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