirrhosis, Hepatic Ascites
- **Ophthalmic Diseases**
- **Respiratory Diseases**
- **Others**

## ANALYSIS & DMPK



**Comprehensive evaluation services on biologics, chemicals, gene therapy and stem cell drugs, etc.**

- Establishment & validation of analytical methods (GLP)
- Identification & analysis of biomarkers
- PK (*in vitro* & *in vivo*)

## BIOANALYSIS

### Services

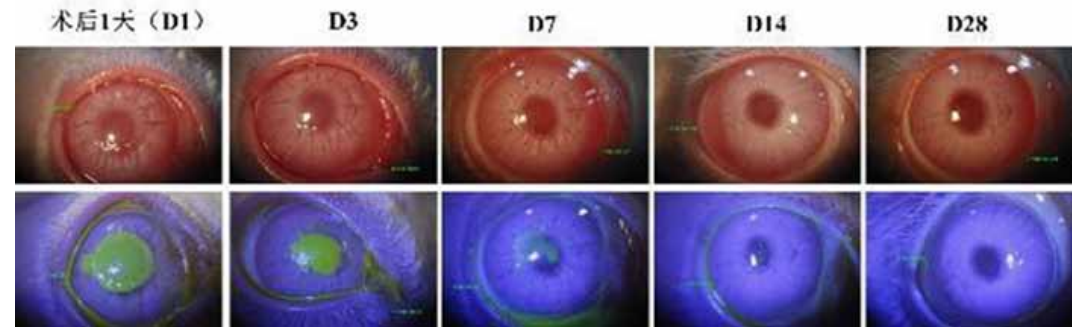
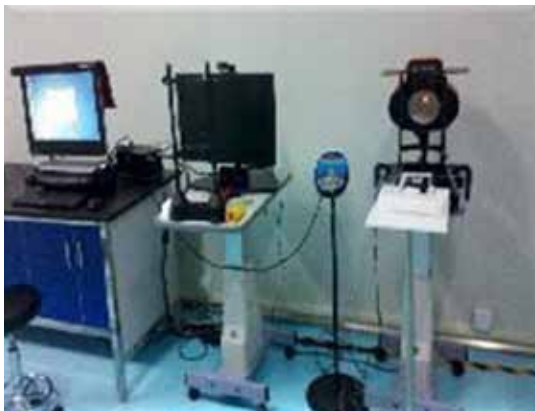
- Method development & validation
- Sample assay
- Data acquisition & statistical analysis
- BE
- PK (Phase I)
- Clinical sample assay
- Training service

### Methods & Equipment

- API6500, API4000, API
- 4000 Qtrap
- Waters Xevo TQ-S, Waters Xevo TQD
- MSD (Meso Scale Discovery)
- LC-MS/MS(n)
- ELISAs/CBA (Cytometric Bead Array)
- HPLC-UV/RID
- Q-PCR/RT-PCR



## OPHTHALMOLOGY



*Outer eye appearance after implantation of artificial cornea in rabbits*

### Services

- Pharmacology
- PK/TK
- Safety assessment

### *In vivo* Models

- Allergic conjunctivitis
- Corneal neovascularization
- Cataract
- Choroidal neovascularization
- Retinal pigment degeneration
- Corneal graft rejection model
- Diabetic retinitis
- Optic nerve disease
- Xerophthalmia
- Glaucoma

### Dosing Techniques

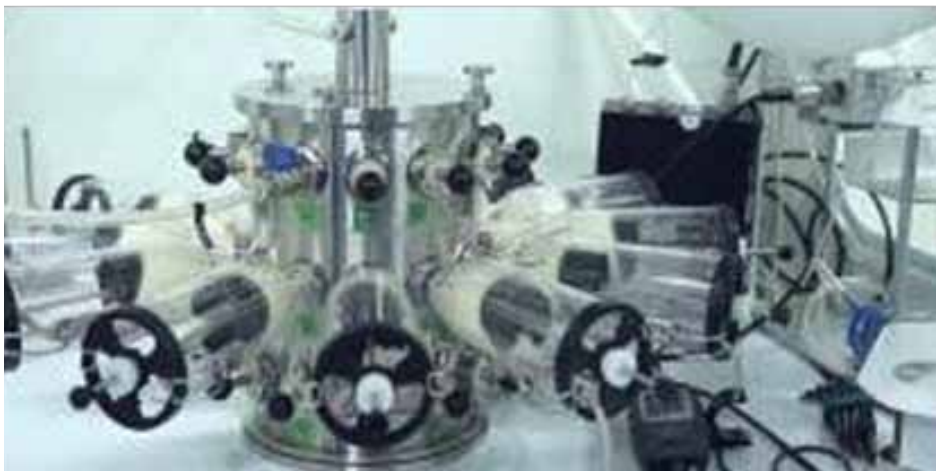
- Conjunctival sac
- Vitreous body
- Retrobulbar injection
- Subretinal injection

