



**Turn-Key Solution for China
Regulatory and CRO Services
in Medical Device and IVD**

Partner for your complete CFDA needs

www.chinameddevice.com

China Medical Device & IVD RA/QA and CRO

Turn key solution for your complete CFDA needs


China Med Device, LLC specializes in accelerating Western medtech companies entry into China by providing the turn-key CFDA regulatory solutions from pre-market submission, clinical evaluation and trial, to post-market surveillance and legal representation.

- Seasoned bi-lingual and bi-culture staff
- Combined 80+ years management team experience in medtech industry
- Strong understanding of both Western & China regulation and business practice
- Combined 1200+ CFDA registrations covering wide range of passive, active, combination devices and In-vitro diagnostics

"In my twenty years of Class III medical device experience, I have not had the pleasure of working with a Chinese regulatory firm as talented and knowledgeable. As CFDA is increasing their technical and clinical review, China Med Device is one of the few companies staffed to assist medical device companies in this area. Their focus and dedicated support has exceeded our expectations. In my search for a strategic partner in China, they exceeded the other companies in all areas. While they have a very experienced Regulatory and Marketing team, their technical engineering, clinical, and international project management expertise place them above other companies in this area."

 Multinational Implantable Device Manufacturer
Vice-President, Global Regulatory/Clinical Affairs

"After almost 2 years of efforts, many conference calls, several staff visits and a couple of personal trips to China, however, we could not get around the roadblock of an unnecessary product testing specification required by the CFDA. It had become a stalemate for almost a year. Then, we met China Med Device, LLC. They understood our issues right away -after only one conference call with our management team. CMD sent a senior partner to visit the CFDA review officer in Beijing along with our original registration agency, with whom CMD had worked before and thus already knew. The meeting between China Med Device and the SFDA review officer resulted in the virtually immediate elimination of the product testing step and allowed us to proceed with the final approval steps, enabling us to receive the CFDA approval certificate several months later."

 U.S. Orthopedic Manufacturer
Chairman and CEO

PHILIPS

zimmer

Dilon

nanotherapeutics

A.I.R.
American Innovative Research Corp.
First in Indoor Air Quality

AB Advanced Bionics®

Intrinsic
THERAPEUTICS

Surgical Dseign

ORTHOMERICA®

Zendura®

VISIONSCOPE®

ZipLine
medical

Nuv
Pharma

rti surgical

echo pixel
technologies

Nathaniel Group
Engineered. Assisted. Delivered.

SeeBreath

Syneron

UNITED 联影
IMAGING

ellman®
Experts in Precision Surgery.

DIAMATRIX®
Because the Future is Clear

DDD
Diagnostic

JMS

AgNovos
HEALTHCARE

Jeisys



TOPCON

+AK
APRO KOREA

Precise
普瑞萨斯

EagleVision®
AN ENTEROPTIX COMPANY

LUMAXIS™
CORNEAL LAMELLA PHASE ALIGNMENT

— More...

- Prepare complete CFDA submission dossier and follow up
- Technical standards writing to meet CFDA regulation
- In country representation

- On site type testing
- Biocompatibility testing
- Shelf life validity period
- Packaging and sterilization

- Clinical evaluation report
- Clinical trial/CRO
- CFDA GCP

**CFDA
Registration &
Approval**

**Verification,
Validation &
Type Testing**

**CER
& CRO**

**CFDA Turn-key
Solution:
your legal agent
from Pre-market
to Post-market.**

**GMP/QMS
Certification
& Compliance**

**Post Market
Surveillance**

**Strategy Feasibility &
Green Pathway**

- Quality management system
- Risk management system
- CFDA GMP certification

- Inspection audit support
- External and internal audit
- Recall & AE handling

- Clients' needs assessment & customized strategy
- Product classification & clinical exempt status
- Competitive analysis and customized pathway for CFDA registration
- Green pathway: innovation & priority

Core Areas of Expertise

Medical Device/IVD CFDA Registration & Approval

- Medical device/IVD registration and regulatory compliance
- CFDA certificate composition strategy
- Technical dossier preparation and on-site type testing support
- Software and cybersecurity documents compliant to CFDA requirements
- CFDA application submission and communication with reviewers
- Registration inspection coordination
- CFDA certification renewal and modification
- Translation and sample importation logistics
- Green pathway: innovation and priority

CER/Clinical Trial/CRO

- Clinical trial assessment
- Clinical trial protocol design
- Sample size
- Hospital & ethical committee review & approval
- Clinical trial auditing
- Monitoring and ensuring data quality with CRC and CRA, data management, analysis and reporting
- Handling AE/SAE
- Statistical analysis



Our CRO Choices



Quality System and Post-Market Surveillance

- Quality system assessment and design
- GMP and ISO13485 QMS establishment
- Manufacturing facility registration and certification with the provincial CFDA
- Clean room complete solution: design, equipment setup and certification
- Internal pre-audit and external audit preparation and management
- Post market surveillance, adverse events, recalls reporting and handling

Our Proven Results

 Capital Equipment	 Surgical Instruments	 In-Vitro Diagnostics	 Software	 Implants
 Dental Materials	 Infusion	 Hemofiltration	 Sutures & Dressing	 Combination Products

Surgical

- General Surgery
- Neurosurgery
- Thoracic surgery
- Breast surgery
- E.N.T. Department
- Orthopedics
- Interventional cath lab
- Vascular surgery
- Ophthalmology
- Gastroenterology



Non-surgical

- Cardiology
- ICU, Respiratory
- Dental
- Oncology
- Physical Medicine & Rehabilitation
- Radiology
- Radiotherapy
- Nuclear
- Ultrasound

In-Vitro Diagnostics

- Hematology Kits and Packages
- Clinical Chemistry Test System
- Clinical Laboratory Instruments
- Immunological Test System



**Choose China Med Device,
LLC as Your Partner for Your Complete
CFDA & CRO Needs**



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