

# PACT UPDATE

## **NEW! - Clinical Manufacturing Support**

PACT has expanded its scope to support manufacturing of cell therapy products for use in clinical trials

Apply now at [www.pactgroup.com](http://www.pactgroup.com)

## **Regulatory Services Support**

PACT is an NIH-wide resource and has the requisite regulatory expertise to address all aspects of the translational process for the development of cellular therapeutics.

PACT can assist with:

- Project gap analysis
- Guidance for INTERACT (pre-pre-IND) or pre-IND discussions with FDA
- INTERACT meeting package preparation
- Pre-IND meeting package preparation
- IND preparation
- Pre-clinical study design
- Chemistry, Manufacturing and Controls (CMC) development