The International Council for Harmonisation (ICH): An Overview

November 2025

Legal Notice

ICH 35th Anniversary 10 years as an Association

ICH = International Council for Harmonisation
of Technical Requirements for Pharmaceuticals for Human Use

- Unique harmonisation initiative, bringing **regulators** and the **pharmaceutical industry** together to discuss the **scientific and technical aspects of pharmaceuticals** and develop **standardized technical guidelines**.
- Originally founded in 1990
- Restructured as a non-profit legal entity under Swiss Law on 23 October 2015

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Purpose of ICH

ICH Guidelines ensure that medicines are safe, effective, and high-quality from development through manufacture and use.

Promotion of public health through **international harmonisation** contributes to:

- Prevention of unnecessary duplication of clinical trials and post-market clinical evaluations.
- Development and manufacturing of new medicines.
- Registration and supervision of new medicines.
- Reduction of unnecessary animal testing without compromising safety or effectiveness.

This is accomplished through **Technical Guidelines** that are implemented by the regulatory authorities.

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ICH Members *(as of November 2025)*

25 Members

Founding Regulatory Members

1. EC, Europe
2. FDA, United States
3. MHLW/PMDA, Japan

Founding Industry Members

4. EFPIA
5. JPMA
6. PhRMA

Standing Regulatory Members

7. Health Canada, Canada
8. Swissmedic, Switzerland

Regulatory Members

9. ANMAT, Argentina
10. ANVISA, Brazil
11. COFEPRIS, Mexico
12. EDA, Egypt

Regulatory Members continued

13. HSA, Singapore
14. JFDA, Jordan
15. MFDS, Republic of Korea
16. MHRA, UK
17. NAFDAC, Nigeria
18. NMPA, China
19. SAHPRA, South Africa
20. SFDA, Saudi Arabia
21. TFDA, Chinese Taipei
22. TITCK, Turkey

Industry Members

23. BIO
24. Global Self-Care Federation
25. IGBA

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ICH Observers *(as of November 2025)*

41 Observers

Standing Observers

1. IFPMA
2. WHO

Legislative or Administrative Authorities

3. AEC, Azerbaijan
4. ANPP, Algeria
5. CDSCO, India
6. CECMED, Cuba
7. CPED, Israel
8. CPPS, Uzbekistan
9. DIGEMAPS, Dominican Republic
10. DIGEMAPS, Peru
11. DINAVISA, Paraguay
12. DPM, Tunisia
13. Indonesian FDA, Indonesia
14. INVIMA, Colombia
15. MMDA, Moldova
16. MOH, Kuwait
17. MOPH, Lebanon

Legislative or Administrative Authorities continued

18. National Center, Kazakhstan
19. NPRA, Malaysia
20. NRA, Iran
21. Philippine FDA, Philippines
22. PPBHK, Hong Kong, China
23. Roszdravnadzor, Russia
24. SCDMTE, Armenia
25. SECMOH, Ukraine
26. SRS, El Salvador
27. TGA, Australia
28. Thai FDA, Thailand

