



GMP LABORATORY

TCA Cellular Therapy's ISO-7, Class 10,000 Good Manufacturing Practice or GMP laboratory has been specifically designed for stem cell processing. GMP is a term recognized worldwide for the control and management of manufacturing and quality control testing of pharmaceutical/biological products and is held to the highest standard by the FDA.

The clean area, which is the production area, has two self-contained tissue suites equipped for the processing and expansion of patient's stem cells.

Many features have been incorporated into the design of this facility to minimize the risk of cross-contamination between products. Some of the specifications of these areas include: unidirectional traffic



flow, single-pass HEPA filtered supply air and 100% exhaust from the biological safety cabinets through dedicated ducts.

The walls, ceilings and floors are coated with distinct compounds to minimize contamination from outside particulate material. Contiguous to the clean area, there is an ante-room used for gowning and storage of supplies in route to the clean areas.

The clean area is equipped with sophisticated tissue culture incubators used during stem cell expansion and reserved for one-donor/one-chamber use. Thus, cells for individual patients can be processed without risk of cross-contamination.

We comply with FDA requirements for the maintenance of equipment, cleaning of laboratory setting, and the standardization of equipment.

An adjacent main lab is used for quality control testing and the receipt and storage of cell culture materials.

All major equipment is on a remote alarm system that automatically contacts our staff when/if conditions should fall outside the accepted limits.