

*Hitachi Chemical*  
**HITACHI**



Global Manufacturing and Development  
Services for the Cell Therapy Industry

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**Manufacturing Transformation**

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## Manufacturing Transformation

The Global PCT Service Platform is the cell therapy contract development and manufacturing of the Hitachi Chemical Regenerative Medicine Business Sector.

Hitachi Chemical Advanced Therapeutics Solutions, LLC, a wholly owned subsidiary of Hitachi Chemical Company, Ltd. offers the PCT Platform in the United States, including:

- Clinical and commercial manufacturing
- Manufacturing development

The PCT Service Platform tagline, **Manufacturing Transformation**, embodies both our commitment to help customers achieve and efficiently deliver life-changing, cell-based therapeutics and to transform cell therapy manufacturing to optimize and enable the future-state.

## Delivering Innovations

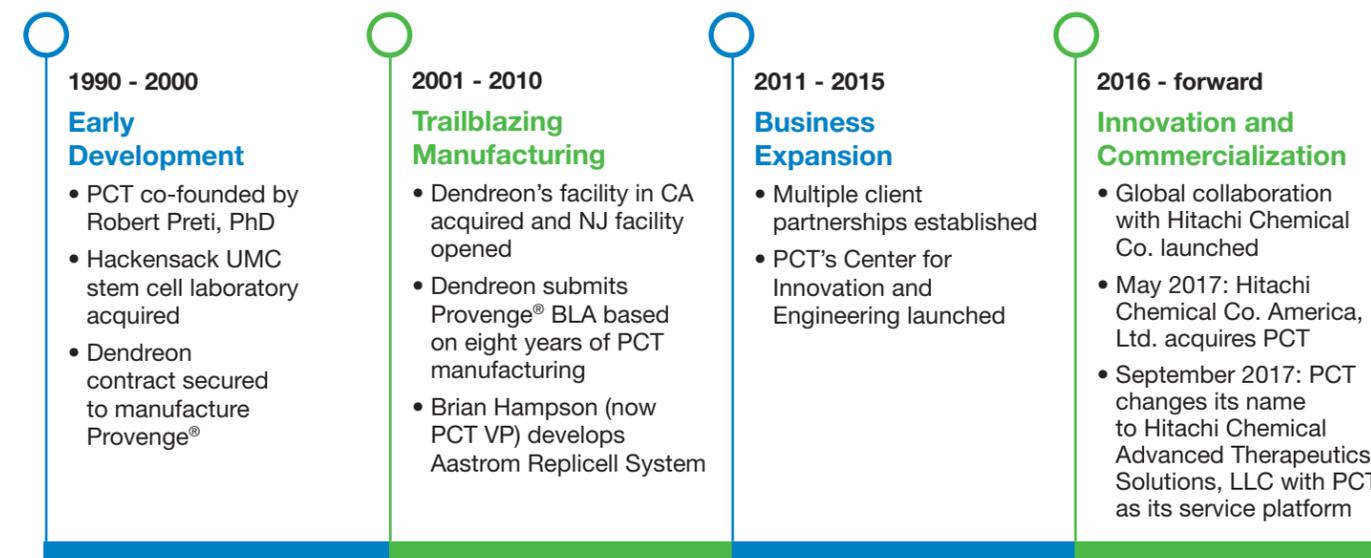


A world in which transformative cell-based therapeutics are accessible to all



To provide our clients with high-quality, scalable, innovative, reliable and cost-efficient manufacturing platforms and services to advance commercialization of cellular therapies

## Focused Exclusively on the Cell Therapy Industry



## Harmonized Global Service Platform Advancing Commercialization

Expansion planned in 2018



● **US:** Commercial manufacturing services

● **Europe:** Expansion targeted

● **Asia:** Yokohama, Japan CDMO facility

Manufacturing Transformation



### Understanding the Process

As the first and last unit operations for manufacturing products involve extraction and infusion of cells, deep knowledge of the manufacturing and analytical unit operations, as well as the logistics associated with patient-specific cell therapies is critical in serving our clients and, ultimately, the patients they treat.

The know-how and commitment of the PCT services, multi-disciplinary, collaborative team combined with the expertise gained through an unprecedented track record in the industry, allows us to develop optimized pathways for clients to achieve commercially viable products.

### Customer-Driven Solutions



#### Clinical and Commercial Manufacturing

##### Technology Transfer

- Systematic and strategic approach
- Understanding critical factors of the process
- More than 30 successful transfers

##### cGMP Manufacturing, Infrastructure and Systems

- Cost-effective approach, ensuring regulatory compliance and timeliness-to-market
- Product manufacturing and comprehensive support systems and infrastructure (QA, QC, information systems, materials control, validation and more)

##### Global Logistics and Storage

- Delivery method includes all biological parameters, quality controls and standardized procedures to ensure efficient and successful delivery of products



#### Manufacturing Development



##### Center for Innovation and Engineering

- Complete spectrum of personalized optimization services from conceptualization to creation of technology



##### Process Development

- Process design, optimization and scale-out/scale-up services through accountable and adaptable teams



##### Analytical Development

- Testing methods satisfy Chemistry Manufacturing and Controls (CMC) requirements of IND or BLA filing



##### Consulting

- Roadmaps for every stage of a process, from understanding and defining a product's attributes to commercial-stage manufacturing

### Experience With Multiple Cell Types



#### Immunotherapy

- Dendritic Cells
- T Cells (CAR, TCR, Treg)
- Tumor Cells
- Natural Killer Cells
- Donor Lymphocyte Infusion
- Macrophages
- B Cells