Regional Harmonisation Initiatives

29. APEC
30. ASEAN
31. EAC
32. GHC
33. PANDRH
34. SADC

International Pharmaceutical Industry Organisation

35. APIC

International Organisations regulated or affected by ICH Guidelines

36. Gates Foundation
37. CIOMS
38. EDQM
39. IPEC
40. PIC/S
41. USP

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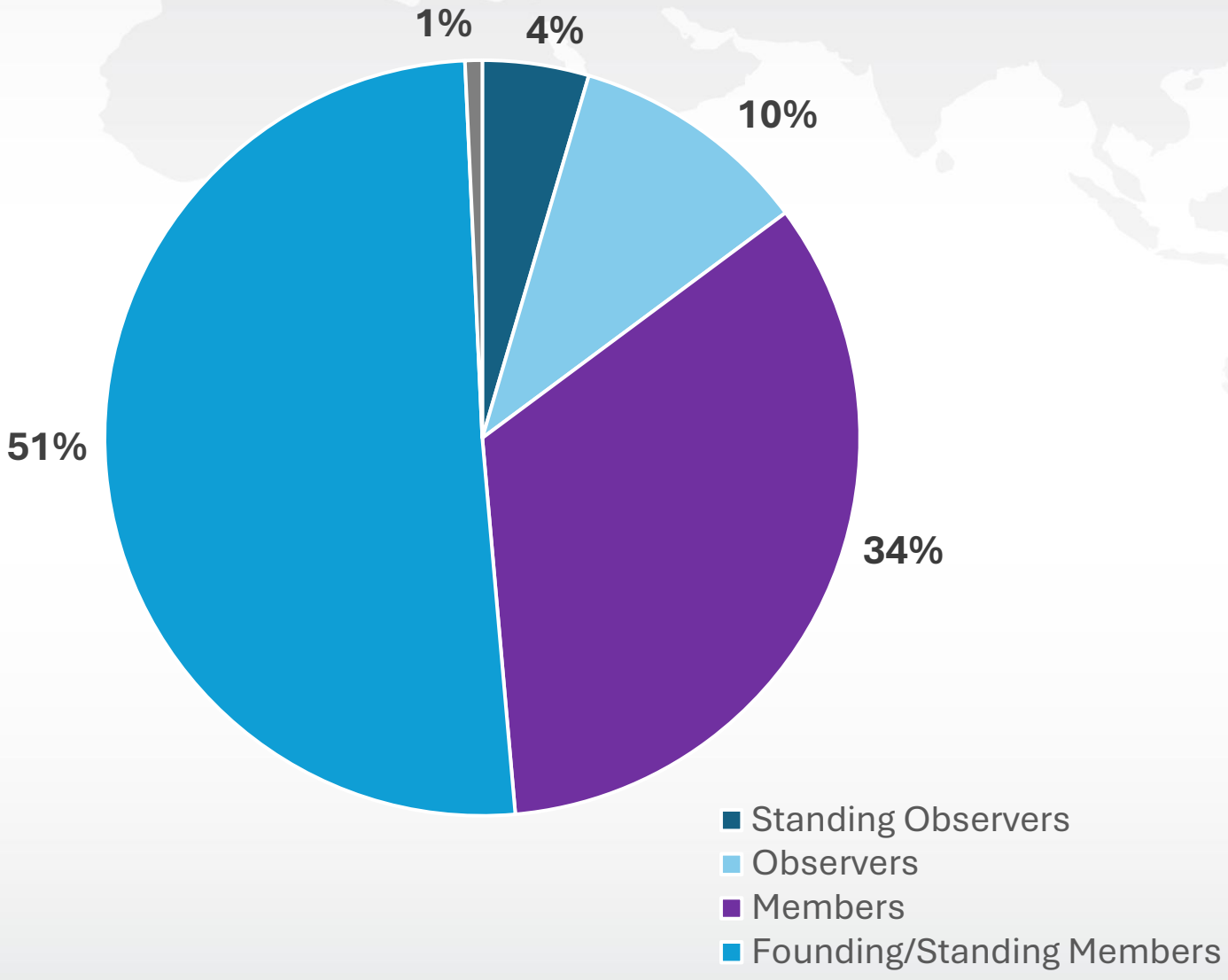
ICH also has a network of 681 experts in 21 Working Groups



