Scientific Archivists Group
Promoting excellence in records management

Detailed Commission guidelines on good manufacturing practice for investigational medicinal products, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014 can be downloaded here

Line	Text	Comment
129	*"…full control and traceability of the changes should be maintained…"*	Change to *""…full control and traceability of the changes should be documented and maintained…"*
130	*"Deviations from any predefined specifications and instructions shall be investigated and corrective and preventive action (CAPA) measures initiated."*	Change to *"Deviations from any predefined specifications and instructions shall be investigated and corrective and preventive action (CAPA) measures initiated and the documentation maintained."*
140-156	Entire section	There is no requirement to provide evidence that personnel are *"competent and appropriately qualified"*
179	*"Premises and equipment are expected to be validated.."*	There is no requirement to provide evidence that premises and equipment are *"validated"*. Add: *"Records shall be maintained to provide evidence that premises and equipment are properly maintained and are subject to appropriate validation."*
257	*"Appropriated records should be maintained."*	Change to *"Appropriate records should be maintained."*
268-273	*"The sponsor has specific responsibilities for document retention of the 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 therefore to make appropriate arrangements with the manufacturer to fulfil his requirement to retain the clinical trial master file."*	It may be difficult to comply with this requirement given the length of the retention period. For example, a sponsor could not provide assurance that records continue to be maintained for 25 years following termination of a commercial agreement with a manufacturer. It would be preferable for records expected within a clinical trial master file (state clearly which records these are) to be copied to the sponsor for filing.
288-290	*"The manufacturing process is not expected*	Add: *"Where carried out, records shall be*

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	to be validated to the extent necessary for routine production but shall be validated in its entirety in so far as appropriate, taking into account the stage of product development."	*maintained to provide evidence that the manufacturing process is subjected to appropriate qualification and validation."*
309-311	*"If a product is modified, data should be available…"*	Change to *"If a product is modified, the modification should be documented and data should be available…"*
515-516	*"Inventory records of returned products should be kept."*	No defined retention period