#### Neuro/Endocrine

- Neural Stem Cells
- Porcine Islets



#### Stem Cells

- CD34+ Gene Edited Cells
- Hematopoietic Progenitor Cells

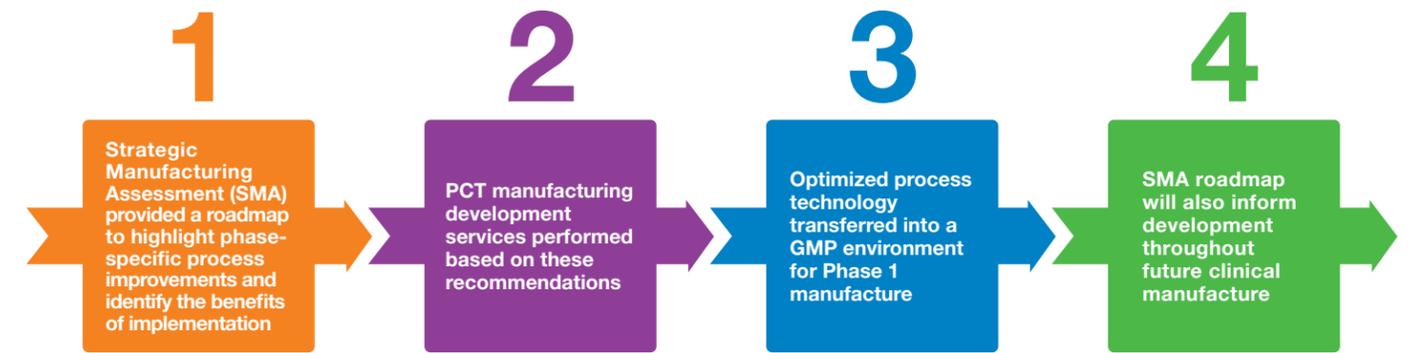


#### Connective/Dermal/Stromal Tissue Cells

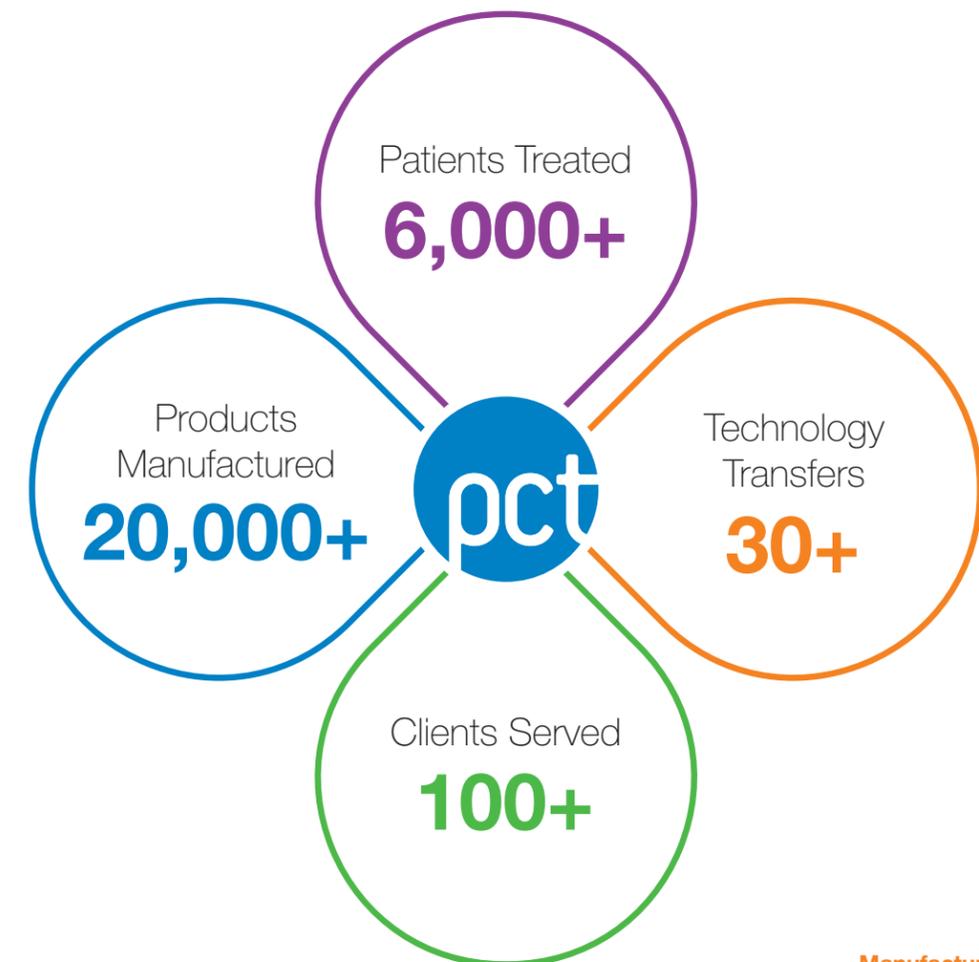
- Mesenchymal Stromal Cells
- Fibroblasts
- Keratinocytes



This case study shows how a major biotech company has leveraged our experience to facilitate product manufacture.



Unprecedented results in meeting milestones through a client-focused mindset



**Our approach to customer engagement has stewardship at its core**

PCT services team employees value a can-do attitude, collaboration, accountability and adaptability. The commitment to these concepts guides our work together, leverages our expertise to innovate, drives us to solve complex problems, and creates value for our clients.

Our employees are the heart of the PCT service platform. Their commitment to project milestones, driven by a passion to help patients in need, puts the stewardship of our clients' products in their dependable hands. We have a deep understanding and respect for the impact of what we do on customer milestones and business results.



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