TRANSFORM CHINESE MEDTECH INNOVATION INTO GLOBAL MARKET SUCCESS

Navigate US & EU Markets with Confidence. Enter Once. Succeed Globally.

Exclusive Strategic Partnership for Your First Expansion into the West.

THE CHALLENGE

Why First-Time Expansion Is Risky—And Costly

- Complex and evolving FDA and European MDR regulations
- Long approval timelines and costly submission errors
- Uncertainty: EU-first or US-first?
- Clinical evidence expectations differ significantly
- Investor, board, and commercialization pressures
- Building credibility and operational structure outside China

One wrong strategic decision can delay market entry by years—and cost millions.

THE SOLUTION

The Definitive Global Expansion Alliance

YUVAL BINUR
Global Regulatory Pioneer. Trusted Worldwide.

Meditrial
DIGITAL RESEARCH ORGANIZATION
Clinical Research & Regulatory Excellence. Delivered.

A unique alliance that combines unmatched regulatory leadership with deep execution capabilities.

YUVAL BINUR
One of the world's leading regulatory strategists and former senior FDA executive. Pioneer of groundbreaking regulatory pathways and global approvals for innovative devices.

MEDITRIAL
A leading full-service CRO and regulatory consulting firm with proven success in global clinical development and market access for MedTech companies.

STRATEGY. EXPERIENCE. EXECUTION. YOUR GLOBAL SUCCESS.

OUR CORE SERVICES

1 REGULATORY PROCESS & STRATEGY

Navigate FDA & MDR with Confidence.

End-to-end regulatory roadmap design, classification, gap analysis, and submission strategy for FDA (510(k), De Novo, PMA) and EU MDR (CE Mark).

2 FDA BREAKTHROUGH DESIGNATION

Accelerate with Priority Pathways.

Expert positioning and pre-submission strategy to qualify for FDA Breakthrough Device Designation and gain market advantage.

3 CLINICAL APPROVAL STRATEGIES

Right Data. Right Design. Right Approval.

Design efficient, authority-aligned clinical programs that meet global standards and support faster, smoother approvals.

4 STRATEGIC MARKET SELECTION

EU-First or US-First? We Help You Decide.

Objective comparison of EU vs. US pathways based on your device type, risk class, data, timelines, reimbursement and commercial strategy.

5 GLOBAL CORPORATE STRUCTURING

Build Your Out-of-China Entity with Confidence.

Strategic guidance on setting up your international presence, subsidiary or affiliate structure, and compliance for long-term global success.

WHY WORK WITH US?

- Proven track record with global innovative MedTech leaders
- Deep understanding of China's innovation and Western expectations
- Strategic guidance tailored to your device, stage and goals
- End-to-end partnership from strategy to market access

TAKE THE RIGHT PATH. RIGHT FROM THE START.

BOOK YOUR PRIVATE STRATEGY SESSION

with Yuval Binur and the Meditrial Team.

- Customized Insights for Your Device
- Clear Strategic Recommendations
- Confidential, Executive-Level Discussion

SCAN TO BOOK YOUR SESSION

or contact us at

intouch@meditrial.net

www.meditrial.net

FROM CHINA TO THE WORLD. TOGETHER