Unit B5 – "Medicinal products – policy, authorisation and monitoring"
SANTE-B5-ADVANCED-THERAPIES
European Commission
DM24 02/133
B-1049 Brussels (Belgium)

Comments from Regea Cell and Tissue Center (BioMediTech, University of Tampere, Finland) on the targeted stakeholder consultation on the draft Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products

Regea Cell and Tissue Center is part of the BioMediTech institute of the University of Tampere. Regea is a non-profit unit and, in addition to housing a clinical tissue bank, it conducts research on stem cells and manufactures cell therapy products.

Chapter 11.2 Qualified person (lines 1657-1661)

We find it important that the qualification requirements of a QP responsible for ATMPs are complemented with training and experience requirements related to the specific characteristics of these products. However, we suggest modifying the qualification requirements description so that it would be unambiguous that relevant topics, such as cell and tissue biology and biotechnological techniques are required as theoretical and practical university courses; and that the person shall have expertise on relevant techniques such as cell processing, characterization and potency testing.

Chapter 12.2.2 Retention of samples (lines 1889-1894)

We agree, that keeping samples of starting materials may be challenging due to scarcity of the materials. However, the justification of not keeping reference samples of such scarce materials should not be limited only to autologous and matched donor ATMPs scenario since there may be also other challenging starting materials that are not possible to keep as reference samples.

Regea Cell and Tissue Center
BioMediTech, University of Tampere
FINLAND