PCT CELL THERAPY SERVICES

CASE STUDY

TITLE: Fast track provision of manufacturing facilities and infrastructure to accelerate clinical trial initiation

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

OPPORTUNITY:

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

- Time: The time cycle time for design, permitting, construction and validation would not enable GMP operations to begin within the required time frame. The city planning department permit review alone was projected at three to six 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 dedicated ISO 7/Class 10,000 CER at PCT's Mountain View, California facility. Within six weeks of contract signing, PCT:

- Renovated a 500ft^2 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 Client to start GMP qualification of their manufacturing process for allogeneic stem cell products in the new CER.

In parallel, PCT fast tracked the design (2 weeks), permit (1 week), construction (4 weeks) and commissioning (2 weeks) of a second 500ft^2 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 Client to commence aseptic fill qualifications in the new CER within 15 weeks of contract signing.

CONCLUSION:

PCT used its integrated solutions approach to collaborate with Client and help them rapidly advance their clinical trial program. PCT provided high quality GMP facilities and infrastructure, providing Client with an excellent return on investment with no dilution or distraction of their internal staff and resources.

PCT is a Client-focused contract development manufacturing organization (CDMO) supporting the development and commercialization of cell therapy and regenerative medicine products through specialized services tailored to address the unique scientific, technical, manufacturing, Quality, regulatory and financial challenges of our diverse Client base. Our services include cGMP-compliant manufacturing, storage and distribution of clinical products, cell and tissue collection, processing and storage, process and product development, engineering and innovation, regulatory consulting, facility design, validation, and due diligence evaluations.

PCT / New Jersey
4 Pearl Court, Suite C
Allendale, NJ 07401
(201) 883-5300

PCT / California
291 Bernardo Avenue
Mountain View, CA 94043
(650) 964-6744

NeoStem, Inc.
420 Lexington Avenue, Suite 350
New York, NY 10170
(212) 584-4180