



CHINA IVD REGULATORY MAP

A practical orientation for global RA teams entering China

START HERE: WHAT IS THE PRODUCT IN CHINA?

1 Confirm Chinese regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and registration depend on the degree of risk to human health and the Chinese NMPA regulatory framework.



IVD reagent



Analyzer / instrument



Software / other

2 Choose the regulatory route

CLASS I



Low risk

Filing / record-filing route

Lower risk products with well-established performance and mature technology.
Notification / record-filing with NMPA for market access.

CLASS II



Moderate risk

Registration route

Greater potential risk; requires technical review by NMPA.
Registration certificate is required before commercialization.

CLASS III



High risk

Registration route

Highest potential risk to health.
Most rigorous review by NMPA.
Clinical evaluation and quality evidence expectations are highest.

3 Build the China market-access infrastructure



NMPA framework

Comply with the Medical Device Supervision & Administration Regulations (MDSAR) and relevant technical review requirements issued by NMPA.



Local agent / local registration holder

Appoint a local agent or establish a legal entity in China to act as the registration holder and be legally responsible for the product.



Chinese localization & submission language

All submissions, labeling and IFU must be in Simplified Chinese. Localize content to meet Chinese regulatory and clinical practice expectations.



Product-specific testing / standards / QMS readiness

Ensure testing to Chinese standards (e.g., YY/GB) and readiness for QMS compliance (GMP / ISO 13485) per NMPA requirements.

4 Build the evidence stack



Administrative

Forms, holder documents, product registration dossier, legal authorization, agent agreement.



Quality

QMS, design controls, supplier management, risk management, process validation.



Analytical performance

Performance, method comparison, accuracy, precision, reference materials, stability.



Clinical / scientific

Clinical evaluation report, literature support, PMCF planning, safety & performance data.



Labeling & IFU

Chinese labeling and IFU with intended use, indications, contraindications, warnings, claims, symbols per NMPA.



RA TRAP TO AVOID

Do not begin with "What is the China timeline?" Begin with product identity → route/classification → local agent/registration holder → Chinese documentation & testing → registration strategy.
The timeline is the result of those decisions.



STRATEGIC INSIGHT

Local agent setup, Chinese documentation, and testing/registration strategy are the biggest drivers of timing. Plan early and align to NMPA expectations.



CHINA IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III
Premarket pathway	Filing	Registration	Registration
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ● ○
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High / comprehensive ● ● ● ● ○
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Extensive ● ● ● ● ●
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ● ○ ○	Very strong ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ● ○ ○	Strict / intensive ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product type, testing needs, technical review, agency workload, and study requirements.



i Filing (Class I) timelines are typically shorter but may vary by product category and local Center.

⌚ Registration (Classes II–III) depends on review complexity, technical questions, and site inspections.

D Labeling & language essentials

Chinese-language support
Provide Chinese versions of key materials (label, IFU, claims).

Product labeling
Labels must be in Simplified Chinese; meet NMPA format and content rules.

Instructions for use
Chinese IFU required; follow NMPA IFU template and content elements.

Claims control
Claims must be truthful, verifiable, and consistent with evidence and labeling.

Product identifier & documentation
Use NMPA product registration code/UDI (where required) and retain traceable records.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- NMPA Medical Device Center (CDE): english.nmpa.gov.cn
- NMPA Laws & Regulations: english.nmpa.gov.cn/lawsregulations.html
- NMPA Medical Device Registration e-Service: english.nmpa.gov.cn/xxgk/gtg/qtggtg/index.html
- Hopestone Capital & Consulting: hopestonecapital.com
- Template also reflects screening-level requirements from Hopestone's internal global device requirements workbook.



IMPORTANT: Product-specific requirements, standards, and recent regulatory changes govern. Confirm current requirements before execution.