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