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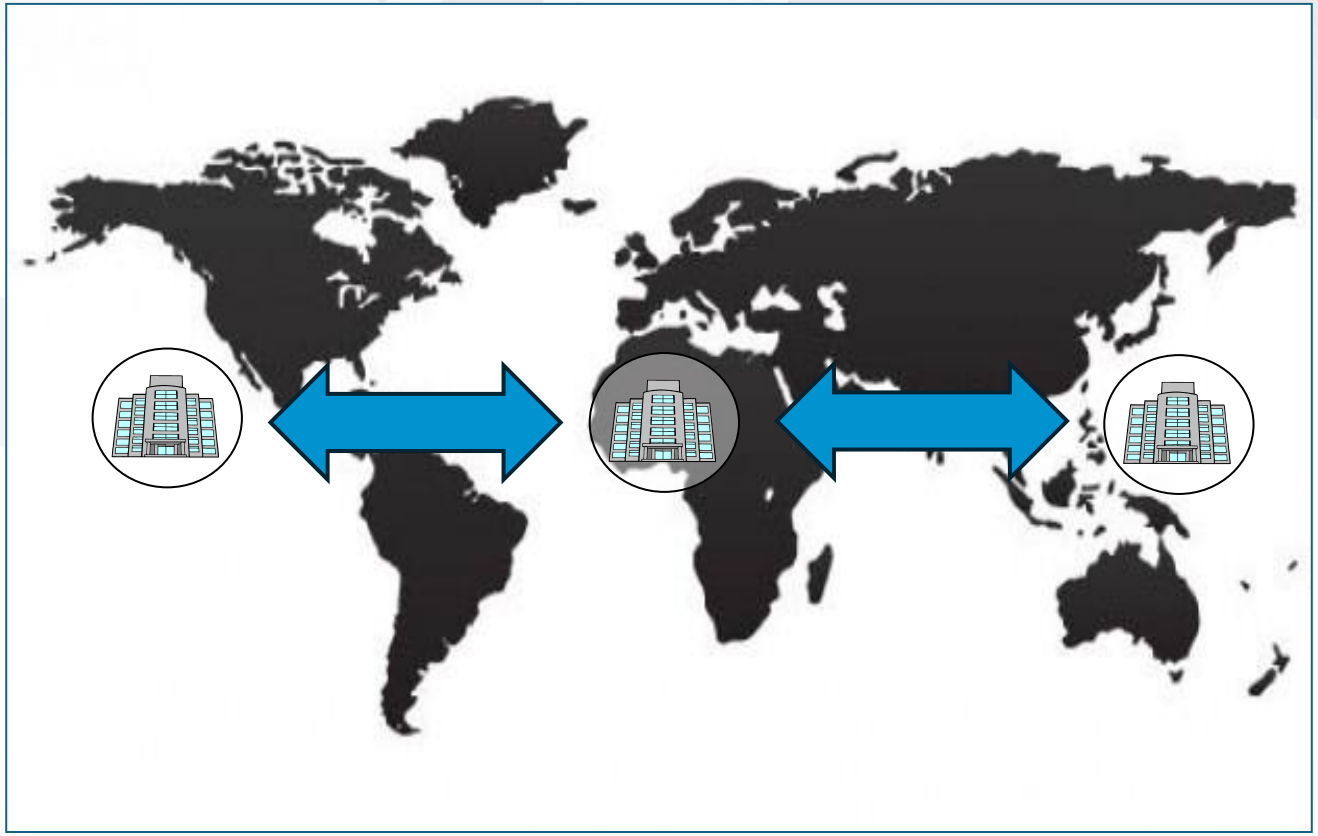
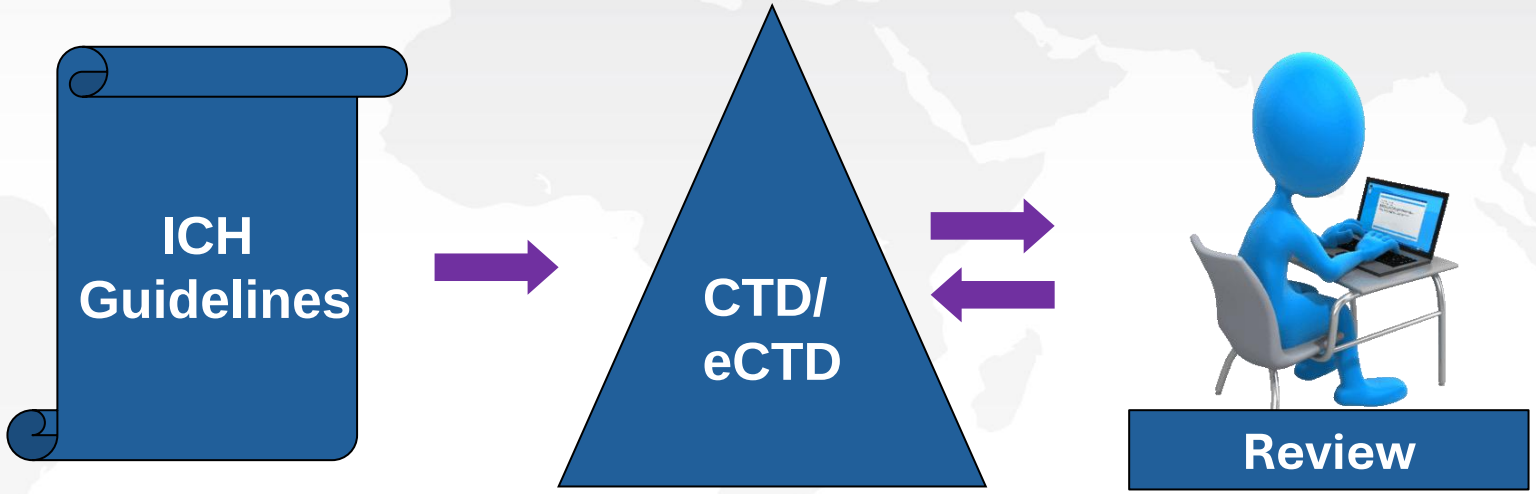
ICH Successes – Good Clinical Practice



Clinical trials conducted in one ICH region can be used in other ICH regions by setting common standards on science and ethics.

