



European
Commission

GMPs for ATMPs

Comments received from FR

1. General comments

- ▶ Structure considered deficient (different ideas under same reference)
 - ▶ Structure mirrors ICH approach; duplications and contradictions removed.
- ▶ Insufficient level of detail
 - ▶ Deliberate approach of avoiding too much prescriptive details : greater emphasis of outcome to be achieved.
 - ▶ However, certain aspects relevant to ATMPs are explained in more detailed than in current Annex 2.
 - ▶ For certain aspects, input from consultation is required to develop details.
- ▶ Insufficient consideration of public health
 - ▶ None of the flexibilities introduced should compromise public health.
 - ▶ Stronger requirements have been introduced also (e.g. cleaning validation for autologous products).

1. General comments (cont.)

- ▶ Absence of glossary and requirements for animals
 - ▶ Starting materials of animal origin are addressed.
 - ▶ Xenogenic cells will be addressed.
 - ▶ Glossary to be added if necessary.

- ▶ Lack of clarity of scope
 - ▶ Consultation document is not a legal document. The scope of the specific guidelines will be clearly explained.

2. Detailed comments

- ▶ 69 detailed comments submitted.
 - ▶ Perceived lack of clarity of provisions which, however, correspond to text in current GMP Guidelines.
 - ▶ Comments referring to issues addressed by ATMP Regulation (e.g. definition of starting and raw materials), Directive 2001/83 (e.g. art. 51(3) Directive), CT Regulation (e.g. definition of sponsor) or Variation Guidelines (e.g. specification of variations that are Type II).
 - ▶ Comments on hospital exemption
 - ▶ GMP guideline cannot amend ATMP Regulation.
 - ▶ Editorial comments and comments on requirements that are clarified elsewhere in the document

2. Detailed comments (cont.)

- ▶ Specific responses to questions in consultation
 - ▶ Consideration for other quality systems for non-substantially manipulated products opposed? (Q3)
 - ▶ Flexibility regarding validation of premises for investigational ATMPs opposed? (Q5)
 - ▶ Flexibility for C&D backgrounds for early CT's opposed. (Q8)
- ▶ Questions about the text or suggestions for further clarification will be thoroughly discussed.
 - ▶ COM has requested input from experts in CAT and IWG GMDP.