China IVD Registration Update

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10 + 2 General Rules to do Business in China

1. Relationship is everything.

2. Relationship is everything.

3. Everything is possible in China.

4. Patience is the key to success.

5. The answer “Yes” is not necessarily an indication of agreement or confirmation.

6. “You don’t understand China” means disagreement.

7. Signing a contract means the beginning of the real negotiation.

8. Understand that no company in China is disconnected from politics.

9. Respect the Chinese view of the world.

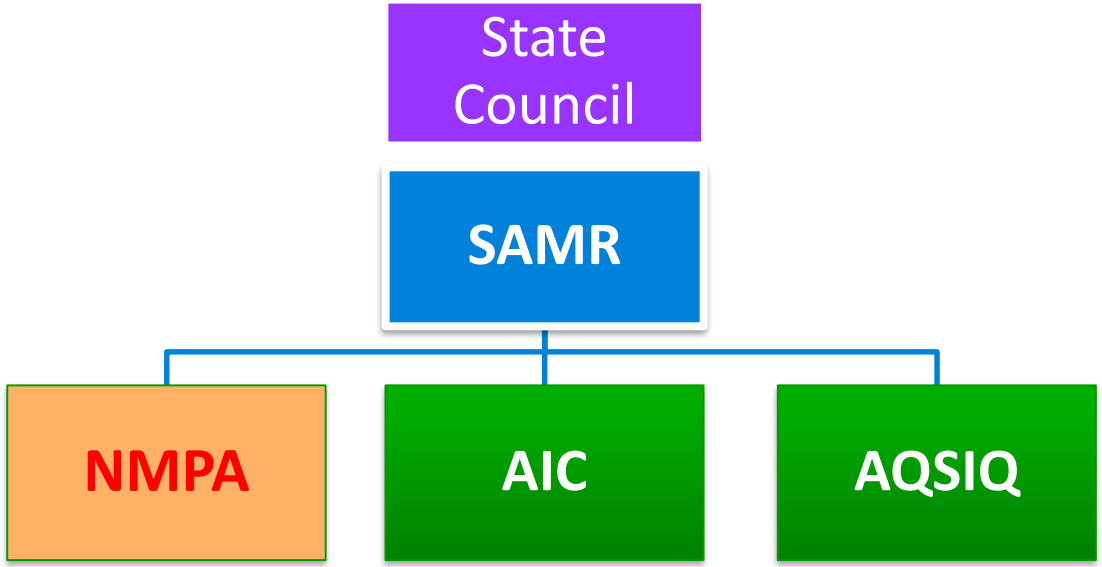
10. Strive for diplomacy, consensus and harmony. Don’t be too direct.

11. When you are discouraged, think about rule #3.

12. When you don’t know what to do, think about rule #1 and #2.

Source: Unknown

National Medical Product Administration (NMPA)

