



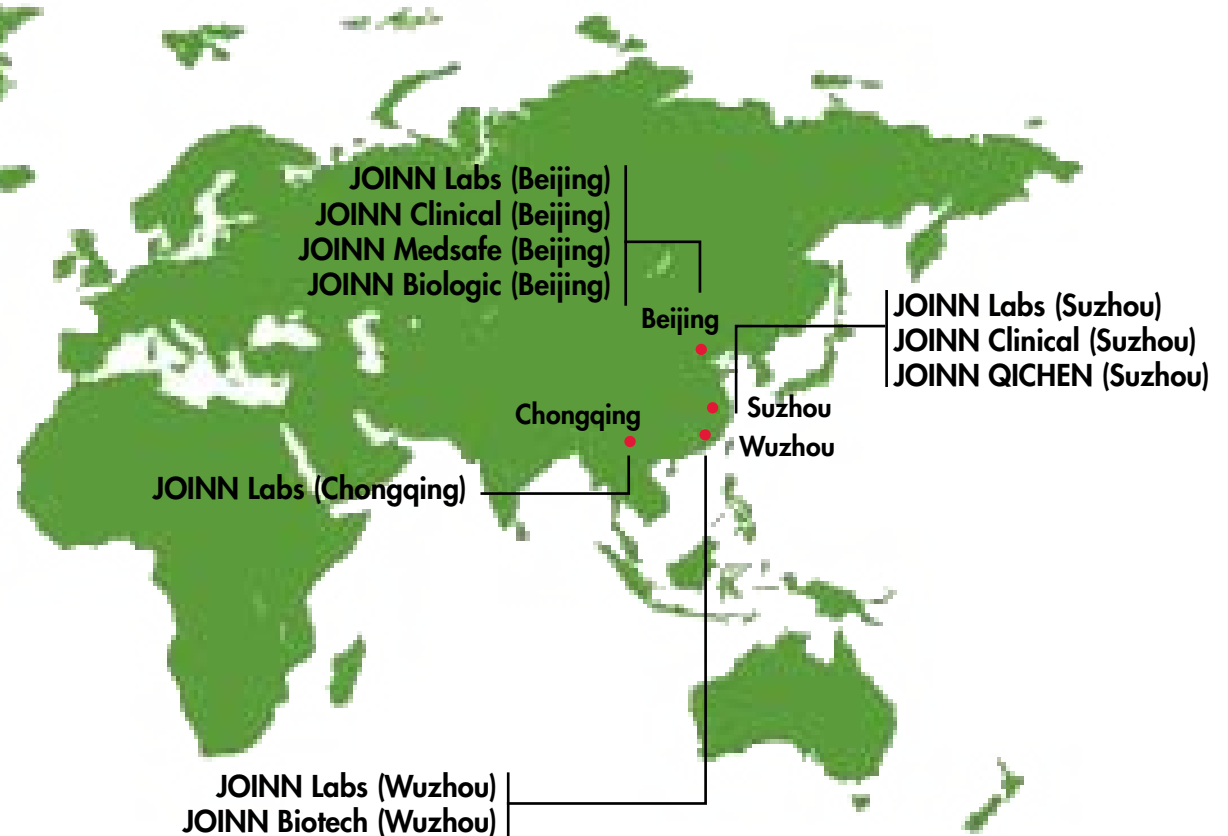
JOINN CAPABILITIES



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

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- α 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

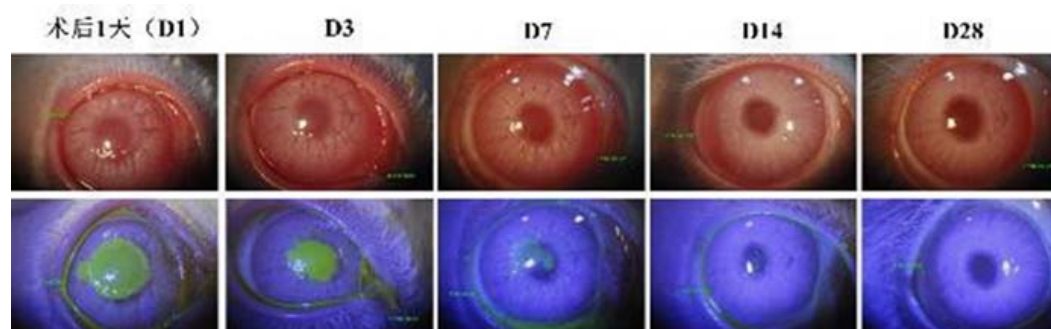
- Method development & validation
- Sample assay
- Data acquisition & statistical analysis
- BE
- PK (Phase I)
- Clinical sample assay
- Training service

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-PRC/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

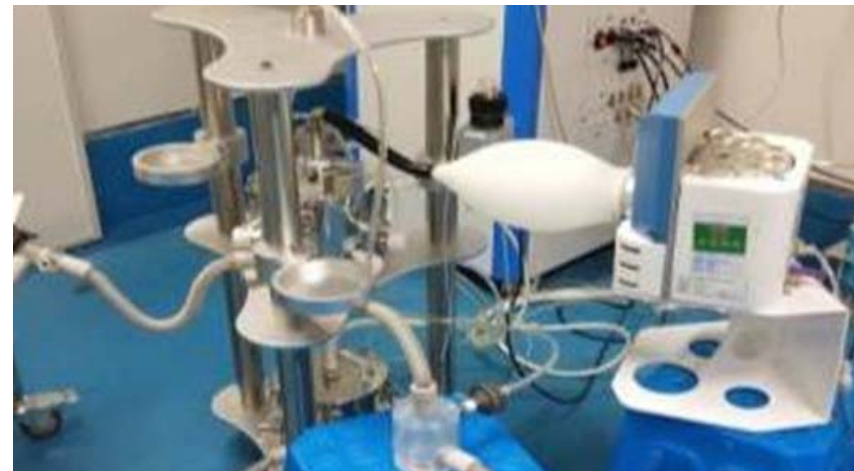
Dosing Techniques

- 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
- 13,000m²
- AAALAC, FDA, MFDS, NMPA GLP



JOINN Labs Suzhou

- Operations started 2011
- 65,000m²
- 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



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

Huiye Sun	MD, DVM VP, FM (JOINN Suzhou) 20+ years drug safety assessment experience
Bo Wei	PhD, Executive VP, JOINN Labs (CA), USA Former UCLA Faculty 30+ years experience in immunology
Hengchang Song	MD, VP, Chief Bioanalysis (Preclinic, Beijing) Former Merck Bioanalysis leader 30+ years experience
Baoxian Wei	PhD, VP, Chief, Bioanalysis (Clinic, Souzhou), Former Pfizer Bioanalytical Leader 30+ years experience
Zhenhong Nan	MD, Director of Pharmacology (Neurology), 10+ years experience in drug safety
Hongling Wang	MD, 10+ years experience in drug development and evaluation
Zhanjiang Du	MSC, Dir. QA, 26 years working experience on pharmaceutical analysis and regulatory affairs
Heping Li	MD, Senior VP, Chief, Ophthalmology, Former Chief at Alcon/Novartis 35+ years experience
Jingling Ma	MSC, 15+ years experience in drug safety assessment and GLP regulations
Hemei Wang	PhD, Chief, Tox Pathology, 26 years experience
Maowu Guo	PhD, MD, Dir. Senior Scientist, 28 years experience
Haifei Zhang	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 / 540-966-4610