Read more at: https://ich.org/page/efficacy-guidelines *(see ICH Guideline E6)*

ICH Successes – (electronic) Common Technical Document



The CTD brings together all Quality, Safety and Efficacy information in a common, harmonised format, accepted by regulators in all ICH regions. It has revolutionised regulatory review processes for regulators and industry.

Read more at: https://ich.org/page/ctd

ICH Successes – MedDRA (Medical Dictionary for Regulatory Activities)

- Highly specific, standardised **medical terminology** developed by ICH to facilitate sharing of regulatory information.
- Used for **registration, documentation, and safety monitoring of medical products** both before and after marketing authorisation.

Read more at: https://ich.org/page/meddra and https://www.meddra.org/

ICH Products *(as of November 2025)*

- **78 Guidelines on technical requirements covering:**
  - **Quality** – **26** Guidelines
  - **Safety** – **16** Guidelines
  - **Efficacy** – **24** Guidelines
  - **Multidisciplinary** – **12** Guidelines
- **Electronic Standards for the Transfer of Regulatory Information (ESTRI)**
- **CTD/eCTD**
- **MedDRA** (standardised medical terminology)

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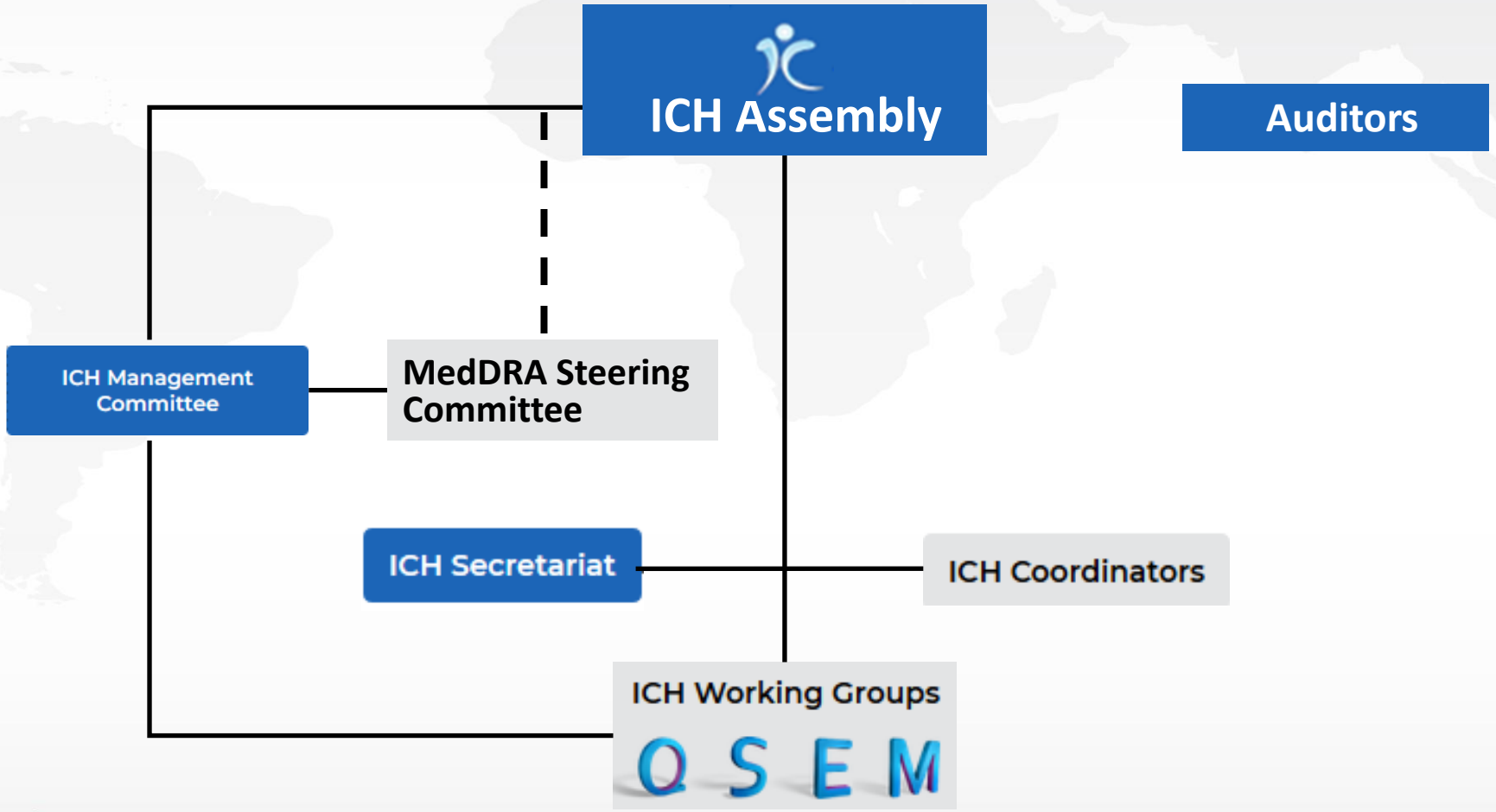
Structure of the ICH Association