### Animal Models

- Neurodegeneration induced by OHT
- Autoimmune uveitis
- Reperfusion of retinal ischemia
- Various ocular pressure/glaucoma
- OIR
- Dry eye
- Cataract
- Deficiency of corneal & epithelial cells
- CNF induced by laser or AAVVEGF
- Genetic retinal degeneration



## INHALATION



### Services

- Validation study of aerosol safety study of inhalational drugs (< mo.)
- Efficacy studies (inhalation agent w/intratracheal dosing)
- Local and systemic PK studies

### Animal Species

- Rodents (rats, mice)
- Non-rodent (dogs, monkey)

### Analytical Support

- Nebulizer, DPIs, MDIs

### Animal Models *(under development)*

- COPD
- Emphysema
- Asthma

## ANIMAL FACILITY

**NHPs  
EU Style Housing**



**Rodents**



**Mini Pigs**



**Dogs**



**Telemetry System**



**Implant**

**Vest**

## ANIMAL WELFARE

Many lifesaving advances in medicine and human health were drawn from the scientific discoveries using animal research and development. We are committed to helping improve the quality of human life while ensuring the highest possible standards of animal welfare.

At JOINN, animal welfare means more than a clean, safe environment and good nutrition. It also means that the animals are provided with the best husbandry available to experience a stress-free life and good health. Both facility sites in Beijing and Suzhou have been accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, which demonstrated our commitment to conducting studies in an ethical and humane way.

As one of the world's leading providers of preclinical drug development services and other services toward human safety, we accept both the legal and the moral obligation to be a leader in assuring that animals in our facilities are treated in accordance with all applicable rules and with high standards of respect and compassion. In addition to laws and ethics, this obligation is scientifically important because failure to meet these rules and standards can undermine the validity of scientific research.

### **Toward that end, all of us at JOINN will follow these principles:**

- We treat our animals humanely and with respect. We follow a Code of Respect and Honor the contribution that our animals make to lifesaving advances.
- We strictly follow all applicable laws and regulations for animal welfare.
- We employ alternative scientific methods to animal use where appropriate.
- We minimize animal discomfort. We apply best practice for animal welfare to minimize or stress to animals.
- We ensure that our employees and processes meet the standards and requirements of AAALAC. We train JOINN employees who handle animals to utilize the best techniques & procedures, and to apply consistent controls to ensure that our Code of Respect is followed.

**If we learn that any of our employees have failed to follow the Code of Respect, we will take appropriate remedial and disciplinary actions.**





## JOINN FACILITIES



### JOINN Labs Beijing

- Founded 1995
- Capacity Extended 2013
- 13,000m<sup>2</sup>
- AAALAC, FDA, MFDS, NMPA GLP



### JOINN Labs Suzhou

- Operations started 2011
- 65,000m<sup>2</sup>
- AAALAC, FDA, NMPA GLP, OECD



### JOINN MedTech Inc. (Taicang, Suzhou)

- NMPA Certified Clinical Research Centers (CRC), multiple cities
- Clinical services (BE & Phase 1)



### JOINN MedSafe Co., Ltd.

- Pharmacovigilance services (iPVMAP®)
- Management of safety signal & risks
- Establish case reports, safety summary reports



### JOINN NHP Center & JOINN Labs (Wuzhou)

- Supply high quality NHPs
- Provide biopharm research service



### JOINN Biologics

- CDMO service
- Chemicals & biologics

## BRANCH OFFICERS



**Yijing Zhang, MSc., CEO,  
JOINN  
MedSafe, Co., Ltd.**

10+ years PV experience  
at Bayer



**Mark Nedelman, CEO,  
Biomere**

30+ years experience, drug  
development and CRO veteran



**Shusheng Geng, PhD.,  
CEO, JOINN Biotech Co.,  
Ltd.**

Immunology Postdoc at  
Harvard Medical School  
15+ years experience in  
Biotech industry



