



**GMP/GDP INSPECTORS WORKING GROUP  
(GMP/GDP IWG)**

**CONCEPT PAPER ON THE IMPLEMENTATION OF ICH Q10**

<b>AGREED BY GMP/GDP INSPECTORS WORKING GROUP</b>	February 2009
<b>RELEASE FOR COMMENTS</b>	March 2009
<b>DEADLINE FOR COMMENTS</b>	30 June 2009

Comments should be provided to [GMP@emea.europa.eu](mailto:GMP@emea.europa.eu) with a copy to [GMP\\_entr@cec.europa.eu](mailto:GMP_entr@cec.europa.eu)

<b>KEYWORDS</b>	<i>ICH, Q10, GMP, Pharmaceutical Quality System, Personnel, Contract Manufacture and Analysis.</i>
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This Concept Paper outlines a proposal to implement ICH Q10 (Pharmaceutical Quality System) in the EU (Step 5 of the ICH process).

Whilst the use of ICH Q10 by companies in establishing or reviewing their quality systems as they apply to the entire life cycle of their products is voluntary, much of ICH Q10 represents existing explicit or implicit requirements of EU GMP. The implementation strategy is therefore aimed at avoiding confusion as to regulatory expectations.

## **1. INTRODUCTION**

In June 2008 ICH Q10 Pharmaceutical Quality System reached step 4 of the ICH process and therefore needs to be implemented into the EU framework of Medicines Guidance (step 5). ICH Q10 represents optional guidance for pharmaceutical companies and provides a model for a quality system considered appropriate for the sector which can be applied across the full life cycle of a product from development through to discontinuation.

It is proposed to incorporate ICH 10 as a new annex to the EU GMP Guide.

## **2. PROBLEM STATEMENT**

Existing EU GMP already requires a pharmaceutical manufacturer to operate with a system of quality assurance, the elements of which are described in chapter 1 of the GMP Guide. The use of ICH Q10 by companies in establishing or reviewing their quality systems as they apply to the life cycle of their products is voluntary, however much of ICH Q10 represents existing explicit or implicit requirements of EU GMP. There is therefore a risk of confusion as to regulatory expectations due for example to the differences in terminology used if Q10 is solely published as an annex. Furthermore existing guidance in Chapter 1 and 2 of the guide do not fully reflect pharmaceutical quality systems as operated in companies in the present day and therefore there is an opportunity for updating the GMP Guide to more fully reflect modern practices and expectations. The glossary of the GMP Guide may also require revision in order to reflect modern terminology.

## **3. DISCUSSION**

Adopted ICH documents are required to be published into the EU framework and it has been previously proposed that ICH Q10 would be adopted as an Annex to the EU Guide, with voluntary application across the entire product lifecycle. However it is necessary to examine the impact of this voluntary guidance on existing GMP guidance, and to consider whether changes to existing guidance are necessary to align the use of ICH Q10 concepts and phraseology to avoid potential for misunderstanding on what is required under GMP and what is optional. Furthermore ICH Q10 uses modern quality terminology and concepts that are now well established in many pharmaceutical companies whilst Chapters 1 and 2 of the guide are now somewhat dated in this respect. There is also the opportunity to make the guidance more explicit in areas such as the handling of deviations and subsequent corrective and preventive action (CAPA) where an expectation is implicit in existing guidance but not clearly stated.

## **4. RECOMMENDATION**

The GMP/GDP Working Group recommends the revision of Chapters 1 (Quality management), 2 (Personnel) and 7 (Contract Manufacture and Analysis) of the EU GMP Guide.

Points to be addressed include:

- 1) Better alignment with the terminology and concepts utilised in ICH Q10.
- 2) Clearer guidance on the handling and investigations of deviations, Corrective and Preventive action and change control.
- 3) Emphasising the role of senior management in ensuring that there is an effective Quality Management System to support GMP.

The revised guidance will apply to manufacturers of medicinal products already authorised and on the market.

## **5. PROPOSED TIMETABLE**

Adoption of the concept paper by GMP/GDP IWG	February 2009
Proposed date for release of draft guidance	July 2009
Deadline for comments	January 2010
Re-discussion in GMP/GDP IWG	February 2010
Expected date for adoption by Commission	May 2010.

## **6. RESOURCE REQUIREMENTS FOR PREPARATION**

It is expected that no more than one rapporteur and an ad hoc working group of 4 – 5 GMP inspectors will be required to complete the work. Drafting group meetings to be break out meetings of the GMP GDP IWG meetings unless exceptional circumstances pertain.

## **7. IMPACT ASSESSMENT**

The benefits of an effective and comprehensive quality management system are well established. The concept paper relating to the establishment of the ICH EWG for Q10 which covers the full product life cycle, provides an impact assessment on companies that wish to implement a full ICH Q10 Pharmaceutical Quality System. The impact of the proposal in this concept paper is expected to be significantly less given the narrower scope of GMP over the product life cycle and given the aim is merely to clarify existing expectations.

## **8. INTERESTED PARTIES**

The revision of the EU GMP guide primarily impacts manufacturers and consultation procedures for these parties are well established.

## **9. REFERENCES TO LITERATURE, GUIDELINES ETC**

ICH Q10 Pharmaceutical Quality System  
Eudralex Volume 4: GMP Guide