

# ROOSTERBIO HELPS SYNTHETIC BIOLOGY COMPANY BECOME TECH-TRANSFER READY

**Company A** is a next generation therapeutics company that is utilizing synthetic biology to program cells to be targeted and responsive to complex diseases. The success of their synthetic biology platform is dependent on the quality of the cells for which they are programming. In their clinical pipeline to demonstrate the robustness of their gene circuit platform, the team decided to use human MSCs as a cellular chassis to develop a targeted and potent therapeutic.

## OVERVIEW

Company A scientists are looking to develop a novel gene modified cell-based therapy that can be delivered to patients as efficiently and safely as possible. Finding a suitable cellular chassis and a trusted allogeneic cell supplier is critical to the success of their program.

## CHALLENGE

To navigate through the complex product and process development stages of this novel therapeutic, Company A team need to find the right partner who can provide them with cellular starting materials for MSC manufacturing and has the expertise to help them create a robust process that can produce a successful product.

## SOLUTION

RoosterBio supplied off-the-shelf RUO and cGMP hMSC starting materials in formats that accelerated their product and process development efforts. By working closely with the Company team, RoosterBio helped train their scientists and develop a manufacturing process that met their production needs for a Phase I requirement.

## RESULTS

Company A scientists gained expertise in MSC manufacturing and successfully developed a tech-transfer ready process that generated the yields and desired outcomes they aimed for within targeted timelines.

## BETTER TOGETHER

As a fast-growing start-up with deep expertise in synthetic biology, Company A team was seeking the right partner who could provide cGMP compliant cell banks to accelerate their clinical program. After an initial evaluation of RoosterBio's RUO hMSCs, they realized that RoosterBio was not only able to provide them with product formats suited for product development and clinical manufacturing but also had deep expertise in MSC manufacturing that would complement the knowledge of their scientists.

## STARTING OFF ON THE RIGHT FOOT

Company A scientists started with RoosterBio's xeno-free development grade hMSCs and expansion media in their early POC studies. The availability of multiple donors at the research level allowed them to screen different donors to gain an understanding of donor characteristics that were important for quality control of their final product. Through this process of screening and extensive testing, the team successfully developed a culture process that produced critical quality attributes such as identity and potency across multiple donors which helped them to decide the optimal set of donors for their phase I clinical trial.

## FROM LAB TO MANUFACTURING

The next step was to take it to the manufacturing scale and this is where the RoosterBio team provided our expertise. By working alongside, we transferred our process knowledge to the Company team and helped them to develop a manufacturing process that was tech transfer ready. Critical to their success was the fact that at each stage of their program from research, product & process development, to GMP manufacturing, they were able to readily assess donors and materials at the appropriate volumes that they need. This allowed the company to work efficiently from an economic and productivity perspective.

## WHY IT MATTERS

By tapping into RoosterBio's industrialized supply chain of hMSCs and manufacturing expertise, the Company quickly ramped up their manufacturing readiness for GMP production of their novel hMSC based gene therapy and met critical milestones in their clinical program. More importantly, Company A scientists were able to focus their time and energy on value-adding activities to their product portfolio, maintaining their strong IP position in the marketplace.