



Progenitor™
Cell Therapy, LLC

The partner of choice for developing and manufacturing cell therapies



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Make Our Business Your Solution.

PCT's management team, extensive manufacturing and regulatory experience, and facilities have made it the industry's partner of choice for the development and manufacture of cell therapies.

Whether you are in the early stages of product development, in clinical trials, or moving to commercialization, PCT can provide you with the consultative or manufacturing partnership you need to get your product to market.

Product Quality ⇄ **Cost Savings**
Regulatory Compliance ⇄ **Experience**



The PCT *Advantage*

◉ *Competence*

100+ years of collective cell therapy experience. 15,000+ procedures. 20+ types of cell products. More products used clinically than any competitor.

◉ *Capacity*

Two USA facilities: California and New Jersey. Experienced professionals at customers' disposal.

◉ *Cost*

Minimize your cost. Maximize your ROI.

◉ *Commitment*

Exclusive cell therapy concentration. Quality and customer-driven focus through entire organization.

◉ *Control*

Maintain complete product and IP control. Our success is your success.

◉ *Compliance*

Simplify the path to regulatory approval. Leverage our involvement in more than 50 regulatory filings in US & EU.



Processing Services

PCT provides a full range of services to support cell-based therapeutics. These services can be contracted as part of a comprehensive package or on an individual basis.

Processing Service Offerings

- ◊ Cryopreservation and storage
- ◊ CD34 cell selection
- ◊ T cell depletion
- ◊ Red blood cell depletion
- ◊ Plasma depletion
- ◊ Donor leukocyte preparation
- ◊ Umbilical cord blood processing
- ◊ Bone marrow & peripheral blood progenitor cell processing
- ◊ Flow cytometric analyses
- ◊ Polymerase Chain Reaction
- ◊ Microbial assays
- ◊ Blood typing
- ◊ Infectious disease testing



Manufacturing

PCT leads the industry in the contract manufacturing of cell therapy products.

Each client benefits from PCT's experience in manufacturing a wide variety of cell, gene, and tissue types. In all client partnerships, PCT places paramount importance on product quality and the protection of proprietary information.

A PCT partnership also affords clients with significant cost savings achieved through a leveraged infrastructure and economies of scale.

PCT's manufacturing experience

- 15,000+ cell therapy procedures
- 100+ clients served
- 20+ different types of cell products
- 100+ years combined cell therapy expertise
 - Construction/validation/operation of 5 GMP facilities
 - 50+ regulatory filings (US & EU)
 - Cell product development & characterization



Consulting

PCT understands the challenges you face and has solutions.

Whether you choose to outsource your manufacturing to PCT or manufacture in-house, PCT's compliance-focused services can support your needs at every stage of the product development cycle.

PCT's Consulting Services

☉ *Process, Assay and Product Development Consulting*

- Process development, optimization and scale-up
- Product characterization, product potency and product stability assays
- In-process and final product test method development
- Product shipping validation
- Assay development & validation for product characterization & potency

☉ *GTP/GMP Manufacturing Consulting*

- Facility design, construction, validation and operation
- Quality systems development and implementation

☉ *Regulatory Services Consulting*

- Product development strategy
- Master File development
- Investigational New Drug (IND) applications
- Pre-clinical study design
- Chemistry, Manufacturing and Controls (CMC) development
- Biologic License Applications (BLA)
- Preparation/representation at regulatory meetings
- Regulatory submissions, amendments, supplements and reports

☉ *Commercialization Strategies & Product Validation Consulting*

- Cost of goods analyses
- Financial modeling
- Product validations
- Technology assessments
- Business evaluations
- Commercialization strategies



Product & Process Development

PCT offers a full spectrum of services to address your development needs.

PCT's Product & Process Development Services

- Process development, optimization and scale-up
- Cost of goods reduction
- Process validation
- Product comparability studies
- Stability studies
- Batch production record development
- Product shipping validation
- Analytical test method development
- Product characterization
- Potency assays
- Analytical test methods validation



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