European Medicines Agency

SUBMISSION OF COMMENTS ON "DRAFT DETAILED GUIDELINE ON GOOD CLINICAL PRACTICE SPECIFIC TO ADVANCED THERAPY MEDICINAL PRODUCTS"
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COMMENTS FROM *F. Hoffmann-La Roche, Dr. med. Adolf Häuser, (adolf.haeuser@roche.com)*
GENERAL COMMENTS
Generally, it would be appreciated if clear distinctions of requirements for e.g. traceability of starting materials/product applicable for different ATIMP products were set, e.g. on certain GTIMPs (can be a plasmid produced by bacteria, virus vector produced in cells – similar situations to production of recombinant proteins/vaccines) vs. human tissues. The risks differ, and consequently requirements should be different.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE		
Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
Page 5 of 14, first paragraph	"4. Where tissues or cells of animal origin are used in the manufacture of an ATIMP, the sourcing procurement and testing should be done in accordance with the 'Points to consider on xenogenic cell therapy medicinal products'8." It is not agreed that the Xenogenic points to consider paper is	Please re-consider this point.

[1] Where available

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	fully appropriate for all cells and tissues of animal origin used in the production of all ATIMPs, e.g. cell lines used for production of viral vectors.	
page 9 of 14, 2.5.	The term “traceability” is mentioned twice. It can be found under “bullet point” [“-“] 1 and 5. The context does not sufficiently explain what sort of “traceability” is meant under those specific points.	Please clarify the term under the respective bullet points (“subject” and “product” traceability).

Please feel free to add more rows if needed.