

Final Concept Paper
ICH Implementation Working Group (IWG)
on ICH Q8, Q9 and Q10
Dated and endorsed by the Steering Committee on 1 November 2007

Type of harmonisation action proposed

Implementation Working Group

Statement of the perceived problem

In Brussels 2003 a new quality vision was agreed on. This emphasised a risk and science-based approach to pharmaceuticals in an adequately implemented quality system. As a consequence, the guidelines on Pharmaceutical Development (Q8), Quality Risk management (Q9) and Pharmaceutical Quality System (Q10) were drafted. As these concepts and principles are rather new in the pharmaceutical area, it is important that, due primarily to departure from the traditional approaches to quality guidance, proper implementation of these concepts is provided by bringing clarity, further explanation and removing ambiguities and uncertainties.

Issues to be resolved

The following issues have so far been identified and will need to be addressed:

- Technical issues & related documentation:
common understanding of terminology; address inter-relationship between Q8, Q9 and Q10; applicability to both review and inspection; final status after partial implementation is established (e.g. level of details in the dossier);
- Additional implementation issues:
influence on existing ICH guidelines;
- Communication and training:
e.g. Q&A, briefing packs from ICH; external collaborations; workshops.

Background to the proposal:

It has become apparent, based on public workshops or other symposia, that deviating views have been observed, setting up non harmonised interpretation and new expectations beyond the intention of these ICH guidelines. Concerns have been raised in the two ICH-Q strategy sessions identifying the need for an ICH Q IWG. An ICH sponsored implementation is considered necessary to ensure the globally consistent implementation of Q8, Q9 and Q10 and to ensure that maximum benefit is achieved from the interaction between these guidelines.

Type of Working Group:

The IWG should comprise of the Six-ICH Parties (up to 3 experts per Party depending on the agenda), Observers to ICH (1 expert per Observer) and Interested Parties (WSMI, IGPA, 1 expert per Interested Party).