White Paper

ICH Guidelines in China: Where are we now?

November, 2021

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Tigermed Group

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In 2017, the Chinese National Medical Products Administration (NMPA) was welcomed as a new regulatory member of the ICH. Only a year later, in June 2018, China's health regulatory authority (National Medical Products Administration, NMPA) was elected to the ICH Management Committee, enabling the country to continue participating in international drug development and registration.

China has become the eighth regulatory member of the International Conference on Harmonization (ICH), committing to progressively reform its pharmaceutical regulatory bodies, industry, and research institutes to adhere to the internationally accepted ICH Guidelines.

Additionally, the NMPA plans to actively support the faster entry of foreign drugs into the Chinese market, as well as to aid the local pharmaceutical sector in its efforts to innovate and compete in the global marketplace.

NMPA Vision Regarding **ICH guidelines**

By translating and implementing ICH guidelines over the last few years, the NMPA has facilitated a positive change in China's drug regulatory system, resulting in innovation in China's drug review reform, promotion of China's domestic drug development innovation, and increased access for Chinese patients to critically needed drugs marketed abroad.

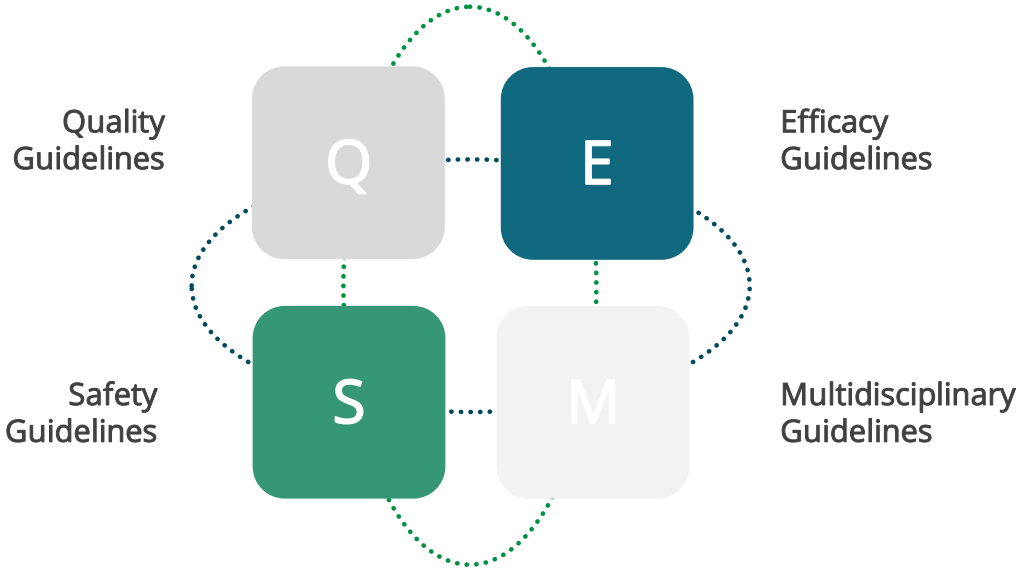
NMPA Objectives:

- ✓ The first is to confirm that its guidance/content complies with ICH standards.
- ✓ The second is to completely absorb the rules of developed regulatory bodies in Europe (EMA), the United States (FDA), and Japan (PMDA) to guarantee that China complies to international standards.
- ✓ The third objective is to amass and share China's experience-based expertise in preparation for future worldwide ICH harmonization.

What are the **ICH Safety Guidelines?**

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use developed the ICH Guidelines (ICH). ICH's mission is to establish consistent technical specifications for medications intended for human use and are created in collaboration with regulatory and pharmaceutical industry stakeholders.

The International Conference on Harmonization (ICH) has so far developed a thorough set of safety guidelines to help identify possible dangers including carcinogenicity, genotoxicity, and reprotoxicity. The ICH themes are classified into four groups, and ICH-topic codes are issued to each group:



No one is required to follow the ICH Guidelines by any means.
While this is true, the power of the ICH process resides in the willingness of ICH Regulatory Members to use suitable national/regional mechanisms to execute it.

Hard Work

According to the most recent statistics available, 69 NMPA experts participated in 1,026 expert working group teleconferences, or around 30 per month on average. Through the International Pharmaceutical Federation, the Chinese pharmaceutical sector has sent 17 specialists to the International Conference on Harmonization (ICH) to participate in the process.

China's authorities moved quickly to incorporate new concepts, methods, instruments, and regulatory standards following its admittance to the International Conference on Harmonization (ICH). Consider the following example: by the end of 2020, the Centers for Disease Control and Prevention will have implemented a comprehensive project management system that will include, among other features, a communication system, an accelerated evaluation and approval system, a therapeutic area team system, an expert consultation system, an information disclosure system, and approximately 200 guidelines. Source: DIA Global

Becoming An **ICH Regulatory Member**

To this end, it is the ambition and desire of all ICH Regulatory Members to apply all ICH Guidelines in their countries, with Tier 1 compliance being a requirement for admission to ICH and Tier 2 compliance expected within five years of membership.

