WEBINAR DIGEST

Rapid translation of a cellular therapeutic from research to clinic

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Cell therapies face regulatory and manufacturing challenges long before they are accessible to patients. Even as therapies prove effective and safe, raw material and manufacturing decisions made during early development can either stall progression or rapidly accelerate it.

Utilizing scalable manufacturing processes and translation friendly raw materials during product development of MSCs and extracellular vesicle (EV) therapies will enable cell therapy developers to accelerate leading candidates into clinical trials, ultimately enabling more curative treatments to reach patients.

CELL-BASED THERAPY MANUFACTURING PROCESS DEVELOPMENT

Developing a cell-based therapy manufacturing process requires varying focus and expertise, as demonstrated in **Figure 1.** The critical quality, scale and expertise needs change as developers move from research and development (R&D) to product development, to clinical implementation. There are key development requirements that can accelerate programs through this journey are described in **Figure 2**.

RoosterBio Cell and Media Systems are engineered to make mesenchymal stem cells (MSCs) and extracellular vesicles (EVs) easy to establish within new programs, and easy to scale for product and process development **(Figure 3)**. The overall goal is to make MSCs and EVs easy to translate into the clinic. Strategically choosing the right supply chain partner can remove years of time and millions of dollars from standard product development timelines.

INDUSTRIALIZED SUPPLY CHAINS & RAPID TRANSLATION

An industrialized supply chain can enable rapid translation of a cellular therapeutic in a number of ways. Where possible, leveraging 'off-the-shelf' products with built-in processes will reduce development timelines. This is because reducing internal resources in cell manufacturing allows a more targeted focus on your IP. Building manufacturing scalability into process development is of great importance, as process development is cyclical. Scalability will enable a smooth transition to larger lot sizes, thus rapidly accelerating therapeutic program development. High-quality fit-for-purpose materials can reduce regulatory hurdles. Development grade materials with cGMP analogs backed by regulatory packages support a seamless transition from pharmaceutical product development (PPD) to the clinic.

THE MONACO CELL THERAPY TRIAL: A CASE STUDY

Initial results from the MONACO study (**Mon**ocytes as an **A**nti-fibrotic therapy after **COVID**-19), which uses RoosterBio Cell and Media Systems in MSC production, have been encouraging and signal towards efficacy. RoosterBio's "off-the-shelf" solutions enabled regulatory compliance as well as rapid translation, which were critical in meeting the escalated need for COVID -19 treatments. With encouraging clinical data and a robust, scalable manufacturing process, Dr Ashish Patel is now working towards a large Phase 1b/2a trial.

Figure 1. Industry standards in the cell-based therapy manufacturing process

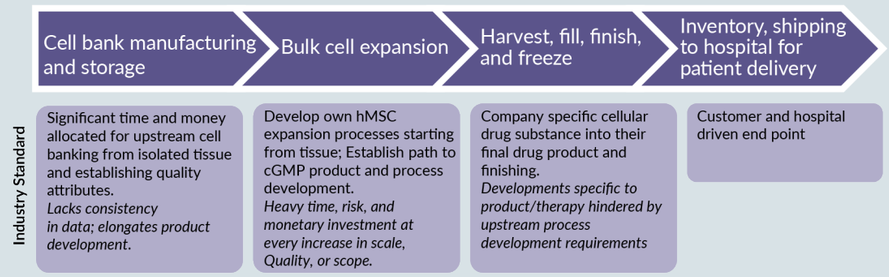


Figure 2. Key requirements in rapid translation of a product

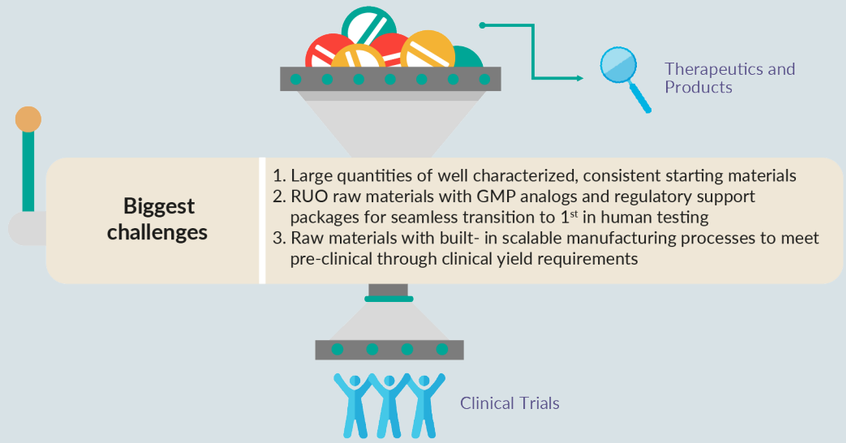
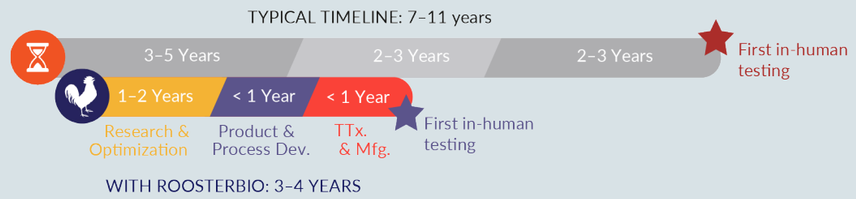


Figure 3. Typical timeline vs. timeline with RoosterBio Cell and Media Systems



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