

Optimising iPSC Manufacturing for Clinical Success

ASSESSING PROCESS TRANSLATION & SCALABILITY FOR GMP MANUFACTURE

THE CHALLENGE

An **innovative cell therapy start-up** required a feasibility study to translate its **iPSC-based academic process** into a GMP-ready clinical manufacturing strategy. Several **non-translatable unit operations** and an **extended culture period** posed significant scalability and regulatory hurdles. The client needed a **cost-effective, efficient approach** to ensure feasibility while maintaining product quality.

OUR APPROACH

eXmoor Pharma worked **closely with the client** to assess and refine the process for **GMP readiness**, ensuring **seamless technology transfer, process optimisation, and scalability**:

- **Technology Transfer:** Documentation review, onsite training, and baseline process execution.
- **2D to 3D Translation:** Evaluated scalable culture platforms to replace small-scale, non-GMP vessels.
- **GMP-Ready Assessment:** Reviewed reagent and protocol compatibility, replacing unsuitable dissociation and cryopreservation steps.
- **New Technologies:** Demonstrated and assessed **automated GMP-qualified** alternatives to replace labour-intensive academic unit operations.

DELIVERABLES

- Road map for future technology transfer.
- Assessment and feasibility reports on key unit operations.
- Comparability studies between research and GMP materials.
- Next step process development and CMC strategy.

IMPACT

eXmoor Pharma provided a **clear pathway to GMP manufacturing**, ensuring process scalability and regulatory alignment. Product **quality and yield were optimised**, demonstrating the impact of a **collaborative approach** between the client's **process expertise** and eXmoor Pharma's **development capabilities**.

EXMOOR PHARMA AT A GLANCE



Philosophy: With a focus on the entire journey from bench to market, we streamline and de-risk projects to maximise product success.



Capability: A full-service partner delivering high-value solutions for better, faster, and cost-effective outcomes.



Trust: Building lasting relationships through trust, transparency, and respect.



Collaboration: An open partnership that complements and enhances your capabilities.



Experience: Over 20 years of expertise, supporting 150+ clients from discovery to patient delivery across diverse programs.



eXmoor worked closely with our process development team to support our iPSC program as we successfully advanced from a very early stage to preclinical stage.

eXmoor ensured a smooth tech transfer from our laboratories, helping to characterise the product, and support shaping the initial process development. Their expertise and collaborative approach made a real difference in working alongside our team, to address our unique scientific challenges."

Gabriella Rolli

CTO, Regenerative Medicine, Tenpoint