China will have completely implemented all three ICH Tier 1 recommendations (ICH Q1, Q7, and E6) and three of the five ICH Tier 2 guidelines (ICH M4, E2A, and E2B) by May 2021, with the other two Tier 2 guidelines (ICH E2D and M1) scheduled to take effect on July 1, 2022. The NMPA spent considerable time studying and adhering to the ICH technical standards before being accepted as a member. In addition, the NMPA has recently referenced ICH regulations and principles in a number of its technical papers. As a result, the content and technical requirements of many of these policy papers are relatively comparable to those of the ICH standards.

The NMPA will continue to be an active participant in ICH activities in the subsequent phases. Additionally, it will motivate China to adopt and implement ICH technical suggestions.

Coordination & Monitoring

During the ICH process, ICH Regulatory Members and Observers approve harmonized ICH Guidelines in their respective nations and regions, made available to the public. According to the Articles of Association of the International Conference on Harmonization, ICH expects its Regulatory Members to follow all ICH Guidelines. Therefore, to become an ICH Regulatory Member, ICH Regulatory Observers must first conform to (certain) ICH Guidelines before obtaining Membership.

When practising the International Conference on Harmonization (ICH) Guidelines, national, local, and regional constraints apply. ICH Guidelines are applied in phases, with each step determining when a new member or observer is admitted to the organization.
The International Conference on Harmonization (ICH) emphasizes monitoring and coordinating worldwide harmonization activities. Therefore, the ICH is researching to understand better how the ICH Guidelines are implemented and adhered to in Regulatory Member and Observer countries and territories.

Implementation Status of ICH Guidelines in China

Tier 1 Completed:

- Q1: Stability Testing Guidelines
- Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- E6: Good Clinical Practice Guideline

Tier 2: Completed

- M4: Common technical document (CTD)
- E2A & A2B: Clinical Safety Data Management

Tier 2 Planned for July 1, 2022

- M1: MedDRA Terminology
- E2D: Post-Approval Safety Data Management

Tier 3

Tier 3 ICH Guidelines comprises all other remaining ICH Guidelines.

Prioritized Tier 3 Guidelines with regards to training needs are:
E2 (E2C(R2), E2E, E2F), E5, E17, M3(R2), M7(R1), M8, Q3 (Priority Q3C), Q5 (priority Q5E), Q6 (A & B), Q8-11 as a package, S6 (R1).
For the actual status of China's (and all other countries') ICH Guidelines implementation check out this page on the ICH official website.

Impact of China Implementing ICH Guidelines

After more than two decades of preparation, the International Conference on Harmonization (ICH) technical guidelines have gained widespread acceptance and adoption in major drug regulatory agencies.

The NMPA gained access to the most up-to-date regulatory, scientific results, and innovative regulatory concepts by joining the ICH. In addition, its membership will improve drug regulatory skills and standards over time through NMPA's participation in the development of worldwide guidelines under the International Conference on Harmonization (ICH).

Without a doubt, global pharma companies will be encouraged to integrate China into their entire drug research and development plan thanks to the NMPA joining ICH, subsequently speeding up the introduction of unique medicines for the Chinese market.

ICH Guidelines & Chinese GCP

Last year (July, 2020), the NMPA also implemented GCP (ICH E2) guidance:

- Good Safety Information Evaluation and Management Practice during Drug Clinical Trial
- Good Clinical Practice
- Good Management Practice for Development Safety Update Report
- Good Practice for Drug Clinical Trial Registration and Information Disclosure

It is another a positive sign that NMPA is actively and purposefully standardizing clinical trials conduct in China. In a next blog we will provide more insight into these available guidelines.

Advantages of China Implementing ICH Guidelines

A consensus on technical requirements, quality and good practices will dramatically save R&D and registration costs globally. Especially pharmaceutical companies that are involved in international procedures, cross-country drug registration including China, will be able to reach more patients.

From the perspective of international development, China's membership in the International Conference on Harmonization (ICH) and implementation of its principles will encourage the entry of novel medicines from outside China into the Chinese market, as well as the export of Chinese products to the rest of world.

By becoming a member of the International Conference on Harmonization (ICH) and implementing its standards in a timely manner, the Chinese pharmaceutical industry will increasingly be able to compete on an equal footing with the rest of the world.

Reference:

https://globalforum.diaglobal.org/issue/august-2021/china-focusing-innovation-through-ich-global-regulatory-vision/

For more information about Tigermed and other additional resources, please contact us: marketing@tigermedgrp.com, or visit www.tigermedgrp.com