4.2.3 Therapeutic cell products should be prepared as in compliance with the GLP/GMP/GTP guidelines and other laboratory conditions depending on the purpose of each use.

4.2.4 All reagents and media used in the process should be of 'clinical grade', intended to be administered to humans.

4.2.5 Stringent characterization of the product with reference to its identity, purity and safety as well as genomic stability, tumorigenicity and potency is essential before its release for human use.

4.2.6 Appropriate quality control and assurances should be in place.

4.3 **Design of Clinical Trials:** Clinical trials using stem cells need to be planned carefully, with follow-up periods suitable for the subject being evaluated, and should also incorporate appropriate end points. It is essential that stakeholders involved in the clinical trials related to stem cells are fully conversant with the current regulations in the field. It is important to ensure that no unproven stem cell therapy is offered outside of the well-controlled clinical trials.

4.4 **Specific Requirements:** Keeping the above considerations in mind, it is emphasized that besides general principles of biomedical research, specific principles need to be