Dear Sir/Madam,

***Please find below the feedback from Sandoz on guidelines on the formalised RA for ascertaining the appropriate GMP for excipients of medicinal products for human use***

***Best regards, Marc Leeflang***

1) Section 5:
   Importers of medicinal products must have the risk assessment / management documentation for appropriate GMP for excipients available on site.
   Proposal: Section 5: Importers of medicinal products must ensure, the risk assessment / management documentation for appropriate GMP for excipients is available

   Explanation: according to the Guidelines, the risk assessment documentation would be extensive and will be subject of change. On that regard, it would be very difficult to keep up to date whole documentation package at importers. At least MRA countries should be excluded (ie Swiss, Canada, Japan … ). The requirement will have impact on EU import of Sandoz's products!

2) General remark:
   The determination of appropriate GMP for excipients and the whole Risk assessment process will require additional resources and will be time consumable. On that regard transition period has to be defined. Proposal is 3 years – to comply with item 13 (data / evidence should be obtained through audit or from information received from exc. manufacturer). As most relevant data are from audit and audit frequency is 3 years, the 3 years transition period would be rational.

3) Section 8:
   a. potential for contamination cannot be identified based on questionnaires/papers only . Audits will be needed to be able to deliver adequate information and cover the request.
   b. Depending on the formulation (sterile, oral) the risk should be addressed adequately.

4) Section 9:
   a. Considering the amount of different possible formulation in a manufacture site - the assessment should be done on a risk based (e.g. worse case) approach, covering the highest/lowest range of the excipient in the produced formulations

5) Section 11:
    a. It is advised to consider as a minimum several high level GMP principles – there is no guidance which ones are mandatory and which ones “nice to have”. How to select what is really relevant? Every time case to case?

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