

**FAST TRACK PROVISION OF MANUFACTURING FACILITIES AND INFRASTRUCTURE
TO ACCELERATE CLINICAL TRIAL INITIATION: A Case Study**

CLIENT: A pioneering biotechnology company developing stem cell-based therapies for tissue regeneration and other therapeutic applications.

OPPORTUNITY: In late 2005, the client identified an imminent requirement for new controlled environment room (CER) space and GMP infrastructure for cell isolation and cell culture expansion of stem cells to create production cell banks and manufacture allogeneic stem cell products for clinical trials commencing in 2006.

Renovation of its own existing facilities to create CER and infrastructure posed the following challenges:

- **Time:** The cycle time for design, permitting, construction and validation would not enable GMP operations to start within 2006. In this regard, the city planning department permit review alone was projected at three (3) – six (6) months
- **Cost:** Design, construction, commissioning and validation activities incur significant direct cost and investment as well as the indirect cost of internal staff to manage and execute the programs
- **Dilution and Distraction:** Significant internal staff resources would be required to manage a program of this nature. Furthermore, the personnel resources experienced in such programs were fully committed to internal product and process development programs

SOLUTION: Client contracted PCT to provide GMP manufacturing support, including provision of two (2) dedicated ISO 7/Class 10,000 CER at PCT's Mountain View, CA facility.

Within six (6) weeks of contract signing in March 2006, PCT had:

- Renovated a 500ft² ISO 7/Class 10,000 CER with appropriate utilities and services
- Wrote and executed a combined total of 16 protocols for the installation (IQ), operational (OQ) and performance qualification (PQ) of systems, utilities, services and equipment, including the dedicated HVAC system and the controlled environment of the CER
- Enabled the client to start GMP qualification of their manufacturing process for allogeneic stem cell products in the new CER

In parallel, PCT executed the fast track design (2 weeks), permit (1 week), construction (4 weeks) and commissioning (2 weeks) of a 2nd 500ft² ISO 7/Class 10,000 CER. PCT also wrote and executed a combined total of 22 protocols for the IQ, OQ & PQ of systems, utilities, services and equipment, including the dedicated HVAC system and the controlled environment of the CER. This allowed the client to commence aseptic fill qualifications in the new CER within 15 weeks of contract signing.

RESULT: Within a few weeks of contract signing, PCT used its integrated solutions approach to collaborate with the client and position them to rapidly advance their clinical trial program. PCT provided high quality GMP facilities and infrastructure, providing the client with an excellent return on investment (ROI) with no dilution or distraction of their internal staff and resources.



Progenitor Cell Therapy is a client-based cell therapy services company that supports the development of cellular therapies by providing cGMP-compliant cell manufacturing and consulting services that address regulatory, financial, technical, process, and quality system strategies. PCT provides a full spectrum of support including process and product development, consulting, validation, due diligence evaluations, tissue collection, processing, and storage, product manufacturing, distribution and transportation.