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To: European Commission
SANTE-D6-DA-GMP-IMP@ec.europa.eu
RE: DA on GMP for IMP

11 November 2015

Shire's Response to the Commission Delegated Act on Principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014

Shire welcomes the opportunity to submit the following questions and comments, in response to the consultative document on Good Manufacturing Practice for Investigational Medicinal Products for Human Use and Inspection Procedures.

1) In reference to Question 1a, it would be beneficial for a PSF or similar document to be introduced, but please keep in mind that it is not a requirement outside of the EU. Such a document improves the efficiency of the entire GMP process. It also facilitates review should there be a Health Authority query at a later date.

2) In reference to Question 1b, yes, as having PSFs is a requirement of the current EU Directives.

3) In reference to Question 2, the second option (2b) is the most efficient as it is easier to file batch documents with the CTMF. This would reduce potential for loss of data, as studies can continue for many years after a batch has been used.

   Plus often one part of a R&D organization is responsible for retaining batch documentation and another part of the organization is aware of when the last clinical trial was performed using a specific batch. Thus option 2b would help simplify.

4) In reference to Question 3, CoAs should accompany each shipment. The timing of receiving the CoA could be prior to or after receiving the shipment, as long as it is before the final release.

   Please keep in mind that it can be difficult to get a CoA from a licensed comparator product from a third country. Under this circumstance, if a CoA is not provided then full testing is recommended prior to release.

5) In reference to Question 4a, Retention samples are already required to be kept by the manufacturer.

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6) In reference to Question 4b, in cases in which a product is not stored at the location of batch release (e.g. if a site does not store controlled substances), having photos of the investigational medicinal product and the original images of packaging and labelling to supplement the reference sample would be useful. Please note that copies of labelling/ cartons are already kept with the batch documentation.

Sincerely,

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