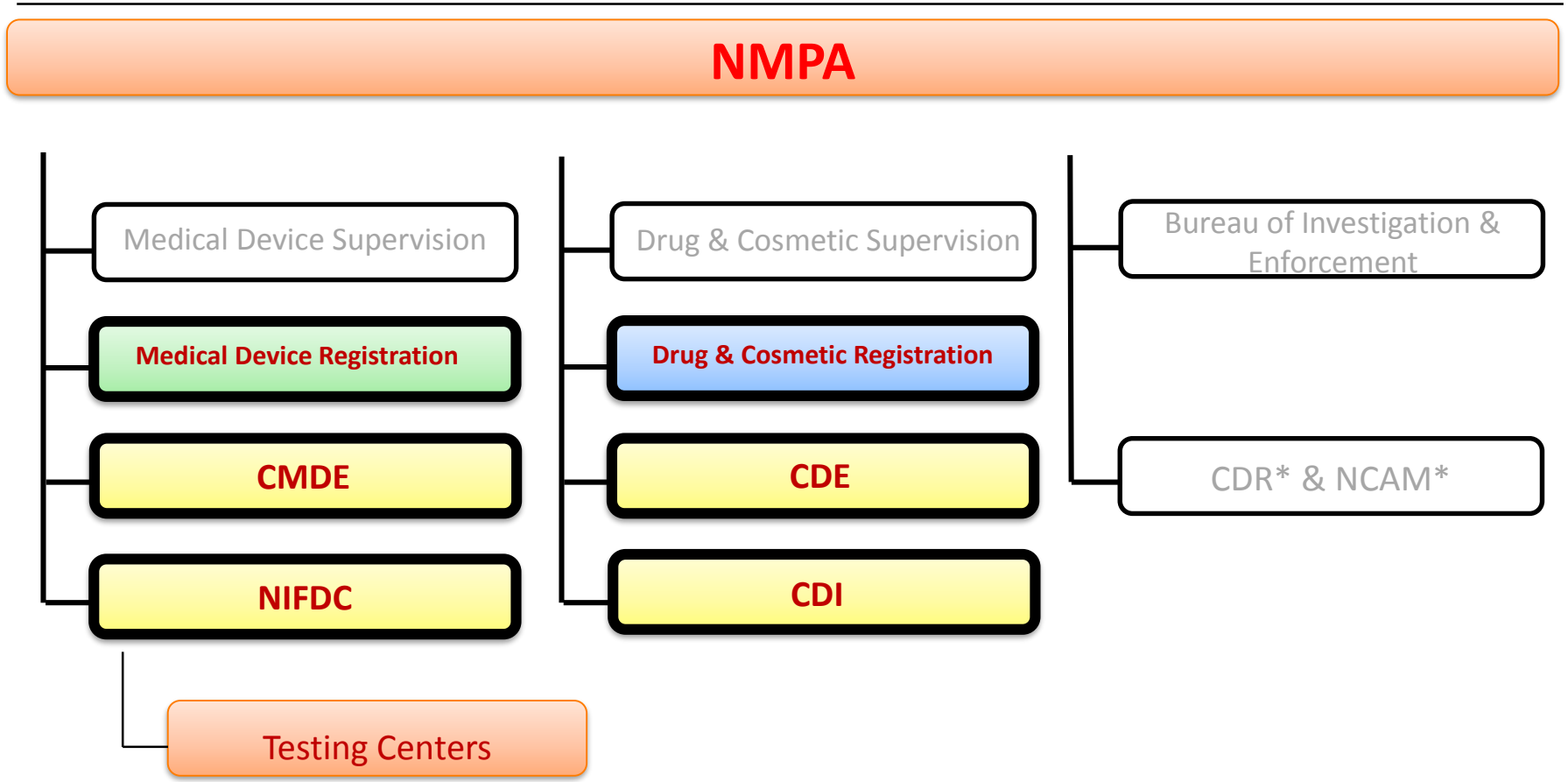


State Council: Government (Cabinet level)

- **SAMR**: **State Administration for Market Regulation**
- **NMPA: National Medical Product Administration**
  - Pre-market application approval and post-market supervision of Medical Devices (incl. IVDs), Drugs (incl. Blood Screening Tests, Blood Glucose Strips)
- **AQSIQ:** Administration of Quality Supervision, Inspection & Quarantine
- **AIC:** Administration for Industry and Commerce

National Medical Product Administration (NMPA)

Departments Involved in Approval Processes



*CDR: Center for Drug Re-evaluation

*NCAM: National Center for ADR (Adverse Drug Reaction) Monitoring

National Medical Product Administration (NMPA)

Departments Involved in Approval Processes

Department of Medical Device Registration

- Determines Registration Policies for IVDs and Medical Devices
- Secondary/supervisory review of registration files
- Issues Registration Certificates

Center for Medical Device Evaluation (CMDE)

- Reviews application files for Medical Devices (incl. IVDs)

National Institutes of Drug & Food Control (NIDFC)

- Oversees Testing Laboratories

National Medical Product Administration (NMPA)

Departments Involved in Approval Processes

Department of Drug & Cosmetic Registration

- Determines Registration Policies for Drugs (including Blood Screening Products)
- Secondary/supervisory review of registration files
- Issues Registration Certificates

