EIPG Response to Consultation on Chapter 1 Quality management
Brussels, 18 November 2009
ENTR/F2/MT/AM/jr D (2009) 37658

The following represents the consolidated response of the European Industrial Pharmacists Associations on changes made to Chapter 1 in order to integrate the principles of "Pharmaceutical Quality System" as described in the ICH Q10 tripartite guideline. The following sections have been added to Chapter 1:**;**

Amended Text	Response
Principal.	• Paragraph 1: As IMP's are also in scope. Beside the relevant Marketing authorization also the relevant CTA should be mentioned. • Paragraph 3: replace "during development of products" by IMP's. Only the IMP used in clinical trials needs to be manufactured under GMP. • At the 3rd paragraph: "discontinuation" is among the applications of the guidance, though this concept is not discussed any more in the rest of the document
Quality Management System - Process Performance and Product Quality Monitoring System and Product Quality Review	**Quality Management System** • 1.1/ I and ii are exact copies of ICH Q10. This is too much detail if ICH Q10 will become Annex 21 • 1.1/ iii is not applicable for IMP's except for the management of the quality system. Is only applicable for marketed products, IMP production is a continuous process of developing and improvement. • 1.2, 1.3, 1.4, 1.5 are copied from ISO 9001. • 1.5 What weight will have the quality manual compared to the SMF. The SMF will also contain information on the quality system. • At point 1.6: the concept of "quality unit" is introduced, specifying that it can be in the form of separate QA and QC units or a single individual/group. In the proposed ***Chapter 2 - Personnel***, at point 2.6, the list of the responsibilities of the Quality Control Department seems to assign Quality Control a wide range of duties. It is recommended that a harmonized concept of QC be reached.

	Quality assurance • At point 1.8 (iv): an evaluation by the quality unit(s) is required for releasing the materials. This requirement is also stated for QC at point 1.10. It seems necessary a clarification on this requirement. • (vi) take out, is described in Good Documentation Practices. • At point 1.8 (vii): it is required that "significant " deviations be investigated. This requirement is repeated at point 1.9 (vi). However, at point 1.11(iv) of **Quality Control**, it is stated that "any deviations" be fully recorded and investigated. A clarification is necessary. • (viii) take out "regulatory inspections" **Good manufacturing practice for medicinal products (GMP)** The document is to be revised as far as the numbering (there are two point 1.8) should be 1.9 **Quality control** • (viii) Reference Annex 19.
- Management of Outsourced Activities and Purchased Materials	
- Management of Review on the Quality Management System	
- Monitoring of Internal and External Factors Impacting the Quality Management System	No clear reference and demand for, risk categorized, with revalidation concerned, Change Control System, Service and Maintenance, Laboratory Management System Control of Packaging and Labelling System and more focus should be place on the control of Material Systems.
- Outcomes of Management Review and Monitoring	

General Comments-

The proposed ***Chapter 1- Quality Management System*** would promote a harmonization with the ISO world, asking for an extension of the quality requirements in the pharmaceutical area.

As clearly stated in the introduction, reference is made to ICH Q10 and one can observe that paragraphs taken from ICH Q10 have been copied and included in the draft Chapter 1, instead of reporting them as an annex, as it was done for the GMP Annex 20 in case of reference to ICH Q9

EIPG Response to Consultation on Chapter 2 Personnel
Brussels, 18 November 2009
ENTR/F/2/MT/AM/jr D (2009) 37672

Some changes have been made to Chapter 2 in order to integrate the principles of "Pharmaceutical Quality System" as described in the ICH Q10 tripartite guideline. The following sections have been added to Chapter 2:

Amended Text	Comment
- Consultants Records should be maintained stating the name, address, qualifications, and type of service provided by these consultants.	Clarification required to avoid confusion of qualification to be regarded as sufficient experience
- Management of Change in Product Ownership reflect the nature of these risks. When product ownership changes, (e.g., through acquisitions) management should consider the complexity and ensure: (a) The ongoing responsibilities are defined for each company involved; (b) The necessary information is transferred	.
- Key Personnel Senior Management should appoint Key Management Personnel including the head of Production, the head of Quality Control, and if at least one of these persons is not responsible for the duties described in Article 51 of Directive 2001/83/EC1, the Qualified Person(s) designated for the purpose. Normally key posts should be occupied by full-time personnel. The heads of Production and Quality Control must be independent from each other. In large organizations, it may be necessary to delegate some of the functions listed in 2.5, 2.6 and 2.7.	No reference is made to QA management as distinct from QC management who a solely responsible for QC testing.

Acknowledgement.
The response quoted was prepared from comments provided by the Industrial Pharmacists Associations in;

- Italy
- Sweden
- Belgium
- United Kingdom