Final IWG Concept Paper Q2(R2) and Q14:
Q2(R2): Validation of Analytical Procedures and Q14: Analytical Procedure Development
29 October 2023
Endorsed by the Management Committee on 30 October 2023

Type of Harmonisation Action Proposed

Establishment of an Implementation Working Group (IWG) to prepare and deliver training materials facilitates an aligned interpretation and harmonized implementation of ICH Q2(R2) and ICH Q14. The intent of this IWG is to illustrate the application of specific concepts or principles of Q2(R2) and Q14.

Background to the Proposal:

ICH Q14 Analytical Procedure Development describes science and risk-based approaches for developing and maintaining analytical procedures which are suitable for the analysis of the quality of drug substances and drug products. ICH Q14 is a new guideline describing the elements of minimal and enhanced approaches for analytical procedure development. The guidance aims to make regulatory communication more effective, especially when novel analytical procedures are employed. Additionally, this guideline provides an opportunity to present the scientific basis for flexible regulatory approaches to post-approval analytical procedure changes.

ICH Q2(R2) Validation of Analytical Procedures presents elements for consideration during the validation of analytical procedures included as part of registration applications submitted. ICH Q2(R2) provides guidance and recommendations for validation of analytical procedures**.** The revision includes validation principles that cover a wider variety of analytical techniques than the original guidance and guides applicants on adequate validation data sets.

The training materials provide an opportunity for inclusion of practical examples to illustrate how Q2(R2) and Q14 can be applied to the development, routine operation, and lifecycle management of analytical procedures. This level of detail is impractical for inclusion in an ICH guideline or its annexes. Of note, ICH Q8-Q12 benefitted significantly through the preparation and distribution of detailed training materials and implementation aids in further clarifying the new concepts presented in those guidelines.

Issues to be Resolved:

To develop the training materials, the following general activities and outputs should be addressed:

- Illustrate the general concepts of ICH Q2(R2) and Q14
- Provide more depth to the discussion of the Annexes in ICH Q2(R2) and Q14 to address some specific implementation aspects relevant for different cases.

Through *Step 3* consultation, EWG identified following specific modules to be prepared and will focus on following modules:

- Module 0: Basics of Q2(R2) and Q14
- Module 1: Fundamental Principles of Q2(R2)
- Module 2: Q2(R2) - Practical Applications
- Module 3: Q14 - General Considerations
- Module 4: Further Concepts in Q14 - Change Management
- Module 5: Multivariate procedures and RTRT in ICH Q14
- Module 6: Q14 case studies

Statement of perceived problem

The development of a comprehensive set of training materials sponsored by ICH is essential to ensure the proper interpretation and aligned understanding of Q2(R2) and Q14 by both industry and regulators. Several types of training materials collectively address specific details relevant to different analytical procedures. The formation of an IWG for development and delivery of training materials provides an effective mechanism to enable harmonised implementation of Q2(R2) and Q14 on a global basis.

In addition to the previously foreseen need for training materials as described in the ICH Q2(R2) and Q14 Business Plan, feedback received during the *Step 3* public consultation period underscores the need for training materials to enable effective implementation of these guidelines. These training materials are required to address the different levels of understanding of key scientific and regulatory concepts amongst regulators and industry stakeholders.

Type of Expert Working Group Recommended:

Given the current contents of ICH Q2(R2) and Q14 guidelines and necessary expertise, it is recommended that the IWG membership be smaller than the current ICH Q2(R2) and Q14 EWG. Subgroups will be formed to develop the materials through email and teleconference. The subgroups will obtain input from the entire IWG.

Timing:

Agreement of Concept Paper by the Q2(R2)/Q14 EWG	September 2023
Adoption of Concept Paper by the ICH Management Committee	November 2023
Establishment of the ICH Q2(R2)/Q14 IWG	November 2023
IWG to finalize training materials	November 2024