Type testing and related process

NMPA Type Testing Regulation

Measures for the Administration of Medical Device Registration, No.4, 2014

Chapter III Product Technical Requirements and Type Testing

Article 15

- Applicant shall draft the Product Technical Requirements (PTR).
- For Class I medical device, PTR shall be submitted to NMPA during filing.
- For Class II and III, the PTR shall be reviewed and approved by NMPA.
- PTR shall include performance indicators (function, safety, and quality control indicators) and test methods.
- Medical device sold in China shall comply with the PTR.

Article 16

- Type testing shall be done for Class II and III medical devices (including IVD).
- Testing center shall test the products as per the PTR.
- Products used for type testing shall comply with QMS requirements.
- Products need to pass type testing before clinical trial/registration process.
- For Class I, applicant can submit self-test reports.

NMPA Type Testing Regulation

China Med Device
Life Science Bridge

Article 17

- When apply for type testing, applicant shall provide required technical documents, samples, and PTR to the testing center.

Article 18

- Testing center shall be certified and does tests within its scope of service.
- Testing center shall issue a **pre-evaluation** with the test report to the applicant.
- If the product has not been included in any of the testing center's scope of service, the NMPA shall designate a capable institute to complete the tests.

Article 19

- Product samples tested in the same registration unit shall be able to represent the safety and effectiveness of other products in the registration unit.

Type Testing & Standards Revision Plan

- 2018-2020: 300+ Standards to be updated (2/2018)
- 2018: 99 Impacted (8/7/2018)
- 2019: 94 medical devices and IVDs affected
- Scope: medical device, IVD and quality systems in performance testing standards, biological evaluation, non-clinical standards