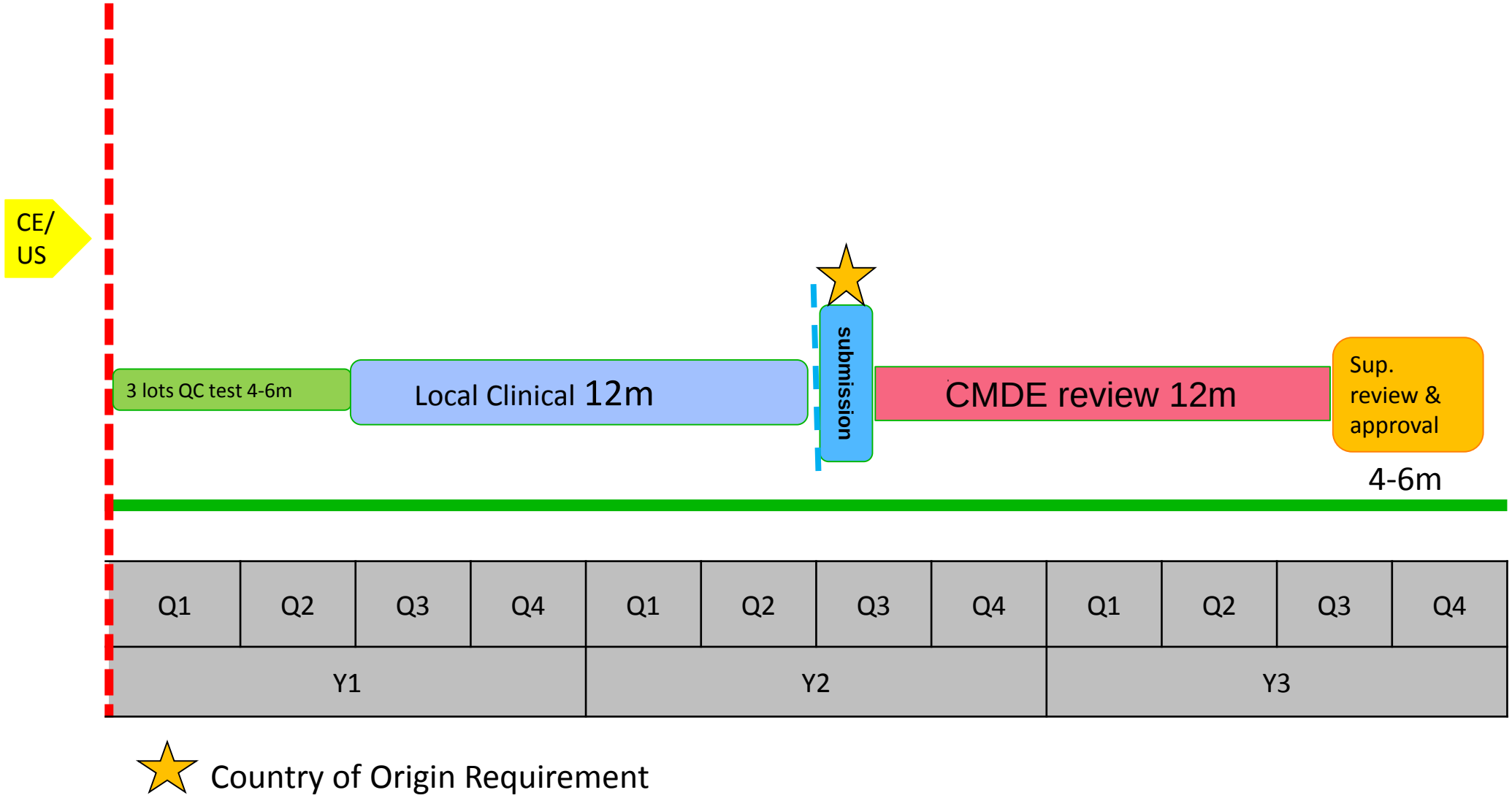
Center for Drug Evaluation (CDE)

- Reviews application files for Drugs (including Blood Screening Products)

