Associazione Farmaceutici Industria
Società Scientifica

Comments to the Consultation Document

"Good manufacturing Practice for Advanced Therapy Medicinal Products

This document encloses the comments collected by the advanced therapy working group (WG) of Associazione Farmaceutici Industria (AFI). The working group is composed by different professionals belonging to private companies, to academy and consultants.

The WG found the document clear and very useful reflecting and summarizing the current guidelines, in the following paragraphs are reported the results of the discussion about the topics that the WG considered most critical.

Q3: in case of non extensive manipulation, the WG agrees with the JACIE accreditation system, even if the cells/tissues are used for a different essential function in the recipient as in the donor.

Q5: when the product is in an early clinical phase, the quantities produced are very small and it's very common that the facility is multipurpose, it should be possible on the basis of the quality risk management.

Q8: the aseptic preparation of products that can't be terminally sterilized can be ensured in A grade with a background of B grade, both for early clinical phases and for pivotal clinical trials/commercial production. A D grade could be possible only if the production is performed in a closed system such as isolator.

Q10/Q11/Q12: since the time of retention of documents is 30 years after the expiry date of the product, the WG suggest as documents to be stored the following: batch production record and attachments, IMPD and Product Specification File.

Q13: when the product is in the early clinical phases is not always possible to have starting and raw material manufactured in GMP. The WG suggests using the better quality standard available on the market and setting up a supply and/or technical agreement.

Q19: the WG suggests reducing the number of the release QC tests if there are robust supporting data in the IMPD. A difference in the request should be if the product is distributed fresh or frozen.

Q22/Q23: the WG completely agrees with the proposal that the reconstitution is not a GMP process.

Q24: reconstitution is a dilution.

Q25: if the product is a ATMP, although the production is automated, the activities should be performed in an authorized facility according to the GMP. The automated system will be helpful in reproducibility and reliability, but the GMP quality system is mandatory to ensure the quality and the safety of the product.

Presidente AFI
Prof. Alessandro Rigamonti
Coordinatore Gruppo di Studio Biotecnologie e Terapie Avanzate
Dott.ssa Marta Galgano