EXCELLOS™

PHACILITATE

cGMP Compliant Primary Isolation, Expansion and Editing of a Novel Cell Therapy for an Oncology Indication

1. Ability to develop and execute a complex cell isolation method from primary umbilical cord tissues
2. Successful tech transfer of a lentiviral transduction procedure for the cell therapy
3. Successful process development of a scale up procedure from tissue culture stacks to a commercial bioreactor system

1. The Challenge

A new cell therapy manufacturing methodology needed to be tech transferred to Excellos manufacturing teams in a relatively short timeline as part of initiation of Phase I and Phase II clinical trials with the product.

2. The Process

This was a highly complex process, including novel isolation methods and *ex vivo* expansion of the adherent cells isolated from umbilical cord tissues for the establishment of an *ex vivo* expanded lentiviral transduced manufacturing intermediate stored in vapor phase LN2. The manufacturing intermediate cell bank inventory was established and subsequently thawed for *ex vivo* larger scale production in hollow fiber bioreactor systems. All processes, from umbilical cord tissue sample collection, primary cell isolation, processing, characterization and expansion, lentiviral transduction and cryostorage of the manufacturing intermediate with subsequent thawing and large-scale hollow fiber bioreactor expansion were carried out under cGMP conditions for clinical trial use. Substantial process development activities were incorporated into the initial manufacturing processes to optimize yield and acceptable product quality.

> *We at Excellos are using our principle of cell therapy excellence not only for starting material and product characterization, but also as an integral part of our QbD processes to select the best cell processing platforms for the production of a high quality cell therapy product.*

CONTACT US

EXCELLOS™

PHACILITATE

3. The Solution

Excellos staff were trained in all aspects of tissue collection, cell isolation, expansion, lentiviral transduction and final product production using the optimized manufacturing design mapped out in collaboration with the client.

4. The Results

The PD and tech transfer activities were completed with Excellos staff and successfully enabled completion of the clients' Phase I and Phase II studies in cancer patients, resulting in FDA RMAT designation and approval to launch pivotal Phase III trials.

5. The Impact

This highly complex manufacturing process demonstrated the capabilities of Excellos staff to engage in unorthodox cell isolation, transduction and production processes. This scenario also demonstrated the real-time abilities of the Excellos manufacturing teams to respond to process development optimization strategies that were evaluated and implemented during Phase I and Phase II manufacturing of the clinical product and manufacturing intermediates.

> *This was a complex Process Development effort that required a shoulder-to-shoulder collaborative effort between Excellos and the client. That's what these de novo PD projects require. Our team brings a spirit of resilience, collaboration, and transparency to every project that we take on. The capabilities of the Manufacturing and Quality teams to successfully complete all the necessary activities on time and on budget enabled this client asset to help patients who needed it.*
>
> **- Robert Tressler, CSO**

CONTACT US