Read more at: https://www.ich.org/page/organisation-ich

Remit of the Assembly and the Management Committee

- **Assembly**

  The **overarching body** of the Association that makes decisions regarding the Articles of Association and its Rules of Procedures, admission of new Members, election of Management Committee representatives, annual work plan, **adoption of ICH Guidelines**, approval of budget, etc.

- **Management Committee**

  The body that **oversees operational aspects** on behalf of all Members of the Association, including **administrative and financial matters** and oversight of Working Group operations.

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Decision-making on ICH Guidelines

- The **Management Committee** provides:
  - Recommendations on the selection of new topics for harmonisation and on the adoption, withdrawal or amendment of ICH Guidelines.
- The **Assembly** takes decisions:
  - By consensus.
  - In the absence of consensus: vote in accordance with the Articles of Association, where **only regulatory members have the right to vote**.

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Membership in the Assembly— Eligibility Criteria for Regulators

- **Engagement in the ICH Process**
  - Regular attendance in at least **three ICH meetings** during the **previous two consecutive years**.
  - Past appointment of experts in at least **two Working Groups**.
- **Application of ICH Guidelines**
  - Having implemented at least the **Tier 1 ICH Guidelines** upon application for Membership:
    - Q1: *Stability Testing Guidelines*
    - Q7: *Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*
    - E6: *Good Clinical Practice Guideline*

… An **Expedited Membership Procedure** is also possible for those with a strong proven record of ICH Guidelines Implementation.

Read more at: https://www.ich.org/page/application-process

Membership in the Assembly— Eligibility Criteria for Industry

- **Type of organisation**
  - International pharmaceutical industry organisation.
- **Engagement in the ICH Process**
  - Past regular attendance in ICH meetings.
  - Past appointment of experts in WGs.
- **Impact of ICH Guidelines**
  - The organisation and/or its members must be regulated or affected by ICH Guidelines.

