

# USE OF RESEARCH GRADE MATERIALS FOR MANUFACTURING DUE TO SOURCE MATERIAL CONSTRAINTS



# BACKGROUND



Various new cell therapies are currently being identified and in early development using novel/rare cell types typically collected and isolated by non-cGMP research methods as there are no cGMP processes mapped for these new materials.

- Currently the criteria for access to research grade materials as source materials for the manufacture of clinical products is unclear. While the FDA has made some requirements for cellular starting material in the 2020 CMC gene therapy guidance, more detail would be helpful.

While the 2022 OTAT town hall meeting indicated that starting material does not need to be GMP compliant, as long as consistency/control are demonstrated, we request that the Agency supply further guidance on the requirements deemed necessary to allow access to research grade materials as starting material for the manufacture of cell therapies to be used in clinical trials and for commercial production of approved cell therapies.



# ISSUE

The variety of cell-based therapies being developed for various indications at times may require access to research grade source material that may not have fully met 21 CFR 1271 guidelines relevant to subparts A, C and D.

Examples are MSC subsets, rare immune cell subtypes, cord tissue derived products and other tissue-derived cellular starting materials that are not typically generated under cGMP, but as research grade materials.

# 1. DESIRED OUTCOME:

1. What specifications for non-GMP research starting material would the agency require as relates to:

- Identity
- Purity
- Safety

2. What guidelines would the agency require for acquisition, collection, processing and handling of research grade starting materials. e.g.

- Informed consent
- IRB approval
- transition to cGMP processing
- traceability

What items should be addressed for material that may not have been initially collected under CFR part 1271 guidelines?

Would post-hoc/in-process testing, e.g. for CMV status be acceptable?

