

**Final Concept Paper
Q3D: Elemental Impurities IWG
dated 1 October 2014**

Endorsed by the ICH Steering Committee on 21 October 2014

Type of Harmonisation Action Proposed

Establishment of an Implementation Working Group (IWG) to prepare a comprehensive training programme and associated materials to facilitate an aligned interpretation and a harmonised implementation of ICH Q3D in the ICH and non-ICH regions.

Statement of the Perceived Problem

ICH Q3D Elemental Impurities is a quality guideline for the control of elemental impurities in new drug products (medicinal products). It is likely, upon decision of the regulators of the three regions, that at a later stage, the guideline will also be applicable to existing medicinal products. The process and principles described in ICH Q3D build upon the science and risk based principles described in Pharmaceutical Development (ICH Q8) and Quality Risk management (ICH Q9). Experience with the introduction and application of the new quality concepts outlined in ICH Q8, Q9, Q10 and Q11 has demonstrated that there are still significant challenges in aligning interpretations and approaches in implementation. In the implementation of these recent guidelines, significant benefits were realised through the preparation and distribution of detailed training materials and implementation aids. The availability of the training materials provided a framework to build a common interpretation of the principles described in ICH Q8-Q11. Drawing upon this experience and the comments that the ICH Q3D EWG received during the public comment period, there is a significant demand and recognition that the development of training materials, supported by the roll out of a training program would provide support to the smooth implementation of ICH Q3D.

Issues to be Resolved

A summary of the activities and outputs which need to be addressed, include:

- Development of comprehensive training materials;
- Training presentations including:
 - General overview of the guideline
 - Example(s) of the execution of a risk assessment
 - Example(s) of application of the guideline to less than daily dosing
 - Example(s) of application of the guideline to other routes of administration
- Frequently Asked Questions (FAQ) document (providing answers to the most often asked questions received during the public comment period);
- Example document providing an approach to documenting the information/data supporting the risk assessment to be presented in a regulatory submission;
- Expert support to the roll out of the training programme (through workshops and/or preparation of web-based sessions) in ICH and non-ICH regions.

Background to the Proposal

Throughout the development of the guideline, external audiences, constituents and interested parties have clearly communicated the complexity of the implementation approaches for this guideline. This was reflected during the public comment period as well as during the two rounds of constituent reviews. While the guideline provides the framework, it cannot provide the detailed examples covering the breadth of potential case studies for products within scope of the guideline. It is clear from the comments received that there exists a lack of unified interpretation of the guideline and the approach it describes. Additionally, similar comments and concerns were raised after the implementation of ICH Q8-Q11 which resulted in the formation of IWGs to address the challenges highlighted.

Consequently, the development of a comprehensive training programme and supporting documentation sponsored by ICH is considered necessary to ensure the proper interpretation and effective utilisation by industry and regulators alike. It is envisioned that the roll out of training materials and/or programmes should take place in the ICH regions as well as being available for use in non-ICH regions. This would provide an effective mechanism to provide more clarity, improve understanding of the risk-based approach and remove ambiguities in interpretation to enable a harmonised implementation of Q3D on a global basis.

Type of Working Group and Resources

The IWG will be comprised of two or three members nominated by EU, EFPIA, FDA, PhRMA, MHLW, JPMA, Health Canada and Swissmedic. One member can also be nominated by WHO Observer, the 3 regions' Pharmacopeias, biotech industry, WSMI, IGPA, IPEC and APIC as well as RHIs, DRAs/DoH (if requested). Given the depth and breadth of experience of the current IWG members, it is recommended that the IWG membership be drawn from the current IWG. In order to have the appropriate expertise and to keep the size of the IWG manageable, it is suggested that each ICH party have the flexibility to nominate up to three experts to allow for a broad range of subject expertise to be adequately represented.

Timing

Agreement of Concept Paper and Business Plan by the Q3D EWG	October 3, 2014
Adoption of Concept Paper and Business Plan by the ICH Steering Committee	October 21, 2014
Establishment of the ICH Q3D IWG	October 31, 2014
IWG meeting to finalize training materials	1Q 2015
Training materials finalised	March 31, 2015