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Via Electronic Mail

April 25, 2007

Ms. Sabine Atzor
European Commission
Enterprise DG, Pharmaceuticals
Rue de Genève, 1
1049 Brussels
Belgium

Mr. David Cockburn
European Medicines Evaluation Agency
7 Westferry Circus
London E14 4HB
United Kingdom

Dear Ms. Atzor and Mr. Cockburn:

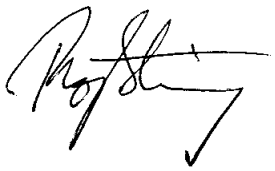
PDA is pleased to provide comments on the proposed revision to Chapter 1 of the GMP guide to include reference to quality risk management (QRM) principles. PDA is an international professional association of 10,000 individual member scientists having an interest in the fields of pharmaceutical manufacturing and quality. Our comments were prepared by a committee of experts in the area of quality, and approved by our Regulatory Affairs and Quality Committee as well as the PDA Board of Directors.

Our comments are embraced by the three general concepts:

1. QRM is based on principles (a way of thinking), and does not suggest an organizational unit be set-up for this function.
2. QRM principles should be an aspect of the reviewer functions, not just GMP and quality, and thus should be reflected in a CHMP guidance and
3. The ICH Q9 guidance is optional and not a requirement

Attached please find our comments in the approved EMEA format. If I can be of further assistance, please feel free to contact me.

With kind regards,



Georg Roessling, PhD
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European Medicines Agency

SUBMISSION OF COMMENTS

EudraLex – The Rules Governing Medicinal Products in the European Union Volume 4

EU Guideline to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use

Part I – Chapter 1 – Quality Management

COMMENTS FROM: Parenteral Drug Association (PDA)
GENERAL COMMENTS
1. Quality Risk Management is not and should not be an organizational unit or department of a pharmaceutical manufacturer. The text can be interpreted as a mix between requirements for departments (Manufacturing, QC, QA) and Quality Risk Management. The guidance should refer to the implementation of QRM **principles.**
2. The ICH Q9 step 5 document is not yet included in the EU regulatory framework at this time. We suggest to publish it as CHMP document as recommended by the official ICH process so that QRM principles are also noted and used by reviewers.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE		
Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
Introduction Par. 1	ICH Q9 provides not only the “when” but also the “where”	… and tools when **and where** applying…
Introduction Par. 3 And 1.5	ICH Q9 Principles are not only valid for GMP / inspections but also for regulatory filing (link to Q8). We recommend publishing it as CHMP-document. Update footnote from section 1.5	*Replace* “An integration into the GMP guide is currently being considered” for “**Publication as a CHMP guide** is being considered” In footnote 1, replace “…which later will be integrated into the GMP guide.” For “…will be **written as a CHMP guide**.”
Principles	Quality Risk Management is not an organization (see general	…Quality Control and Quality Risk Management **principles**.

[1] Where available

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SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION TITLE		
Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
Par 1:	comment 1 above)	
Principles Par. 2	Same as above	…Quality Control and Quality Risk Management **principles**.
1.5	A purpose should be added to this section.	*Add new introductory sentence:* Quality Risk Management can be applied proactively, with the primary purpose of controlling risk to the patient, by understanding, assessing, controlling, and managing risk to the quality of the medicinal product.
1.5	The section refers to ICH Q9 without actual reference to the ICH Q9 version step 5 which has yet to be publishing in the EMEA/EC environment (preferably as CHMP document.) Clarify the sentence.	*Change to read:* Two primary principles **fundamental to** all Quality Risk Management **(see ICH Q9) activities** are:
1.5	For clarification, we suggest to add after the principles:	*Add after the principles:* These principles can be applied to Quality Assurance, Good Manufacturing Practice and Quality Control for the purpose of transparency, decision making and to facilitate communication.
1.5	The optional aspect of ICH Q9 is not mentioned. This chapter, being a regulation, should not require adoption of an optional guideline.	Specify that the ICH Q9 guideline is optional.