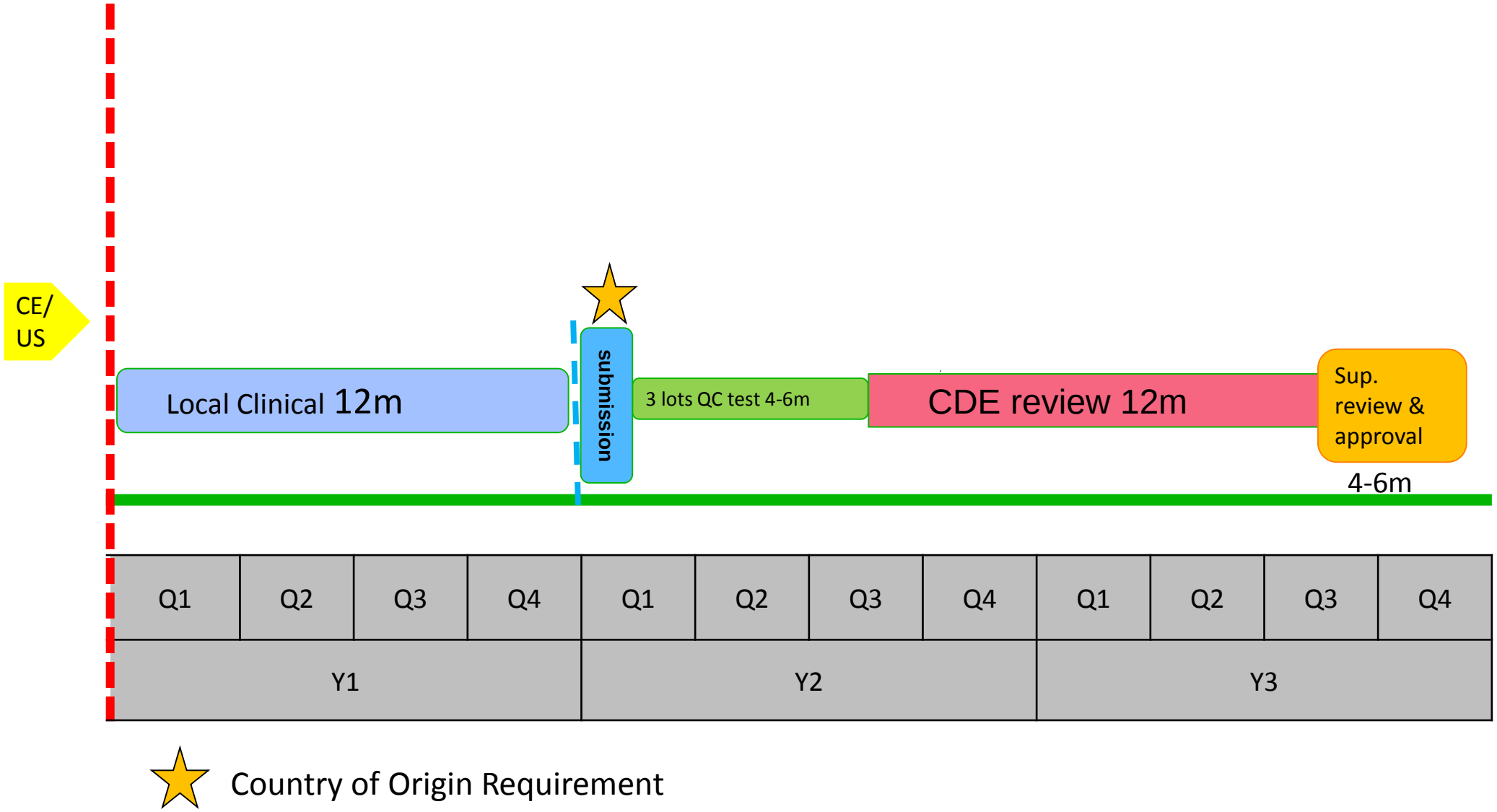
Center for Drug Inspection (CDI)

- Inspection of manufacturing sites (IVDs, Medical Devices, Drugs)
- Inspection of shipments at point of entry into China

Registration Process Medical Device IVD



Registration Process Blood Screening IVD (Drug)



QC Testing/Type Testing

Scheduled and performed with the National Institute for Food and Drug Control (NIFDC).

Local testing specifications generally set by the NIFDC if there is a National Standard.

Be prepared to support locally.

Draft amendment Order 680 – Manufacturers may have opportunity to perform.

Clinical Evidence (Local)

Blood Screening	100,000 donation Samples (Pooling counted), 3 Blood Banks (or plasma fractionation sites).
Tumor Marker (Class 3)	1,000 Patient Samples in 3 Clinical Labs
Infectious Disease (Class 3)	500 Patient Samples in 3 Clinical Labs *
Clinical Chemistry (Class 2)	200 Patient Samples in 2 Clinical Labs**

*10,000 for screening assay
**1,000 for Brand new assay

Each Marker, Each Sample Type (ie. Plasma & Serum)

Before conducting clinical trials involving China's genetic resources, overseas enterprises shall report to Human Genetic Resources Administration of China (HGRAC).

Clinical Evidence (Overseas)

Shall Include:

- Protocol, Ethics Committee, Clinical Study Report.
- Comparison to predicate device.
- Population data can be extrapolated to Chinese population.
- Tested conditions must parallel those in China.

Submission Requirements Class II/III

Certificates

- Country of Origin Approval (ie. EU, US)
- ISO 13485

Data

- QC/Type Testing Reports, Stability, Verification*
- Clinical
- EMC, Safety Reports

Technical Documentation

- Specification, Manufacturing, Validation, Cybersecurity
- Risk Analysis
- Labeling

* 3 lot expectation for Critical Studies

Product Technical Requirements (PTR)

Established during QC testing.

May include China specific requirements, or Chinese or International Standards, which will be tested against.

Collection of Main Raw Material, Component, Final product specifications and manufacturing information.

