Quality

To help developers of gene therapy medicinal products (GTPMs) and cell-based medicinal products (CBMPs) navigate the important quality-related regulatory requirements.

What you should know

Additional information applicable to all the above objectives

Your checklist

- Develop and validate a potency assay
- Follow the EMA’s guidance on advanced therapy medicinal products (ATMPs)
- Map the development of the manufacturing process and ensure the products assessed are comparable
- Explore what is included in the authorization dossier
- Identify any drug substance and that drug product
- Identify use materials and starting materials
- Check the clinical activity of investigational medicinal products (CBMPs) to see if a similar medicinal product is used for the same therapeutic indication in CBMPs

Develop a biocompatibility paper for assessing biocompatibility of ATMPs

Regulatory support

ATMP certification: This procedure aims to identify any potential issues of quality and non-clinical data. For more information see ATMP certification guidelines.

ATMP classification: It is determined if the product meets the scientific criteria to be considered an ATMP and is used to classify the medicinal product for regulatory purposes. For more information see ATMP classification guidelines.

GTPM: For the evaluation of GTPMs, the GTPM multidisciplinary group that includes scientific, regulatory and legal competences. It sets up as a forum for early dialogue with applicants on innovative aspects in GTPMs.

GTPM checking: To see if a similar medicinal product is used for the same therapeutic indication in GTPMs.

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