



Report on Virtual ICH Incheon Meeting- ICH Assembly/MC Representative

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June 18, 2021

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ICH Management Committee elections

□ *Composition: ICH Articles of Associations Article 28:*

- No later than 1 January 2018, the Management Committee shall consist of up to **sixteen (16)** Permanent Management Committee Representatives and **twelve (12)** Elected Management Committee Representatives.
- The Regulatory Members shall be entitled to up to **eight (8)** Elected Management Committee Representatives in total representing up to **four (4)** Regulatory Members and the Industry Members entitled to up to **four (4)** Elected Management Committee Representatives in total representing up to **two (2)** Industry Members.
- The term of office of the Elected Management Committee Representatives shall be three (3) years.
- Elected Management Committee Representatives may be re-elected.

□ *Election: Rules of Procedure of the Assembly (Section 3.6.4)*

- The Assembly is responsible for the appointment of Elected Management Committee Representatives.
- The decision by the Assembly should be adopted by simple majority of the votes cast and by secret ballot.

ICH Management Committee elections

- **Eligibility Criteria for Elected Management Committee Representatives from Regulatory Members**
 - ✓ Regular participation in all ICH meetings during the previous four (4) years;
 - ✓ Have appointed experts that have participated in at least two (2) Working;
 - ✓ **Starting in 2018:** full implementation of at least 1 of the Tier 2 guidelines, and adequate implementation of other Tier 2 guidelines by 2023; documented implementation of at least 12 (25%) of the Tier 3 guidelines. **Starting in 2021:** Confirmed adequate implementation of at least 3 of the Tier 2 guidelines, and adequate implementation of the remaining Tier 2 guidelines by 2023; adequate implementation of at least 50% of the Tier 3 guidelines.
 - ✓ MC assessment of eligibility related to an applicant's record of adequate implementation will be confirmed by the assessment of an independent third party (CIRS).
- **Regulatory Member Applicants for the 2021 MC elections:**
NMPA, China; ANVISA, Brazil; and MFDS, Republic of Korea
- **MC assessment of eligibility:** Eligible.

ICH Management Committee elections

- **Eligibility Criteria for Elected Management Committee Representatives from Industry Members**
 - ✓ Have participated in Assembly meetings during the previous four (4) years, or to have been an Interested Party prior to the establishment of the Association, and have appointed experts that have participated in the Working Groups during the previous four (4) years.
 - ✓ The organisation and/or its members are regulated or affected by the majority of the ICH Guidelines.
- **Industry Member Applicants for the 2021 MC elections:**
BIO, Global Self-Care Federation, and IGBA
- **MC assessment of eligibility:** Eligible.

ICH Management Committee Elections

- **Before the MC Elections:**

MC Elected Regulatory Members:

ANVISA, Brazil

NMPA, China

HSA, Singapore

MFDS, Republic of Korea

MC Elected Industry Member:

BIO

IGBA

- **After the MC Elections:**

MC Elected Regulatory Members:

ANVISA, Brazil

NMPA, China

MFDS, Republic of Korea

MC Elected Industry Member:

BIO

IGBA

Amendments to ICH Procedural Matters

- ICH Articles & Procedures: **ICH Articles of Association, Assembly Rules of Procedure, Management Committee Rules of Procedure, MedDRA Management Committee Rules of Procedure, and Standards Operating Procedures of the ICH Working Groups.**
- Usually amended twice a year, as needed.
- Recent amendments focus on maintenance of confidentiality, additional participants at meetings/teleconferences, use of the ICH logo, and ICH budget cycle, etc.

ICH Training Progress

- During the Assembly Meeting, the Assembly members were updated on ICH training related activities, including work with ICH's two Training Associates to develop online training materials on ICH Q1 Stability Guidelines, ICH M4 Common Technical Document Guidelines, and ICH E2 Pharmacovigilance Guidelines. The Assembly additionally welcomed finalisation of training modules on the ICH Q12 Guideline on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management, which aim to provide a comprehensive training programme to facilitate an aligned interpretation and a harmonised implementation of ICH Q12 globally.

NMPA's Implementation of ICH Guidelines

- Participating in harmonization of ICH topics;
- Developing the timetable and roadmap for implementation;
- Translating original ICH English guidelines and forming official Chinese translations;
- Publishing announcements on the adoption of ICH guidelines; together with Chinese translations, to achieve adequate implementation.

