

Customized Roadmap: A Strategic Commercial Manufacturing Plan

The pathway from conception to regulatory approval and commercialization of a cell therapy is long, complex, and resource intensive. To help inform numerous decisions along the way, an effective commercial manufacturing strategy for a cell therapy should be built on the four principles of what PCT calls development by design (DbD): quality, cost of goods (COGs), scalability, and sustainability. Proactively implementing a DbD strategy does not force a cell therapy developer to make a large manufacturing investment early in a project, but it does mean that the company must plan ahead. As a cell therapy moves through clinical development, working through the four facets of DbD at an early stage can provide significant cost and time advantages as well as effective management of comparability risk.

With DbD in mind, a prudent cell therapy developer will initiate and produce a strategic commercial manufacturing plan (SCMP) with the support of an experienced manufacturing partner. An SCMP provides a comprehensive, strategic, detailed roadmap to commercial deliverability. An SCMP is most appropriate for a cell therapy product developer with at least preliminary process and product definition, some first-in-man clinical testing, and a reasonable sense of commercial prospects for their candidate product.

An SCMP should include three primary segments: an evaluation of a developer's current manufacturing processes; an analysis of areas for optimization and improvement; and a practical, implementable strategy to take a process from its current state to a future, commercial-ready state while reducing risks.

The **evaluation segment** should provide a thorough description of the current state of a developer's manufacturing process. It should include current-state descriptions of a quality target product profile (QTPP), critical quality attributes (CQAs), and unit operations.

The **analysis segment** should take into account information derived from the evaluation segment. That information helps identify opportunities for optimization and improvement as well as particular areas of challenge and risk. Here, strengths and weaknesses in a developer's manufacturing process are identified to outline what is needed to successfully evolve from the current state to a state of commercially viable manufacturing. Manufacturers must determine whether anything about the current state of their products and processes might lead to problems later in commercial manufacturing. Does a product have too high a COGs? Is it not scalable to meet market demand or not sustainable over its commercial life?



The **strategy segment** should provide concrete recommendations in the form of an optimization plan based on evaluations and analyses performed. Successful implementation of this plan is needed to meet commercial manufacturing. Although the scope of an SCMP is focused on manufacturing development, the plan must be crafted and executed in the context of all the other elements of commercial product development. An **SCMP from PCT** includes

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

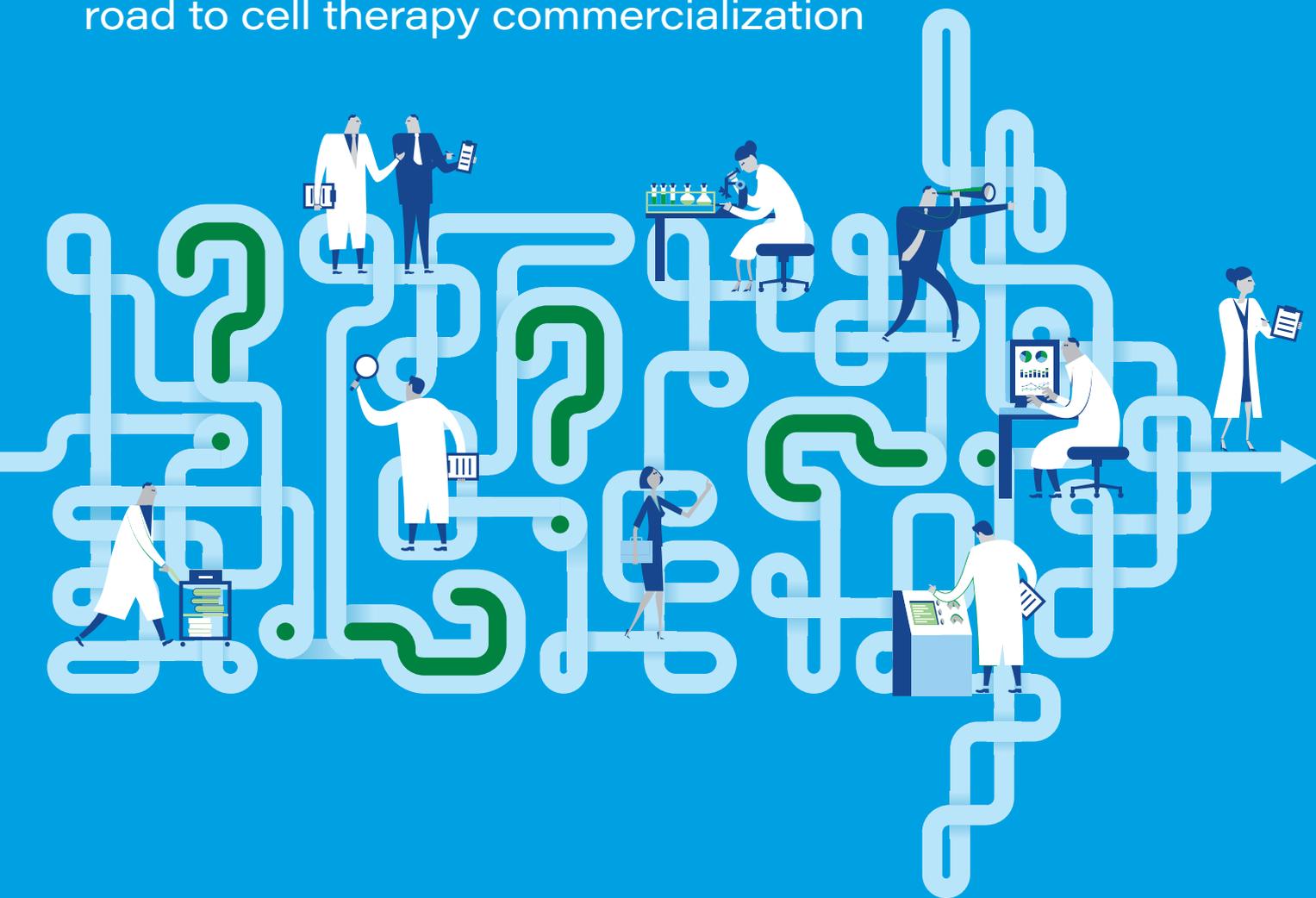
- Optimization recommendations for production and testing unit operations
- Comparability risk assessment
- Optimization and development planning chart
- Future state unit operations diagrams
- Strategic timeline
- Budget estimation.

PCT's SCMP allows a 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 postlaunch. An SCMP provides a developer with actionable recommendations to ensure that it is in the best possible position to travel the road to commercial success. 🌐

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A Strategic Commercial Manufacturing Plan from PCT

Make informed decisions on the road to cell therapy commercialization



The pathway from concept to commercialization of a cell therapy is long, complex and resource-intensive.

A PCT Strategic Commercial Manufacturing Plan provides you with actionable recommendations including a breakdown of the cost, duration, timing, justification and expected impact of each development and optimization objective PCT recommends for your product candidate. This customized plan is based on our Development by Design approach supported by more than 17 years of cell therapy experience.

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