Warsaw, November 24, 2015

European Commission

Directorate-General for Health and Food Safety

Unit D6 “Medicinal Products – Quality, Safety and Efficacy”

Ref. Consultation Document “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”

Dear Sir or Madam,

SciencePharma welcomes the Commission’s initiative to consult with stakeholders draft of the delegated act on principles and guidelines on GMP for investigational medicinal products for human use products and appreciates the possibility to provide its comments.

SciencePharma is a Polish consultancy company offering regulatory services to the pharmaceutical industry. SciencePharma falls within the EU definition of a small and medium-sized enterprise.

Line(s)	Comment
Question 1a 120-124	Provisions in respect to “product specification file” provided in the detailed GMP guideline for investigational medicinal products for human use are, in our opinion, sufficient and therefore, there is no necessity to introduce such term into the delegated act.
Question 2 130-137	The preferred period of batch documentation retention is option a) “at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used, whichever is the longer period”. It should be emphasized that if data presented in the batch documentation for products used in clinical trials are critical for supporting information in the Marketing Authorisation, according to point 4.12 of Chapter 4 “Documentation” such data should be retained whilst the authorization remains in force (potentially even longer than 25 years as described in option b). Reference to the above point is recommended to be made. The above approach is also supported by the fixed retention period of the clinical trial master file (25 years).
Question 3	In our opinion CoAs issued by third countries manufacturers should be required to be available to QP before certification in case of not performing analytical control in EU. It is also considered that CoAs not necessarily have to accompany the shipment.

	Proving CoAs by another means (mail, email) may also be satisfactory.
184	The term “bulk formulated product” is recommended to be clarified. Moreover, it should be indicated that, in some cases, storage of samples of bulk formulated product is difficult e.g. in case of sterile bulk solution for injection.