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Clontech TaKaRa cellartis

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TOP 5 TIPS

for working with embryonic stem cells

1 Utilize a trusted sourcing partner to obtain quality starting material

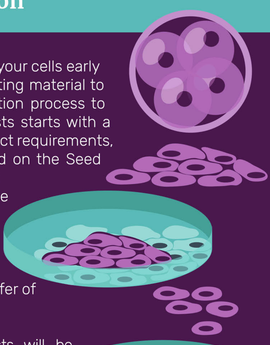
The quality of your finished product is reliant on the quality of your starting material. Working with a reliable sourcing partner will help you define the exact specifications for your cells and provide you with consistently high-quality starting material by taking care of sourcing and derivation under stringent ethical and safety conditions.

2 Ensure personnel are highly trained and have experience in deriving clinical grade lines

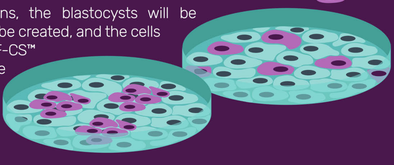
Working with Takara Bio provides access to a dedicated team of technical experts, all of whom have hands-on experience in basic and applied sciences and many of whom have been with Takara Bio since the beginning. From the initial consultation to the comprehensive donor screening process, they will prepare you to produce the highest quality finished product once the starting cell lines have been banked, characterized and handed into your care.

3 Define your cells early to ensure predictable and reliable production

Defining clear and exacting specifications for your cells early on will ensure high cell quality, from the starting material to the finished product. The Takara Bio derivation process to create hES cell lines from sourced blastocysts starts with a detailed consultation to determine exact project requirements, desired quality control tests to be performed on the Seed Banks and Master Cell Bank, deliverables, and timelines. The services team will use those specifications to oversee the sourcing process, including IRB/ethical approval, donor consent, donor screening (medical history interview, physical examination, and testing for infectious diseases), and transfer of blastocysts to the services.



Under GMP-grade conditions, the blastocysts will be thawed, the hES cell line will be created, and the cells expanded in our Cellartis® DEF-CS™ 500 Xeno-Free GMP Grade Basal Medium. The final cell materials will be banked and characterized, then delivered to you.



4 Use a GMP manufacturing facility with appropriate licensing, that is compliant with EUR and US regulations

As we are compliant with regulatory standards around the world and can assist with navigating regulations, your cell or gene therapy will have the best possible start to reach patients around the world. The proprietary hES cell establishment method is feeder-free and animal/human-component free. The starting material is retrieved from FDA-compliant sources according to FDA guidelines. In 2018, our specialized facility in Gothenburg, Sweden was granted a manufacturing license by the Medical Products Agency (the Swedish national authority) for clinical-grade human embryonic stem cell line derivation and banking. Our rigorous and comprehensive quality control system has been designed in collaboration with Kyoto University's Center for iPS Cell Research and Application (CiRA), headed by Shinya Yamanaka.

5 Consider your ability to expand to scale early in the commercialization process

With the Cellartis Clinical Grade hES Cell Derivation Service, Takara Bio will deliver clinical-grade human ES cell lines for use in clinical research settings. Our long history of quality is now paired with GMP compliance, bringing an added level of confidence and consistency to our product and service portfolio. Our GMP-grade products and the deliverables of your custom projects are manufactured under rigorous standards to ensure quality and consistency, in facilities compliant with GMP regulations and guidelines.

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