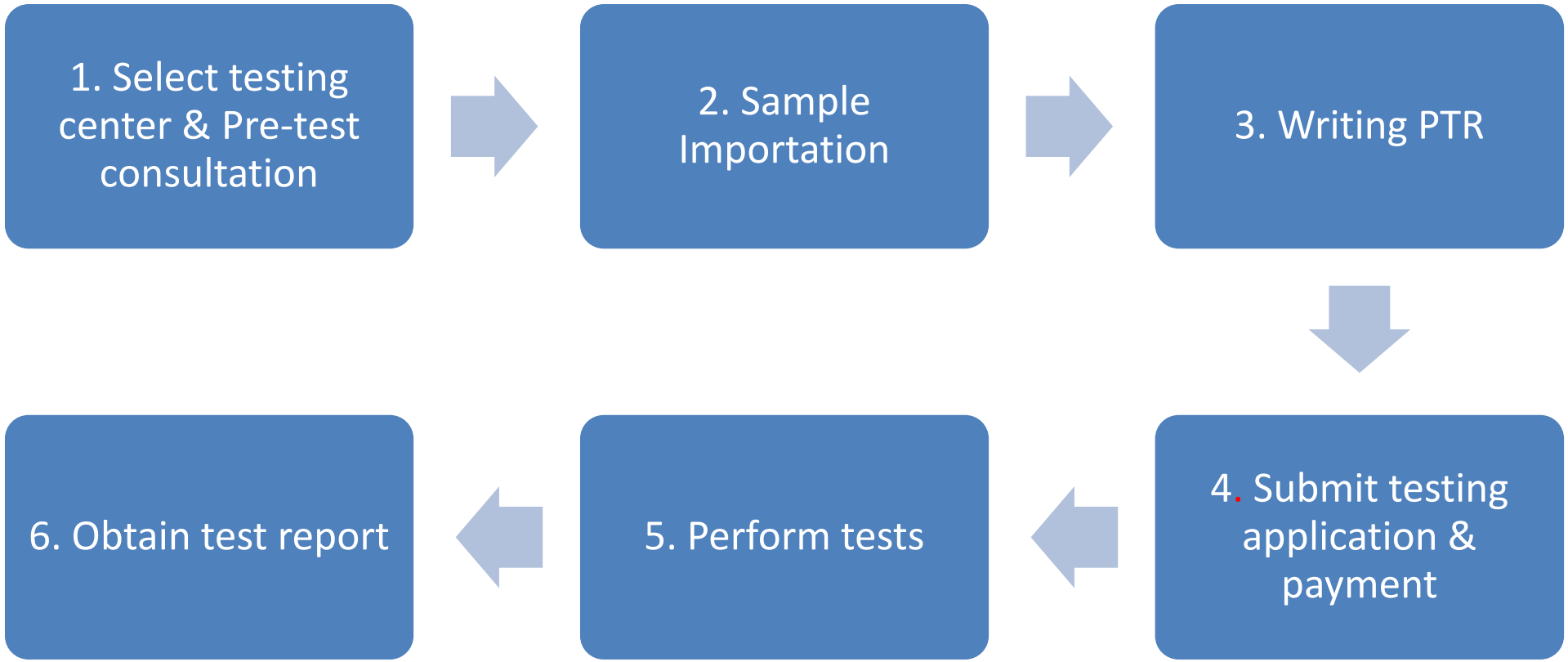
Type Testing & Standards Revision Plan

China Med Device
Life Science Bridge

Unprecedented number of IVD standards revisions 12/18/2018

1. Immunohistochemical reagent
2. IVD testing systems – Performance evaluation methods – Part 1: Precision
3. IVD testing systems – Performance evaluation methods – Part 2
4. Sperm quality analyzer
5. Blood gas analyzers
6. Blood analyzer calibrator
7. Mass spectrometer – Part 2: Matrix-assisted laser desorption/ionization (MALDI) time-of-flight mass spectrometry
8. Fluorescence immunochromatography analyzer
9. Gram-negative bacterial lipopolysaccharide (bacterial endotoxin) assay kit
10. Hepatitis B virus e antibody detection kit (chemiluminescence immunoassay)
11. Amino acid and carnitine detection kit (tandem mass spectrometry)
12. Hereditary hearing loss gene detection kit

Type Testing Process



3. Writing PTR: Basic Requirements

NMPA PTR guidelines, No.9, 2014

- Prepare PTR in accordance with relevant national laws and regulations
- Use standard and general terms. Clearly define special terms in the terminology section.
- Write number performance indicators and test methods consistently
- Use standard words, figures, formulas, units, symbols, charts
- When refer to national standards, industry standards or Chinese Pharmacopoeia, include the specific code, year, and version

3. PTR Contents

NMPA PTR guidelines, No.9, 2014

Product Name

- Use Chinese product name; be consistent with the registration submission.

Product Model/Specifications and Description

- List model/specifications, description of each model

Performance Indicator

- Include functional, safety, and quality control indicators that can be objectively determined.
- No need to include evaluative contents (e.g. biocompatibility evaluation) during product design and development.
- Combine standards with product characteristics/intended use/quality control level
- DO NOT use “see annex” or “by supply contract”.

3. PTR Contents (continue)

NMPA PTR guidelines, No.9, 2014

Test Method

- Match with corresponding performance indicator
- First consider well-recognized standard methods
- Methods need to be repeatable and practical
- Use figures if needed
- Can be provided in annex if too much contents
- PTR code = registration certificate number; for products to be registered, leave the PTR code blank

3. PTR (Product Technical Requirements)

Process for Writing PTR:

- Applicant agency writes based on manufacturer previous tests and Chinese standards

Format requirement:

- NMPA has specific format requirements: Guidelines for Preparation of Medical Device PTR (No.9 of 2014)

Sources:

- National standards (GB), industry standards (YY+Others) or Chinese pharmacopoeia
- Registration review and registration technical guidance
- Design specification and product performance evaluation requirements
- Manufacturer process requirement
- Foreign standards can be used if there is no comparable Chinese standards

3. PTR (Product Technical Requirements)

Importance of PTR: test center report vs PTR annexed to final certificate

- registration dossier
- part of the original certificate packet
- mandatory for renewal registration, modification, and post-market inspection
- sales process required by hospitals

PTR as affix with approved certificate is reviewed and finalized by CMDE during submission review and approval period.

3. PTR and Standards

- Integrated in the entire product life cycle
- Product development process with the regulatory assessment
- Submission (PTR, CER)
- Post-market (recall)
- Amendment and extension registration