Response to public consultation on the Detailed Commission Guideline on Good Manufacturing Practice for Investigational Medicinal Products for human use.

General comments

The above committee agrees with the amendments which promote quality improvement, including reference to recording of deviations with appropriate level of root cause analysis and CAPA.

Specific comments

Reference	Subject	Annex 13	Guidance	Comments
Annex 13 paragraphs 26 - 33 Commission guideline 2.7.5	Labelling	Detailed guidance is provided as to label information requirements	Reference is made to Regulation (EU) 536/2014 for label information. There is a requirement for additional information on small labels used on immediate packaging e.g. ampoules. This may cause issues with space available.	It is suggested that the detailed requirements for label information currently provided in Annex 13, be replicated in the new Commission Guidelines, instead of a reference to Annex VI in Regulation (EU) No 536/2014. Having all relevant information available in Annex 13 has proved to be successful and we recommend this is continued under Regulation (EU) No 536/2014.
Annex 13 paragraphs 43 - 47	Shipping	Guidance is provided on the two stage release of investigational medicinal products.	The section on shipping has been removed and there is no reference to technical or regulatory approvals (two stage release).	The committee feel that this is unacceptable and support the MHRA view that Commission Guidelines should continue to refer to a two stage release process for IMPs. Unlike Annex 13, the Commission Guidelines do not refer to the Sponsor responsibilities relevant to Good Manufacturing Practice (GMP) and two stage release of manufactured IMPs. The above committee supports the need to include Sponsor responsibilities as relevant to GMP within the context of the Commission Guidelines and retain the two stage release process. This will support continuity of clinical trial subject safety through the prevention of administration of doses without the appropriate approvals being in place, in accordance with the CTA.

Annex 13 - paragraphs 13/14 Commission guideline - 2.6.6	Documentation retention		Additional paragraph - Sponsor has specific responsibilities for document retention of clinical trial master file according to Article 58 of Regulation (EU) No 536/2014 and is required to retain such documentation for 25 years after the end of the trial. If the sponsor and the manufacturer are not the same entity, the sponsor has to make appropriate arrangements with the manufacturer to fulfil his requirement to retain the clinical trial master file".	Although the committee does not object to a 25 year documentation archiving period, the following points are raised for consideration. The proposed extension to the archive period for batch documentation may not adequately cover specific trial areas, e.g. ATMPs and Paediatrics. The additional archiving storage facilities required presents a practical issue in terms of storage space and assurance of ability to access electronic systems and read documentation over a 25 year period.
Annex 13 Principle	nIMPs	Information included on nIMPs	No reference to nIMPs within Scope section	Reason for removal ?