

Choosing a CDMO: The Questions That Reveal How an iPSC Program Will Actually Run

Most CDMO evaluations are designed to answer one question: can this partner manufacture the product? For an iPSC program, the more revealing question is how well the entire process will hold together once they do.

Cleanroom capacity, regulatory inspection history, quality systems, geography, cost, and technical capabilities are essential screening criteria. But among qualified candidates, they reveal relatively little about how a multi-week iPSC workflow will behave across banking, differentiation, harvest, formulation, testing, and release.

That is where continuity becomes consequential. Every handoff introduces another place for process assumptions, documentation, and analytical strategy to diverge. The questions below are designed to uncover those seams before the program is running through them.

How Closely Are iPSC Differentiation Development and GMP Manufacturing Connected?

Start by asking how differentiation development incorporates the requirements of GMP execution. The answer should describe how teams work together, including when manufacturing and quality colleagues review the process and how their input informs development decisions.

A process developed without that input may need changes at transfer. Handling steps may require closure, stage transitions may need to accommodate staffing and scheduling, and in-process decisions may need measurable, documented criteria. Depending on their timing and impact on product quality, those changes can create additional characterization or comparability work.

Ask who owns the transition, how development records support transfer, and how process changes are reviewed across teams. A coordinated framework

helps identify execution constraints while there is still room to address them.

Have They Banked iPSCs Before?

Banking is a foundational part of an iPSC manufacturing strategy. Ask how the partner establishes and manages master and working cell banks, and what experience it has with the proposed cell type.

Confirm:

- Experience banking pluripotent lines, including passage tracking and genetic stability monitoring
- Capability to bank a differentiated intermediate where the process design calls for it
- Which banking activities are performed in-house and how any external work is managed
- How bank characterization, storage, and inventory planning support the program's anticipated needs

Ask how the proposed bank size was calculated, including projected demand, passage limits, testing requirements, and reserve material. The answer should also address what happens if the bank needs to be replenished or replaced, and how any resulting characterization and comparability work would be planned.

What Does the Analytical Package Actually Include?

An analytical capability list is a starting point. Ask which methods are established, which require product-specific development, and how qualification and validation will progress with the program.

The discussion should cover:

- Identity and purity of the intended derivative cell type
- Residual undifferentiated cells
- Genetic stability
- Functional potency aligned with the intended mechanism of action

Ask how methods are selected for each purpose, whether their sensitivity supports the proposed acceptance criteria, and how their suitability is assessed in the material being tested.



Confirm which activities are performed in-house and which use external laboratories. For outsourced testing, ask who owns method transfer, sample logistics, data review, and turnaround times. The analytical plan should distinguish characterization, in-process testing, and release requirements, with clear responsibilities and timelines.

Potency deserves a direct discussion early in development. Ask for relevant examples of function-linked assay development and how the team establishes suitability for release testing. Experience with another program is useful evidence of capability; the proposed approach still needs to fit your product.

Is the Facility Built for Long Campaigns?

Differentiation timelines measured in weeks change what a facility needs to be good at.

A suite occupied for three or four weeks by a single campaign creates specific operational demands. Ask about:

- Suite availability and scheduling flexibility
- Segregation strategy when long campaigns overlap
- Infrastructure for closed media exchange, sampling, and transfers
- Process and environmental monitoring across an extended culture window

Ask how campaign scheduling is managed and what happens when a program's timeline moves. The answer should explain how the facility accommodates delays or extended culture periods, and what those changes mean for suite access and subsequent batches.

Where Does Starting Material Come From?

For iPSC programs, the starting material is a pluripotent line whose provenance, documentation, and characteristics shape the downstream manufacturing strategy.

Ask how the CDMO evaluates a proposed line's:

- Provenance
- Consent and donor documentation
- Characterization
- Suitability for the intended development stage

If early work uses research-use-only material, the program should have a defined route to clinical-grade starting material and an assessment of what that transition may require.

Established supplier relationships can support that planning, alongside a documented assessment of the selected line. Ask who owns the review, what gaps remain, and how any changes in starting material would be evaluated before GMP manufacturing.

Where Made Scientific Fits

Made Scientific brings process and analytical development, GMP manufacturing, and quality functions into one integrated framework, with a U.S. manufacturing network spanning Princeton, New Jersey, and Philadelphia, Pennsylvania. For iPSC programs, early collaboration across these teams helps align banking, differentiation development, manufacturing execution, and testing requirements while the process is still being defined.

That framework covers:

- **Starting material:** iPSC lines and upstream technology through the partnership with Pluristyx, connecting line selection and characterization with development and manufacturing strategy
- **Process and analytical development:** differentiation process and analytical method development shaped by GMP requirements
- **Manufacturing:** engineering runs, aseptic process simulation, and GMP manufacturing in closed, single-use workflows
- **Regulatory and quality support:** stage-appropriate quality systems aligned with FDA, EMA, and ICH expectations

Bottom Line

A CDMO evaluation should establish both technical capability and how the partner will coordinate the program across development, banking, manufacturing, and release. Clear ownership, connected documentation, and early analytical planning help teams manage changes and the comparability questions they may introduce.

For iPSC-derived therapies, decisions made upstream influence the material entering every subsequent step. Look for a partner that can explain how those decisions are carried through the workflow, how performance is assessed across transitions, and how issues are resolved when the process behaves differently than expected.



Ready to discuss what your iPSC program needs from a manufacturing partner?

[Let's talk.](#)

About Made Scientific

Made Scientific is a leading U.S.-based clinical- and commercial-stage cell therapy contract development and manufacturing organization (CDMO) specializing in the development, manufacturing, and release of autologous and allogeneic cell therapy products. With GMP facilities located in New Jersey and Pennsylvania, Made Scientific combines the agility of a specialist CDMO with the technical depth to deliver reliable, scalable manufacturing.

Made Scientific is supported by GC Corporation, a long-term strategic owner providing stability, global access, and sustained investment in the business. This partnership reflects a shared commitment to building deliberately, prioritizing scale and quality over short-term outcomes, and positions Made Scientific to advance cell therapy manufacturing with a long-term vision. For more information, visit madescientific.com.