

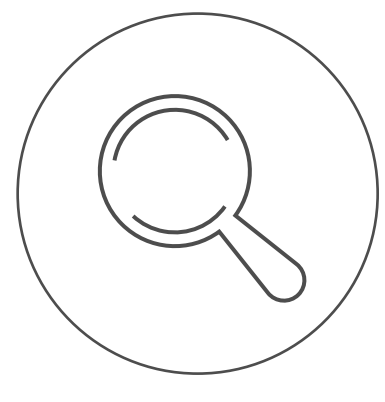
Proper Preparation for Entering the U.S. Market

Case Study

The Company

An international technology provider specializing in the application of artificial intelligence in molecular medicine is revolutionizing transplant compatibility and immunological risk assessment with a fully digital, state-of-the-art epitope-matching technology.

The goal is to provide physicians with a data-driven decision-support tool. The platform uses advanced algorithms to improve the accuracy of donor-recipient matching and long-term immunological risk, thereby ultimately optimizing transplant outcomes worldwide.

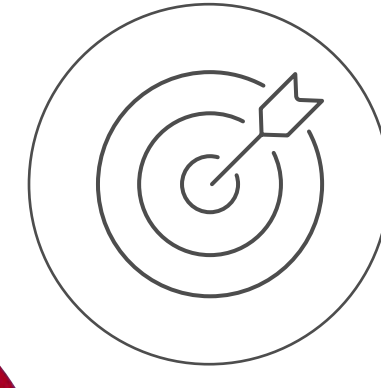


Overview

The company developed software to predict compatibility between donors and recipients prior to kidney transplants and aimed to launch the product in the highly regulated U.S. market.

Due to the lack of reference products, a de novo application was identified as the optimal path to approval. Our FDA experts developed a targeted regulatory strategy, thoroughly prepared for the pre-submission meeting, and provided support both during and after the meeting. This approach resulted in clear and prompt feedback from the FDA, enabling the company to advance the approval process efficiently, purposefully, and with a concrete strategy.

- ✓ Development of a tailored regulatory strategy
- ✓ Conducting a successful pre-submission meeting
- ✓ Laying the groundwork for an efficient and targeted approval process



Challenge

The software developed by the client is specifically designed to accurately predict compatibility between donors and recipients prior to a kidney transplant.

The goal was to initially launch this medical device in the demanding U.S. market. However, upon analyzing the regulatory strategy, it became clear that there was no comparable product that could serve as a reference. Therefore, the De Novo application was identified as the most promising and appropriate path to approval in the U.S.

To establish this complex strategy on a sound basis and prepare the De Novo application optimally, it was necessary to submit specific detailed questions and necessary information to the FDA in advance and discuss them in depth during a pre-submission meeting.



Solution

The FDA experts at the Johner Institute first developed a comprehensive and forward-looking regulatory strategy that provided a clear framework for the entire FDA approval process.

They then thoroughly prepared for the pre-submission meeting by systematically addressing the relevant issues and defining a clear agenda.

During the meeting, we actively supported the company to ensure that all open issues were addressed in a targeted manner.

Even after the meeting, our experts assisted with the follow-up to precisely document the insights gained and immediately integrate them into the approval planning.

AN OVERVIEW OF THE SOLUTION

- ✓ Development of a comprehensive regulatory strategy
- ✓ Thorough preparation for the pre-submission meeting
- ✓ Active support during the meeting
- ✓ Detailed documentation of the findings to be integrated into the regulatory planning



Result

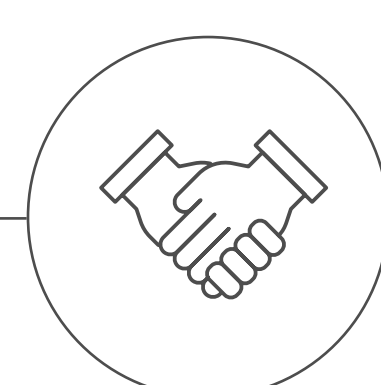
Thanks to the careful preparation of the pre-submission application and expert guidance during the meeting, our client received prompt and precise feedback from the FDA.

This enabled the company to clearly define its regulatory strategy and proceed with a clear roadmap.

This laid the foundation for efficiently and effectively advancing the approval of the innovative product – a crucial step toward a successful market launch in the U.S.

Conclusion

By carefully preparing the pre-submission application and providing support throughout the meeting, we laid the groundwork for a successful market launch in the United States.



Would you like to work with us?

CONTACT