Response to Public Consultation

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

Response submitted by the

November 2015

Question 1a -
Would requirement for a product specification file (a reference file containing, or referring to files containing, all information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of investigational medicinal product) be useful to be introduced?

The product specification file is already in use in manufacturing units within the in the UK and therefore we would support this approach.

Question 1b -
Do product specification files exist for manufacture of all investigational medicinal products in the EU?

Not known

Question 2 -
Different options exist for the retention period of batch documentation

a) **Retention for at least 5 years after the completion or formal discontinuation of the last clinical trial in which the batch was used, whichever is the longer period**

b) **Retention for at least 25 years after the end of the clinical trial in line with the retention period for the clinical trial master file**

Please indicate preferred option with justification

To align the retention period of batch documentation with the clinical trial master file as described in option (b) would be appropriate. However, there are clinical trials in specialist areas where the current retention period is in excess of 25 years.

Under option (b), would the current retention time for these trials need to be amended?

Question 3

Would it be feasible to require that Certificates of Analysis should accompany each shipment of imported investigational medicinal products as a means to ensure that analytical control has been carried out in the third country?

Feasibility is unknown but this would be the preferable situation. How would blinded trials be addressed?

Question 4a

Should retention samples also be required to be retained by the manufacturer?

manufacturing units already retain samples for testing on expiry.

Question 4b

If only reference samples are required, would a requirement for photos of the investigational medicinal product, the packaging and the labelling to supplement the reference sample be useful?

Yes, however, electronic systems used to retain this information would need to comply with Annex 11.

Question 5a

In how many clinical trials authorised under the Clinical Trials Directive has Article 13(3)c of that Directive been used?

Not known

Question 5b

In how many clinical trials authorised under the Clinical Trials Directive, is the comparator product not authorised in an ICH country (EU, US, japan, Canada and Switzerland)

Not known

Contact for further information :-