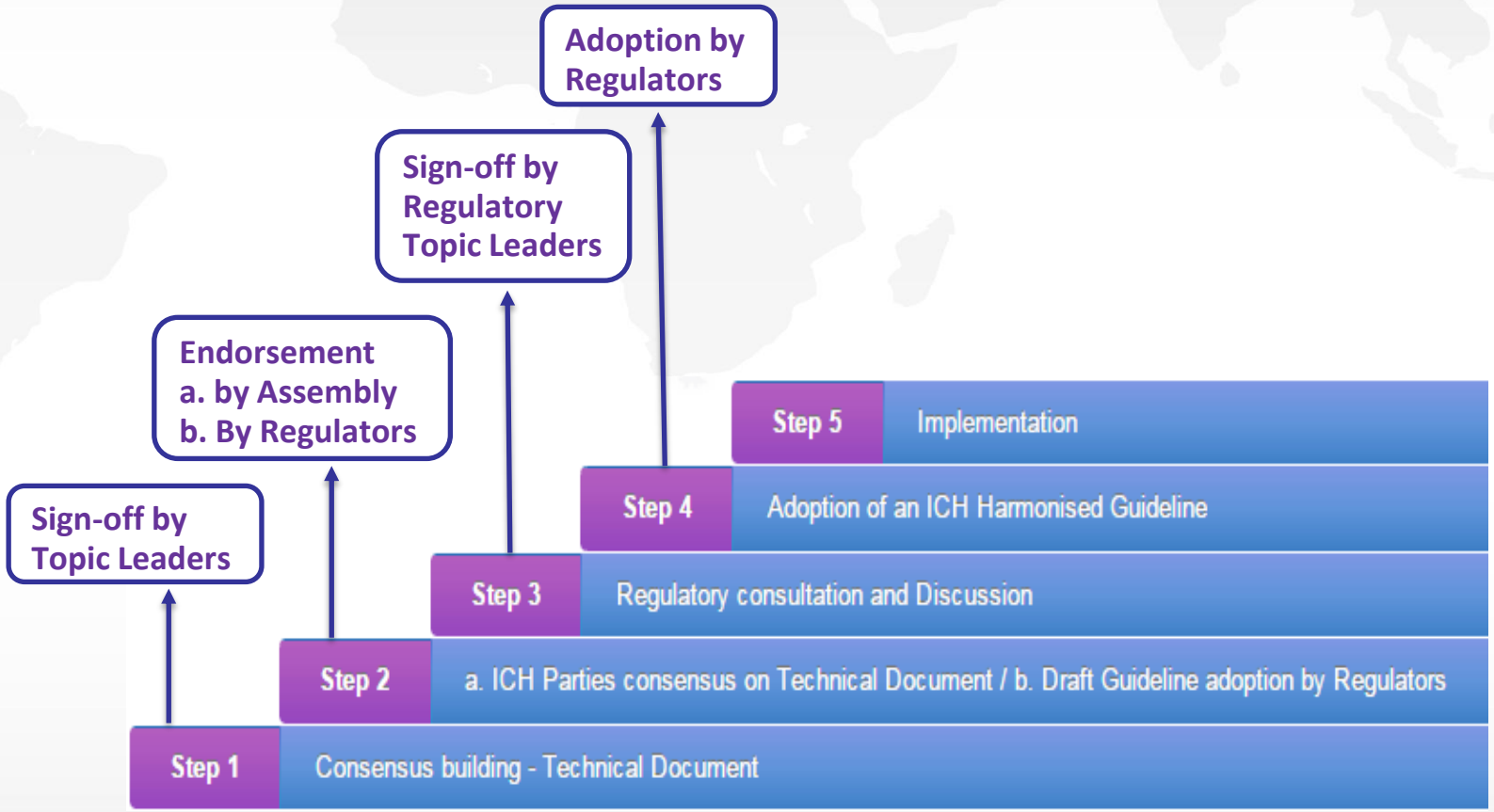
Read more at: https://www.ich.org/page/application-process

ICH Observers

- Limited eligibility criteria for new Observers.
- Rights of Observers:
  - To attend ICH Assembly meetings, but no right to vote or automatically appoint experts in Working Groups.
  - Standing Observers (WHO and IFPMA) maintain their right to appoint experts in Working Groups.
- No duties are imposed on Observers.

Read more at: https://www.ich.org/page/application-process

Steps in the ICH Process for Guideline Development



Read more at: https://www.ich.org/page/formal-ich-procedure

The ICH Step Process *(1)*

- ***Step 1:***
  - *The WG works to prepare a consensus draft of the technical document.*
- ***Step2:***
  - ✓ ***Step 2a:***
    - *The Members of the ICH Assembly are invited to endorse the technical document.*
  - ✓ ***Step 2b*:**
    - *The Regulatory Members of the ICH Assembly are invited to endorse the draft Guideline.*

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The ICH Step Process (2)

- ***Step 3:***
  - *Public consultation by the ICH Regulatory Members and ICH Secretariat. All comments are considered by the WG.*
  - *Step 3 is finalised once consensus is reached by the regulatory experts of the WG.*
- ***Step 4:***
  - *The Regulatory Members of the ICH Assembly adopt the final ICH harmonised Guideline.*
- ***Step 5:***
  - *Implementation by the ICH Regulatory Members.*

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Keys to ICH Success

- Involves expertise from both regulatory authorities and regulated industry
- Science-based, consensus-driven
- Clear and effectively managed process
- Close collaboration of parties with comparable regulatory and technical capability
- Commitment of regulators to implement products of harmonisation
- Common global platform and tools
- Revised processes and governance

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Summary

- ICH has achieved international harmonisation of technical guidelines, with engagement of regulators and industry.
- ICH has clear governance and increasingly global membership following ICH reform.
- Five transparent steps in the ICH process for Guideline development.

Thank you

www.linkedin.com/company/ICH-association

ich.org