**Tao He, PhD., CEO, JOINN  
Biologics Inc.**

Former Pfizer Biotech Leader  
30+ years experience in  
biotech manufacturing

## BOARD / MANAGEMENT TEAM



**Yuxia Feng, MD,**  
**Founder, Chairwomen,**  
**Board of Directors**  
25+ yrs biomed & drug safety  
assessment experience



**Dylan Yao, MD, PhD,**  
**CSO, Senior VP**  
13 yrs USFDA review & GLP  
regulations, 40+ year biomed  
research experience, 8 yrs with  
JOINN NMPA, Invited reviewer



**Yunxia Sun, MSc, Senior**  
**VP, FM (JOINN Beijing)**  
20+ yrs drug safety  
assessment experience,  
NMPA Invited reviewer



**Conglin Zuo, MD,**  
**Co-founder, Vice Chairman,**  
**Board of Directors**  
25+ yrs biomed & drug safety  
assessment experience NMPA  
Invited Reviewer



**Dapeng (Daniel) Gao,**  
**MSc. CEO & CFO**  
12+ yrs experience in finance



**Jingliang (Leon) Gu,**  
**MSc., Executive VP,**  
**JOINN Labs CEO,**  
**JOINN Clinic Inc.,**  
11 yrs analytical experience,  
marketing expert

### Technical Backbone

<b>Huiye Sun</b>	MD, DVM VP, FM (JOINN Suzhou) 20+ years drug safety assessment experience
<b>Bo Wei</b>	PhD, Executive VP, JOINN Labs (CA), USA Former UCLA Faculty 30+ years experience in immunology
<b>Hengchang Song</b>	MD, VP, Chief Bioanalysis (Preclinic, Beijing) Former Merck Bioanalysis leader 30+ years experience
<b>Baoxian Wei</b>	PhD, VP, Chief, Bioanalysis (Clinic, Souzhou), Former Pfizer Bioanalytical Leader 30+ years experience
<b>Zhenhong Nan</b>	MD, Director of Pharmacology (Neurology), 10+ years experience in drug safety
<b>Hongling Wang</b>	MD, 10+ years experience in drug development and evaluation
<b>Zhanjiang Du</b>	MSC, Dir. QA, 26 years working experience on pharmaceutical analysis and regulatory affairs
<b>Heping Li</b>	MD, Senior VP, Chief, Ophthalmology, Former Chief at Alcon/Novartis 35+ years experience
<b>Jingling Ma</b>	MSC, 15+ years experience in drug safety assessment and GLP regulations
<b>Hemei Wang</b>	PhD, Chief, Tox Pathology, 26 years experience
<b>Maowu Guo</b>	PhD, MD, Dir. Senior Scientist, 28 years experience
<b>Haifei Zhang</b>	PhD, Dir. Safety Pharmacology, 10 years experience



昭衍  
JOINN

## MEET YOUR PERSONAL CONCIERGE TEAM:

**Dylan, April and Ted live in the U.S. and will manage your JOINN study plan in China to assure your experience is as seamless and personal as working with Biomere in the U.S.**



**Dalin ("Dylan") Yao, MD, PhD**  
**Senior VP & CSO JOINN Laboratories**

Dylan Yao is a 40+ year veteran of the medical and biopharmaceutical fields. He served as a senior pharm-tox reviewer in the Metabolism and Endocrinology Products Division at the US FDA for 10 years and later as Compliance Officer in the Division of Bioequivalence and GLP at the FDA.

Dr. Yao brought this experience to JOINN Labs in 2012 and has been instrumental in establishing JOINN as a leading nonclinical CRO in China and the first to have successfully been audited and approved by US FDA.



**April Hall, MS, MBA**  
**Chief Business Officer, Biomere**

April Hall is a veteran of the CRO industry and bioengineer by training. April has over 25 years of experience in pharmaceutical and medical device research.

For the past 20 years, April focused on the sales and marketing aspect for preclinical contract research testing. She has led business development efforts at a number of leading contract labs including Charles River Laboratories, Transgenomics and Sinclair Research Center. She serves on the SAB for the Pediatric Medical Device Institute.



**Ted Ira, MS, MBA**  
**Head of Sales & Business Development, Biomere West**

Ted joins Biomere from Vium where he led the market launch of a digital vivarium platform used by biotech, pharmaceutical, and academic institutions to transform *in vivo* research. He has held various sales and business development positions with pre-clinical, clinical, and technology innovation industry leaders.

Ted's extensive commercial, technical, and customer partnership background makes him the perfect fit for Biomere's culture of quality and responsiveness.

**Contact us: [ahall@biomere.com](mailto:ahall@biomere.com) / 540-966-4610**