bio-techne®

Key Considerations for Cytokine Supplier Selection for Cell Therapies

In the cell therapy space, GMP ancillary materials include cytokines and growth factors used as culture supplements to make cell-based medicines. The success of a cell therapy can depend on the quality and consistency of supply of these ancillary materials, making the choice of supplier a crucial decision to get right.

Effective partnering is central to ensuring end-users' primary considerations of patient safety, lot-to-lot consistency, and supply chain reliability are addressed. Relationships with suppliers must be more than transactional.

A smooth transition into clinical production can be facilitated by integrating RUO-grade cytokines with equivalent GMP-grade options early in discovery (FIGURE 1).

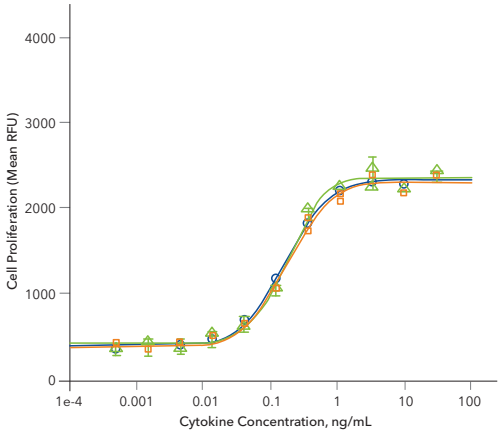
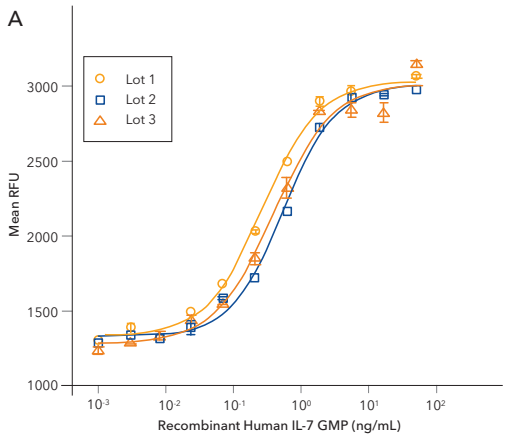


FIGURE 1. Equivalent bioactivity with RUO, animal-free preclinical, and GMP grades of Bio-Techne's IL-2 cytokine as measured in cell proliferation assays. RUO, animal-free preclinical, and GMP grades of human IL-2 (blue, orange, green, respectively).

CONSISTENCY

Cytokines and growth factors are inherently prone to variability, due to their origins in biological systems. Partnering with the right suppliers will help to maintain production consistency throughout the lifecycle of a product. Spanning lots is almost inevitable, so to ensure consistency in cell culture, data from at least three past lots should be observed to confirm lot-to-lot consistency. If possible, testing material from three separate lots to examine the consistency in data (FIGURE 2) should be performed.

Controlling for assay variability can be managed using master control lots. These master control lots are tested with each new lot and should have identical activity every time. Variation in the activity of the known control is indicative of variability in the assay itself.



SUPPLY CHAIN

Planning early and anticipating late-stage requirements will help to avoid disruptive changes later. Ensuring that a supplier can meet your needs through later stage trials and commercialization requires a few considerations. First, lot size, including history of lot size, lot-to-lot consistency and past stability data should be queried. A master supply agreement can give the supplier visibility of the client's needs, whilst also giving the client confidence that material will be available when required. Considering a secondary supplier will also decrease risk. These considerations should be made early on to avoid the necessity of significant changes to critical raw materials, like cytokines and growth factors, mid-stream.

REFERENCES

1. Cell & Gene Therapy Insights 2022; 8(5), 621; DOI: 10.18609/cgti.2022.097

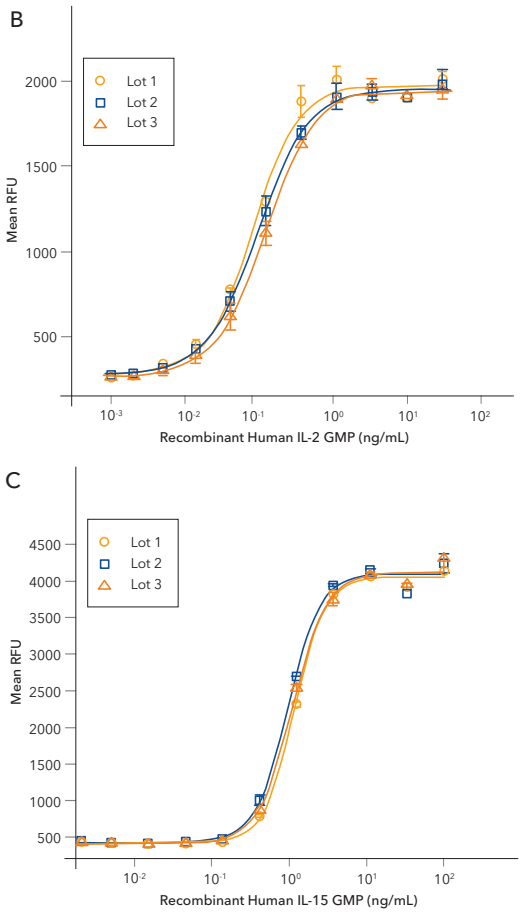


FIGURE 2. Bioactivity assays using IL-7 (A), IL-15 (B), and IL-2 (C) from three separate bulk lots. The bioactivity curves are overlapping, suggesting that spanning lots with these particular proteins would not affect the cell culture consistency.

GMP CUSTOM SERVICES

Since you have optimized your cell manufacturing process for your desired outcome, we will work with you to develop and deliver GMP raw materials and services that meet your specifications. We can provide customized vialing as well as construct design, formulation, and quality control analysis. With a dedicated project manager, our expert scientists, quality assurance team, and world-class technical support, we will deliver solutions exactly tailored to bring you success faster and more economically.

Read the following Case Study to learn about how Bio-Techne can support your cell therapy manufacturing process with customized GMP cytokines.

Read Case Study | bio-techne.com/gmp-proteins/ruo-gmp-protein-case-study

bio-techne®

Contact Us

R&D Systems™ Novus Biologicals™ Tocris Bioscience™ ProteinSimple™ ACD™

STRY0246398_CGT_FL_Insights FastFacts_FR