GTP Working Party (Gene Therapy Products)

Terms of reference

- Revision of the general chapter *5.14 Gene transfer medicinal products for human use* (raw materials part) to account for the chapter *5.2.12 Raw materials of biological origin for the production of cell-based and gene therapy medicinal products;* Evaluation of the general chapter *5.14* in the view of development in the field within last decade and its potential revision as decided by the Commission
- Participation in elaboration/revision of transversal texts elaborated by other Groups of Experts or Working Parties, (e.g. general chapter 2.6.35 Quantification and characterisation of residual host cell DNA)
- Drafting and revision of other general chapters and monographs allocated to the working party by the Commission in the field of gene therapy

Profile for experts

- Current expertise in analytical methods related to development and quality control of gene therapy products and in development of control methods
- Several years of experience in one or more of the following fields:
    - Development of gene therapy products
    - Quality control of gene therapy products in a pharmaceutical manufacturing setting or in a hospital environment
    - Assessment of applications for marketing authorisation of gene therapy products
    - Marketing surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of methods for control of gene therapy products in a research and development environment