PCT CELL THERAPY SERVICES

CASE STUDY

TITLE: Design and implementation of Quality Systems for a cell processing facility

CLIENT: A company responsible for the receipt, processing, cryopreservation, testing, storage and distribution of Human Cellular and Tissue Products.

OPPORTUNITY:

Client considered accreditation by an international, government sponsored organization to be an urgent mission critical business objective. However, in a voluntary audit, Client was denied accreditation due to non-compliance with required cGMPs. The accrediting auditor cited:

- Significant gaps in the overall design, implementation and compliance of Quality Systems
- Failure to comply with existing written procedures
- Significant concerns regarding the design and operation of the cell processing facility

Client recognized that it needed to rapidly address these issues but did not have the requisite experience and knowledge base internally, nor the time and resource to recruit suitably qualified staff to remedy the situation consistent with their business objectives.

SOLUTION:

Client contracted PCT to assist them to overhaul their quality systems and operations to address the issues cited by the auditor due to PCT's significant experience in the design, construction, validation and operation of GMP manufacturing facilities, the associated quality systems and all elements of regulatory compliance. To this end, PCT:

- Redesigned the cell processing facility and implemented better flow patterns for materials, personnel, products and waste.
- In collaboration with Client's staff, (re)wrote and implemented:
    - Standard Operating Procedures (SOPs) describing facility operations, including the controlled movement of materials, personnel, products and waste through the facility
    - A document control system
    - Systems, SOPs and training for materials control, vendor qualification, equipment maintenance, internal auditing, deviation reporting and corrective and preventative action (CAPA)+
    - Revised procedures for the receipt, processing, storage and release of raw materials and products
    - Defined and implemented a program for documented compliant training of staff involved in GMP operations
    - Provided appropriate training to Client's staff
    - Managed the follow-up audit by the government sponsored agency and all responses to observations arising from that audit resulting in successful accreditation

CONCLUSION: A voluntary follow up audit by the government-sponsored agency was coordinated and managed by PCT on behalf of Client. PCT subsequently managed the responses to minor observations made by the auditor during the follow-up audit. Client received the accreditation required for execution of their business in a timely and cost-effective manner.

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