29 June 2022

1. How and why ICH was created and which is its mission nowadays?

ICH was created as there was an identified potential to harmonise technical requirements in respect of pharmaceutical development on a more global scale (EU, Japan and the US), based on some experience on pharmaceutical harmonisation in the EU (at the time the European Community). In the early 90's, the divergent regional requirements for drug development created inefficiencies, redundancies and conflicting requirements and this was at a time when the pharmaceutical industry was becoming more international. However, not even the founding fathers of ICH expected that ICH would take off so rapidly and develop into a permanent international organisation.
ICH's mission today remains the same as it was from the outset i.e. to achieve greater harmonisation worldwide to ensure that safe, effective and high quality medicines are developed, and registered and maintained in the most resource efficient manner whilst meeting high standards. For more information, see the section on the history of ICH on the website: https://www.ich.org/page/history

2. Which are the difference between members and observers?

The main difference is that members have voting rights whereas observers do not. Members also have the possibility to be elected to the ICH Management Committee whereas observers do not. In addition, Members have the right to appoint experts to Working Groups (that are developing guidelines), with some exceptions, whereas observers can request to appoint experts. The rights and obligations of ICH members and observers are provided in the Articles of Associaiton: https://www.ich.org/page/articles-procedures
For general information on the value of membership, see: https://www.ich.org/page/value-membership

3. How there is an essential need to bring together the regulatory authorities and pharmaceutical industry in terms of production guidelines?

The value of having experts from both regulators and industry involved in the guideline development has been recognised in ICH from the outset. The ICH guidelines are scientific and technical and during the development stage of the guidelines (i.e. whilst developing the technical document), having access to the technical and scientific expertise from industry has been useful. The decisions on the adoption of the draft guidelines (Step 2b) and the final guidelines (Step 4) is taken by the ICH regulatory members only in the ICH Assembly.

4. A definition of Good manufacturing practices;
5. Which are the main challenges in harmonizing GMPs practices between developed countries and the more developed ones;
6. How is ICH trying to reduce those gaps between countries;

ICH Quality guidelines address various aspects of pharmaceutical quality. Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management. For more information see: https://www.ich.org/page/quality-guidelines

In addition to its work to develop guidelines, to support regulatory authorities newly adopting ICH guidelines, ICH supports the development and delivery of training on the harmonized guidelines including those addressing Quality topics. For more information see: https://www.ich.org/page/training

7. Did covid-19 show trade-offs between the need for regulatory flexibility in the requirements for manufacturing and controls to enable rapid availability of large volumes of vaccines vs the increased stringency and the lack of harmonization in the regulatory environment for vaccines globally
8. Soberana is a Cuban anti covid vaccine, the only one authorized (for now) for children between two and five years old. Soberana is a product that could be interesting as well for our European market, but there is a difference in GMPs standards. How could those differences be treated, if it's possible?
9. Are conjugate vaccines (like the Cuban Soberana) requiring significantly updated GMPs standard that the Cuban production coud not meet?
10. For the Cuban anti-covid products could exist the possibility of recognition of existing GMP inspections for waiving the need for each country inspection

ICH has continued its work on the harmonization of technical standards throughout the period of the COVID-19 pandemic, however COVID-19 pandemic response activities, including related to COVID vaccines or therapeutics, remain outside the scope of ICH work. It is suggested that questions related to COVID-19 pandemic response and vaccines be referred to organizations engaged in such activity, such as the WHO.

11. Is mounting pressure for harmonization coinciding with rising cost for pharmaceutical research and development ("R&D")? Are some GMPs standards -in a way-so high that they are not guaranteeing drug access to all citizens of the world because they depend too much on economic capabilities in terms of acquiring new and expensive technologies?

On the contrary, the growing interest in harmonization is driven by the desire to reduce costs for research, development and manufacturing while ensuring access to the safe, effective, quality medicines that patients around the world expect and deserve.

12. Which relations ICH has with CECMED?

CECMED, Cuba is an Observer in ICH and thus has the right to participate in the ICH Assembly meetings and can request to appoint experts to the ICH Working Groups that are developing guidelines. Observers can also propose topics for harmonisation during the ICH yearly process on topic selection.

13. Are there any significance differences between WHO GMPs standards and ICH ones?

The WHO, currently a Standing Observer in ICH, has been an active participant in ICH since its early years including in the expert working groups. ICH is not aware of any significant differences in GMP standards.

14. Is it possible that the presence of industry in ICH could guide choices, in terms of GMPs, capable of limiting access to drugs in less developed countries?

ICH is harmonising technical and scientific requirements through developing ICH guidelines, which are referred to as international standards. ICH guidelines are adopted by the regulatory members of the ICH Assembly thus giving the regulators the final say. ICH today comprises 20 Members and 35 Observers, most of whom are regulatory authorities including from less developed countries, and

industry is usually very interested in increasing the uptake of ICH guidelines globally as it facilitates access to more markets.

15. Which measures ICH put in place to guarantee transparency about industry funding and presence?

Following the reform of ICH in 2015 (establishing ICH as a non-profit association under Swiss law), clear rules and procedures have been put in place to improve the transparency of the decision-making and a sustainable funding model based on membership fees. The main decision-making body is the ICH Assembly where the Members take important decisions, such as on the budget of ICH (as mentioned above, the majority of the members and observers are regulatory authorities).
In line with ICH's Articles of Association, the amount of membership fees should be fair, proportionate and transparent, with Members in the same membership category to be treated equally. Although the rights of ICH's different Members are similar, the Assembly has agreed to set fees for the category of new Regulatory Member and new Industry Member at an amount which ensures ICH is accessible. The need to revise membership fees is assessed periodically in view of the budget situation and the number of ICH Members. For more information about funding see: https://www.ich.org/page/funding
For more information about ICH governance and operations see: https://www.ich.org/page/articles-procedures