

ICH Press Release

ICH Assembly Meeting, Prague, Czech Republic, October/November 2023

Excellent Progress made on ICH Harmonisation Activities

Geneva, 8 November 2023

The Assembly of the International Council for Harmonisation (ICH) met in-person on 31 October & 1 November 2023, in Prague, Czech Republic in parallel of meetings of 16 Working Groups, and preceded by meetings of the ICH Management Committee and the MedDRA Management Committee.

The ICH continues to expand and welcomed PPBHK, Hong Kong, China as a new ICH Observer, bringing ICH to a total of 21 Members and 37 Observers.

Elections

The Assembly, Management Committee and MedDRA Management Committee Chair and Vice-Chair elections were held during the meeting which saw the following appointments:

- Ms. Lenita Lindström (EC, Europe) and Dr. Gabriela Zenhausern (Swissmedic, Switzerland) were re-elected as Assembly Chair and Vice-Chair respectively to serve a two-year term;
- Dr. Theresa Mullin (FDA, United States) and Mr. Naoyuki Yasuda (MHLW/PMDA, Japan) were re-elected as Management Committee Chair and Vice Chair respectively to serve a two-year term;
- Dr. Barbee Whitaker (FDA, United States) and Dr. Craig Simon (Health Canada, Canada) were elected as MedDRA Management Committee Chair and Vice-Chair to serve respectively for a two-year and one-year term.

Progress on ICH Guideline Development and Important Revisions

- ICH Q5A(R2) Revised Guideline on “Viral Safety Evaluation of Biotechnology Products Derived from Cell lines of Human or Animal Origin” reached *Step 4* and was adopted by the ICH Assembly Regulatory Members. The revision retains key principles of the original Guideline and provides additional recommendations on the established and complementary approaches to control the potential viral contamination of biotechnology products.
- ICH Q2(R2) Revised Guideline on “Validation of Analytical Procedures” and new Q14 Guideline on “Analytical Procedure Development” which were developed in parallel by the Q2(R2)/Q14 EWG reached *Step 4* and were adopted by the ICH Assembly Regulatory Members. The scope of the revision of ICH Q2(R1) includes validation principles that cover analytical use of spectroscopic or spectrometry data (e.g., NIR, Raman, NMR or MS) some of which often require multivariate statistical analyses. While Q14 provides principles relating to the description of analytical procedure development process. This new guideline is intended to improve regulatory communication between industry and regulators and facilitate more efficient, sound scientific and risk-based approval as well as post-approval change management of analytical procedures. Following the adoption of the ICH Q2(R2)/Q14 Guidelines under *Step 4*, the EWG will transition to an IWG allowing the development of training materials.

New Implementation survey

Following on from the successful 2021 ICH-driven independent third-party survey conducted to understand the level of implementation and adherence to ICH Guidelines by Regulatory Members and Observers, the Assembly was updated on the upcoming launch of the next survey in December 2023, with the main objective of informing the ICH Management Committee elections in June 2024 and identifying training and capacity building needs.

Collaboration with PIC/S

The ICH Assembly welcomed the signature of a Memorandum of Understanding (MoU) between ICH and PIC/S (Pharmaceutical Inspection Co-operation Scheme) in October 2023. Both parties are engaged in pharmaceutical harmonisation activities, PIC/S being an Observer in ICH since 2017 and many regulatory members in ICH are also “participating authorities” in PIC/S. This MoU is intended to facilitate collaboration on a number of ICH Guidelines that are relevant also for inspectorate activities and provide training for both assessors and inspectors.

MedDRA

Having gained over 600 new subscribers since the start of the year, the MedDRA user community, in 138 countries, is growing. Accordingly, work is ongoing to support MedDRA’s global reach through MedDRA training opportunities, which in 2023 saw in-person events resume globally, and a higher number of classes conducted in countries such as Brazil and China. In view of this continued vigorous growth in subscribers, ICH is pleased to announce a 10% decrease in 2024 MedDRA MSSO subscription rates across all levels, with an additional redefining of the subscription levels which will allow a number of Level 3 subscribers to now obtain a Level 2 subscription.

With the goal of ensuring MedDRA’s continued responsiveness to the needs of global MedDRA users, MedDRA is now available in 20 languages, with the release of Arabic in January and Estonian in September 2023. Coordination with other international organisations also continues, particularly on targeted mappings with MedDRA, helping to increase the availability of MedDRA-coded data for analysis purposes, for the benefit of patient safety.

Training

The Assembly was updated on ICH training related activities, including the recent publication on the ICH website of the ICH Q9(R1) “Quality Risk Management” Training Materials developed by ICH Q9(R1) IWG. Plans were also noted for further enhancement of the work with ICH Training Associates, accredited non-profit training organisations, to assist ICH Working Groups in their efforts to develop training materials. Over the next few years, the Training Associates will develop online training materials for the ICH E6(R3), E8(R1), E17, Q3, Q5 and ICH Q8 to Q12 series of Guidelines, with additional materials to be confirmed.

ICH Award

At its meeting, the ICH Assembly gave for the second time the ICH Award for Outstanding Contribution to ICH Harmonisation for Better Health, with recipients of the 2023 award recognised for their significant and sustained contributions in ICH leadership roles in ICH Working Groups. The names of the awardees will be published on the ICH website.

Communication

The next ICH Assembly meeting is planned on 4 and 5 June 2024 in Fukuoka, Japan.

NOTES FOR EDITORS

This press release, together with more information on the ICH Guidelines mentioned above and the work of ICH, can be found on its website: www.ich.org

For further information, please contact the ICH Secretariat at pressrelease@ich.org

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