NMPA's Implementation of ICH Guidelines

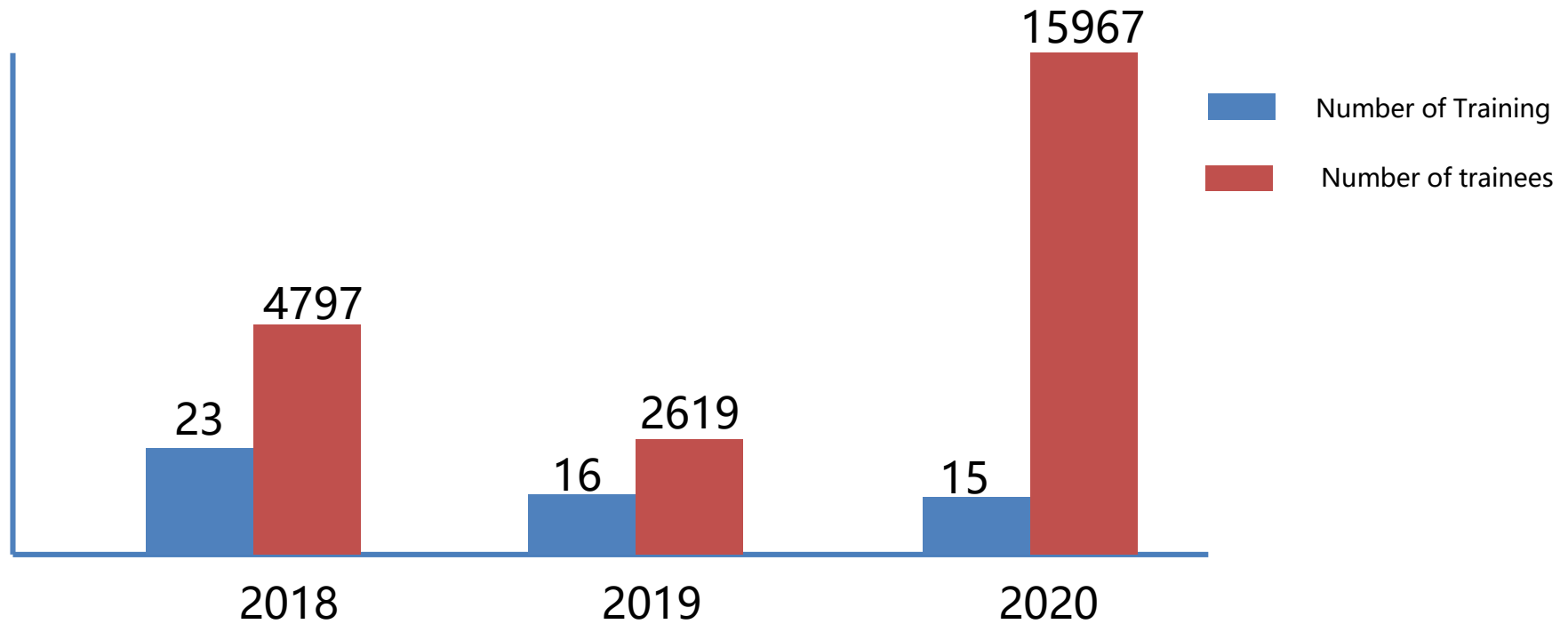
- Adherence: In its practice, the regulatory authority consistently adherences to (applies) all identified relevant elements, concepts and principles of the ICH guidelines over time (**ICH Definition**).
- There were 57 finalized ICH guidelines before NMPA joined ICH in 2017, and there are 10 new/revised ones after that. How to adhere during the implementation of ICH guidelines and how to assess adherence are a very complex topic, and the assessment should be made on a case-by-case basis. It is necessary to enhance the exchanges among regulatory authorities and between regulatory authorities and the industry, which is a complementary process. Looking forward, it is necessary to establish unified standards, and reach consensus with the industry.

NMPA's Training Activities

- NMPA has conducted training on 47 ICH guidelines in the past 3 years.

Tier 1 guidelines (3)			
Q1, Q7 and E6(R2)			
Tier 2 guidelines (5)			
Training of E2A, E2B, E2D, M1 and M4 in face to face or in virtual format			
Tier 3 guidelines (39)			
Q (14)	E (14)	S (6)	M (5)
Q3D(R2) , Q4B, Q5A(R1) , Q5B, Q5C, Q5D, Q5E, Q6A, Q6B, Q8, Q9, Q10, Q11, Q12	E1, E2E, E2F, E3, E4, E5, E8, E8(R1) , E9, E9(R1), E10, E11(R1), E15, E17	S1, S2, S5, S6(R2), S9, S11	M2, M3(R2), M8, M9, M10

NMPA's Training Activities



NMPA's Training Activities

Looking forward, NMPA's training will be focused on small-scale, in-depth and targeted training sessions, which will be involved by other regulatory authorities and the industry.



Thank you for your attention!