Final Concept Paper
ICH Q7 Q&As
Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Dated and endorsed by the Steering Committee: 17 October 2012

Type of Harmonization Action Proposed

Implementation Working Group (Q7 IWG) on Q7 (Q&A document).

Statement of the Perceived Problem

The ICH Q7 Guideline is implemented successfully in the regulatory framework by WHO and most authorities around the world. However, experience gained with the implementation of ICH Q7 since the approval in November 2000 shows that uncertainties related to the interpretation of some sections exist. Furthermore, the importance of the application of the life-cycle approach addressed in the new ICH Q8/Q11, Q9, Q10 Guidelines to API manufacturing procedures is emphasized by the ICH Quality Implementation Working Group (Quality IWG). Technical issues with regard to GMP of APIs – also in context with new ICH Guidelines - need to be addressed in order to harmonize expectations during inspections.

A document would be helpful in removing these ambiguities and uncertainties and also in harmonizing the inspections of both small molecules and biotech APIs.

Issues to be resolved

The following issues have so far been identified by practical experience and will need to be addressed in a Q&A document on Q7:

1. Output from the review of existing Q&As (e.g., from PIC/S Expert Circle on APIs, from initial Regulatory/PDA training 2002) currently underway by PIC/S teams will be considered for endorsement.
2. Technical issues for clarification such as application in the supply chain control, contractor/supplier management (outsourcing), monitoring of impurity profiles, quality systems, applicability to biologicals/biotech and relationship with Q5D, and GMP expectations in the development phase (manufacturing for clinical trials).
3. Impact of the implementation of ICH Q8/Q11, Q9, and Q10 on Q7 (see also Quality IWG Q&As and Points to Consider).

Background to the Proposal

It has become apparent, based on the approval and implementation of ICH Q8, Q9, Q10, Q11 principles into GMP of APIs that certain individual implementation approaches are leading to non harmonized interpretation and new expectations beyond the intention of ICH Q7. The Pharmaceutical Inspection Cooperation Scheme (PIC/S) launched the 'International Collaboration on APIs - Training programme on ICH Q7'. This training programme includes a basic training, an advanced training and a Q&A document on interpretation of ICH Q7. This provides a feedback by the global knowledge of its network of inspectors. PIC/S will be supportive of the Q7 IWG work.

Type of Implementation Working Group and Resources

The Q7 IWG should comprise of the Six ICH Parties (2 experts per Party), Observers to ICH (1 expert per Observer), RHIs, DRAs and DoH (1 expert per RHI/DRA/DoH), and Interested Parties (WSMI, IGPA, Biotechnology Industry, PIC/S, API Industry and CEP programme of EDQM, 1 expert per Interested Party).

Timing

Concept paper approved at ICH SC teleconference, 3Q 2012.
First meeting of the Q7 IWG in San Diego, November 2012.
Step 2/4 expected in 2014.