BioSpherix®

XVIVO SYSTEM

ASEPTIC cGMP COMPLIANT CELL PRODUCTION MINI-FACILITY

- **SAVES MONEY**
- **SAVES TIME**
- **SAVES SPACE**
- **REDUCES RISK**
- **PRODUCES BETTER CELL PRODUCT**

COMPLETELY CLOSED-SYSTEM PRODUCTION LINE

Cells are produced in a series of modular interconnected chambers. All instruments and processing tools are integrated inside according to process steps. Cells and supplies enter on one end. Waste is expelled aseptically along the way. Cell product emerges at the opposite end. One advantage over traditional bricks-and-mortar, walk-in clean rooms is that the process can be developed anywhere. Then when it is time for cGMP certification, surround it with, or move it to, Class 100,000 (ISO 8, Class D) clean zone.

GMP PRODUCTION FOR PHASE 1 CLINICAL TRIALS

Cell manufacturing process can be debugged, optimized, and characterized during translational research phase. Once validated, cell production mini-facility can be converted to GMP by simply surrounding it in minimally classified space. Surrounding by Class 100,000 (ISO 8) cleanspace, isolators meet regulations. Modular softwall clean rooms can be constructed around isolators for ISO 8. Any production line can be fitted. Any room can be fitted. System can be moved to cleanroom, down the hall, or across the ocean.

Economical and practical alternative to expensive brick-and-mortar clean rooms!

The ***XVIVO*** is a new cell production system based on isolation technology. Isolation barriers are proving valuable for food and pharmaceutical manufacturing, and now we offer the first one for therapeutic cells.

It saves money in many ways. Capital costs are less. Operating costs are a lot less. Your investment is rock-solid because modular design is flexible. Accommodate different processes. Move it to different locations. Adapt it to any existing space. Scale up indefinitely. Scale out indefinitely.

Implementation is fast. Prefabricated modules can be assembled and installed quickly. Qualifications and validations are straight forward and assured. GMP compliance can be achieved faster than ever before. Time-to-clinic is measured in months, instead of years.

Flexibility and low cost also reduces risk considerably, compared to massive inflexible clean room facilities. Now one can invest in cell therapy with confidence.

Complete isolation between the cells in an aseptic environment and the contaminated world outside maximizes quality. Unprecedented new features, unachievable in traditional brick-and-mortar clean rooms, may even produce a better product!