Dear Sir, Dear Ms,

Please find hereunder my brief comments on the proposed revision of the Chapter 8 of the EU-GMP guide "Complaints, Quality Defects and Recalls"

My comments will be very brief because my opinion is that this proposed text is well under the current Chapter 8 (for it "practical" content). The proposal has too much "wording" and as for a number of recent literature insists too heavily on "QRM".

a) the paragraph 8.1 miss an important point that there shoud be a designated person (one person in the company) to be responsible on the complaints, etc.

b) paragraph 8.7 should be renumbered as paragraph 8.19 because ADE is a little bit lost here. Placing it just before the "recall" section would be more a kind of conclusion and a check that ADE has not been forgotten.

c) the new Chapter 8 lacks the previous § 8.5 which requested to put a minimum of information within the corresponding batch record(s). Indeed, this is very important from the inspector or the auditor point of view : when reviewing randomly a batch record this information should be directly available, not through tables. Moreoiver it's the demonstration that the BMR has actually been reviewed during the complaint investigation.

d) the new Chapter 8 lacks the previous § 8.7 about the importance of considering the risk of counterfeited products when dealing with any complaint

e) to my opinion it is important to renumber respectively paragraphs 8.26 and 8.27 as 8.20 and 8.21 because it is more than important that any reader of the guide would find diectly the fact that "all competent authorities should be informed in advance..." . I am afraid that placing this requirement at the 8.26 position is far to remote for those who are reading too quickly the GMP guide.

I hope that these simple comments will have some value for you.

With my best regards,

Dr Jean-Denis Mallet
Pharmacist
Ex-Inspector
International Auditor