

TITLE: Reduction of Cost of Goods While Increasing Capacity and Geographic Coverage for Manufacturing of Product

CLIENT: A biotechnology company with a vaccine product

OPPORTUNITY:

Client had an existing wholly-owned satellite operation (facility and staff) in California. Due to a limited product shelf life, Client required the addition of significant East Coast clinical manufacturing capabilities for its portfolio. Client required a reduction in cost of goods during clinical manufacturing for product, while still maintaining its geographic coverage and required a cost-effective and high-quality solution to its manufacturing needs. Client also required a transition to its own commercial manufacturing plant in preparation for commercial launch.

SOLUTION:

PCT entered into an agreement with Client to commence manufacturing for its cell vaccine in PCT's East Coast facility, which included vaccines for multiple indications. After extensive analysis, Client concluded that PCT's model provided the most cost-effective solution of any of its cell processing center models, proving superior to hospital-based processing, a not-for-profit blood center, a wholly-owned satellite facility and in-house capacity. During the term of the eight year engagement, PCT:

- Provided for patient specific treatments to Client's specifications and manufacturing instructions.
- Provided the flexibility to accommodate patient processing and shipping logistics.
- Provided manufacturing capacity to enable Client to continue to treat patients in an ever-changing regulatory environment.
- Provided a significant part of the platform from which Client provided manufacturing and QC testing data to gain commercial approval.

CONCLUSION:

- Client estimated that outsourcing its California cell processing operations saved the company millions of dollars.
- Over eight years, PCT manufactured the majority of products for trials supporting Client's product (over 1,200 cell therapy products), including Phase 1, 2, 3, and 3b trials and BLA submission.
- Subsequently PCT successfully transferred the manufacturing process to Client.

PCT was the first, and remains the only, contract manufacturer in the cell therapy sector to manufacture Phase 3 cell therapy products that were subsequently approved by the FDA for commercial sale.

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.

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