



Hitachi Chemical
HITACHI

STRATEGIC MANUFACTURING ASSESSMENT

A PCT Consulting Product



Start With the Best Plan for Your Cell Therapy

Accelerate Progress Towards Clinical Adoption and Minimize the Risk

The pathway from conception to clinical adoption for a cell therapy is long, complex and resource intensive. To be successful, the cell therapy product must be manufactured to high quality standards using a robust, cost-effective process, in a manner that will scale to meet clinical demand and be sustainable over the commercial life of the product.

Preclinical and clinical developers can optimize their chances for success and avoid costly mistakes and delays with a PCT Strategic Manufacturing Assessment (SMA). Our experts will review your current approach against critical success factors such as cost of goods, quality and scalability to deliver to you a detailed roadmap for establishing a commercially viable manufacturing process.

Strategic Manufacturing Assessments can help companies at all stages:

- **Early-stage companies** with preclinical data and basic intellectual property on which to base development of a cell therapy manufacturing process. The SMA provides strategic guidance, definition of unit processes, equipment recommendations and more.
- **Clinical-phase cell therapy developers.** You've encountered delays and now want to restart or potentially transfer out of a small CMO or an academic manufacturing environment.
- **Mature companies** with a clinical-phase product being manufactured in-house or with a CMO. You need the help of cell therapy experts to optimize processes and accelerate timelines.

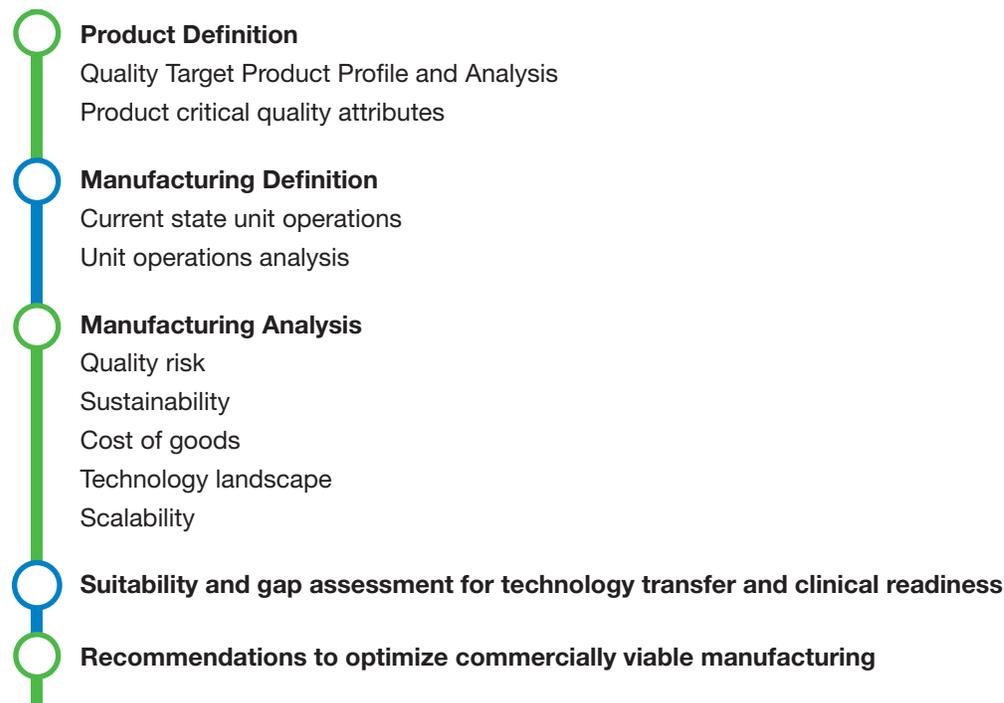
Create Your Roadmap for Success

A PCT Strategic Manufacturing Assessment builds on nearly two decades of innovation in cell therapy manufacturing. We leverage our vast experience to deliver an objective, systematic and rapid appraisal of your cell therapy manufacturing process, with immediately actionable recommendations to drive product development and commercialization timelines.

An SMA delivers immediate and lasting value to a cell therapy process, and can be leveraged in multiple ways, from facilitating and streamlining technology transfer to building investor confidence.

The SMA incorporates elements of Development by Design (quality, cost of goods, scalability, and sustainability) priorities to facilitate GMP compliance to support clinical studies, opportunity for incorporation of advanced technology (e.g. closed systems, automation, bioreactors, etc.) and strategic considerations for commercially viable manufacturing.

Our detailed analysis will include the following:



Plan Ahead for Your Product's Future

Target Product Profiles and Quality by Design

For cell therapies, where product attributes heavily rely on process, commercialization is unlikely to be successful without an effective development process. Various approaches to optimizing process and product development exist. The figure below outlines components recognized by the FDA and other regulatory agencies regarding Target Product Profiles and Quality by Design (QbD).

