Remit of the Informal Quality Discussion Group

22 October 2018

Endorsed by the ICH Management Committee on 13 November 2018

General Description

The Informal Quality Discussion Group (IQDG) will serve as a technical discussion forum for issues relevant to the ICH Quality Vision to "develop a harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science" as described in the ICH Quality Reflection Paper on Advancing Biopharmaceutical Quality Standards to Support Continual Improvement and Innovation in Manufacturing Technologies and Approaches.

The IQDG will operate in line with the applicable ICH procedures, similar to other ICH Technical/Discussion Groups, under the oversight of the ICH MC, and with reporting to the ICH Assembly. As the remit of ICH is to harmonise technical standards, the IQDG should in its work remain focused on technical and scientific aspects and ensure that ICH guidelines are kept up-to-date with the evolution of science, whilst not striving to drive policy choices for regulations as this falls under the remit of the regulatory authorities in different jurisdictions.

Scope of Activities

The Informal Quality Discussion Group will:

- Review the need for new ICH Quality-related harmonization work.
    - In this regard, upon requests from the New Topic SubCommittee, the IQDG will discuss and recommend approaches to advance new ICH Quality topic proposals through the development of ICH guidelines (e.g., new guideline vs. Q&A vs. revision to an existing guideline, etc.) and the logical sequencing of new ICH Quality topics to efficiently achieve harmonization and the ICH Quality Vision. Any new topic proposal recommended by the IQDG would need to be submitted through the ICH annual new topic process, per the applicable Rules of Procedure and Standard Operating Procedures.
    - In support of reviewing the need for new ICH Quality-related harmonization work, the IQDG will review all existing ICH Quality (and relevant Multidisciplinary) Guidelines with the goal of identifying and recommending those that need updating. In addition, this activity should include developing and maintaining a priority list all Quality-related (and relevant Multidisciplinary) harmonization work that is to be sequenced, including existing Guidelines subject to updating and new topics proposals, for review by the ICH Management Committee in order to facilite efficient planning and deployment of experts across several related ICH EWGs.
- Review and recommend training needs related to the content and/or implementation of ICH Quality guidelines. Training needs might additionally be based on feedback data collected through periodic surveys and interactions with the ICH Training Subcommittee on how effectively and consistently ICH Quality-related guidelines are being interpreted and applied across various ICH regions.

- Review and recommend any necessary updates to the ICH Quality Reflection Paper and ICH Quality Vision statement as needed. Any approved updates should also be reflected in the priority list of all Quality-related harmonization work to be maintained by the IQDG, as appropriate.

Type of Expertise Needed and Resources

The IQDG should be comprised of a diverse group of strategically-oriented experts that collectively have extensive knowledge of the scientific and regulatory aspects of all the ICH Quality Guidelines and others under development. Expertise should be balanced across a number of scientific (e.g., pharmaceutical sciences, process analytical technologies, quality manufacturing systems, and modelling, etc.) and regulatory (i.e., cGMP, CMC requirements and approval standards, etc.) aspects of the product-types subject to ICH Quality guidelines, including small and large molecules, and vaccines.

It is envisioned that the IQDG should be comprised of experts from Members and Observers of the ICH Assembly, in accordance with the applicable Articles of Association, Rules of Procedure, and Standard Operating Procedures. ICH Members and Observers participating in the IQDG should be allowed to nominate standing experts and alternate experts to enable an appropriate balance of expertise while keeping the size of the IQDG manageable, in accordance with the applicable Standard Operating Procedures.

Operating Model and Term

The IQDG should complete its activities in a virtual setting via email and teleconference. In exceptional cases, the ICH Management Committee may consider granting a face-to-face meeting of the IQDG during a biannual ICH Meeting upon approval of a specific work plan in line with current practice for other ICH Working Groups.

The leadership of the IQDG should be comprised of a Rapporteur and a Regulatory Chair, in accordance with the applicable Standard Operating Procedures.

The IQDG will operate within an initial 2-year term beginning on the date upon which the Remit of the IQDG is approved by the ICH Management Committee, further to the ICH Assembly approval of the ICH Quality Reflection Paper. The IQDG should provide an update of its activities and progress biannually to the ICH Management Committee and the ICH Assembly, in line with current practice for other ICH Working Groups. Further to the recommendation of the Management Committee, the ICH Assembly will consider whether to grant an extended term to the IQDG within 6 months of the end of the initial 2-year term.

In support of the IQDG Scope of Activities, the IQDG should specifically endeavour upon completing the following actions in its first calendar year:

- Assess the impact of ongoing ICH Quality Topics on future ICH Quality harmonization work envisioned under the ICH Quality Vision (i.e., the impact of ICH Q12 on other ongoing or newly proposed ICH Quality topics)
- Consider ICH Quality topic proposals envisioned under the ICH Quality Vision that have not been endorsed by the ICH with the goal of assessing how the proposal could be strengthened for reconsideration
- Design and recommend to the ICH Management Committee for execution a survey of existing ICH Quality Guidelines in need of revision