Random Testing to PTRs

Part of NMPA's market surveillance

Samples of on-market products are tested

Labeling

- Products without Chinese labelling should not be imported into China.
- Chinese Labeling includes printed package inserts.
- Shelf Life of Expiry Date in human readable format.
- Production Date / Date of Manufacture (DOM).
- DOM must reflect a date subsequent to NMPA approval.

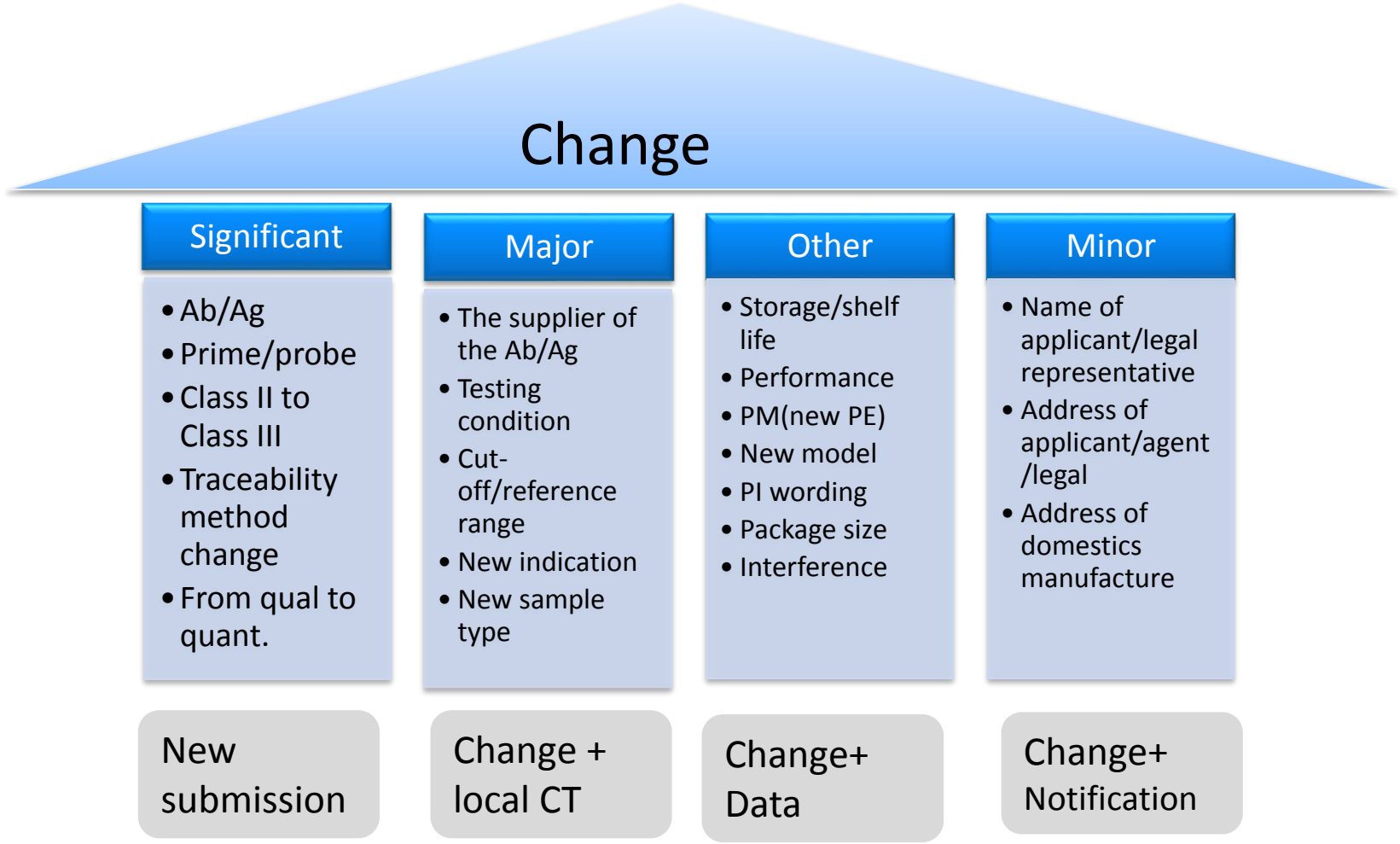
Inspections

Audit by NMPA

- Clinical Sites and data generated will be audited by NMPA
  - Critical deficiencies are published:
    - Restrict legal manufacturer from submitting applications for 1 year.
    - Restrict legal manufacturer from submitting applications for same product for 3 years.
- Foreign Manufactures
  - QMS
  - Product Specific, including PTR related documentation

Change Registration for IVD (MD)

All changes require submission and approval before implementation.



DOM of implementation must come post approval.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