STRATEGIC COMMERCIAL MANUFACTURING PLAN

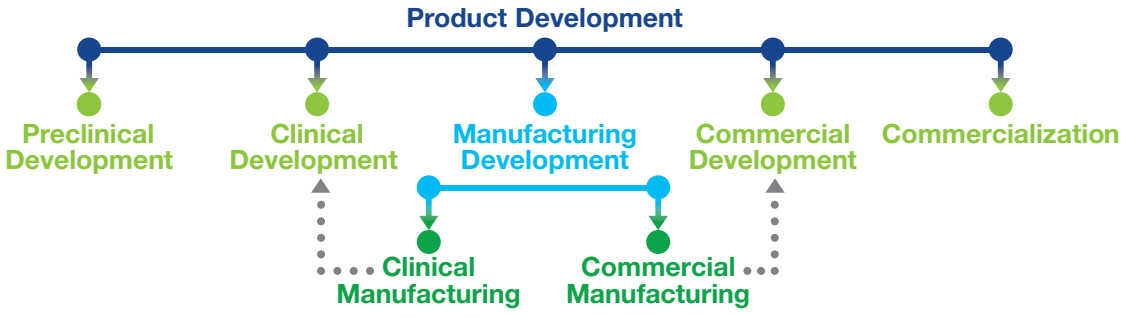
A PCT Consulting Product

Strategize Your Manufacturing Development

PCT's Strategic Commercial Manufacturing Plan (SCMP) allows the cell therapy developer to apprise and align its stakeholders, make informed choices as to its needs to fund further development, plan for future-state unit operations and project COGs both at commercial launch and at scale post-launch. The SCMP provides the developer with actionable recommendations including a breakdown of the cost, duration, timing, justification and expected impact of each development and optimization objective for its product candidate.

An SCMP includes three primary segments:

- Structured breakdown and critique of current-state manufacturing definition and implementation
- Data-driven analysis of historical manufacturing experience to identify optimization, improvement and risk mitigation opportunities
- A comprehensive, practical, priority-driven roadmap for optimization and development to achieve a future state of commercially viable manufacturing taking into account surrounding clinical and business objectives of your company



Hitachi Chemical Advanced Therapeutics Solutions, LLC

For true cell therapy commercial readiness, think well beyond regulatory approval

The pathway from conception to regulatory approval and commercialization of 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.

A PCT SCMP incorporates elements from PCT's strategic manufacturing assessment (SMA) and uses them, among other building blocks, to deliver a thorough assessment and to provide a clear path to commercial success.

The SCMP is most appropriate for a cell therapy product developer with at least preliminary process and product definition, manufacturing data to support data-driven recommendations, some first-in-man clinical testing and a reasonable sense of the commercial prospects for their candidate product.

The plan is crafted in the context of all elements of commercial product development (diagram below) and intended to facilitate alignment across this diverse set of stakeholders.

The SCMP will include:

Product Definition

Quality Target Product Profile and Analysis

Product Critical Quality Attributes (CQAs) and CQA Analysis

Manufacturing Definition

Unit Operations Overview and Analysis

Manufacturing Analysis

Quality Risk Analysis

Cost of Goods Analysis

Scalability Analysis

Sustainability Analysis

Technology Landscape Analysis

Optimization and Development Plan

Optimization Recommendations for Production and Testing Unit Operations

Comparability Risk Assessment

Optimization and Development Planning Chart

Future-State Unit Operations Diagrams

Strategic Timeline