EMA'S GUIDE ON ADVANCED THERAPY MEDICINAL PRODUCTS

Quality checklist

- [ ] Develop and validate a potency assay
- [ ] Check the GMP regulations for importing products into the EU
- [ ] Map the development of the manufacturing process and ensure the products across all studies are comparable
- [ ] Explore what is needed in the authorisation dossier
- [ ] Define the active drug substance and final drug product
- [ ] Identify raw materials and starting materials
- [ ] Check the Community register of orphan medicinal products to see if a similar medicinal product for the same therapeutic indication has been granted market exclusivity protection
- [ ] Develop a traceability system that enables bidirectional tracking of cells/ tissues contained in ATMPs