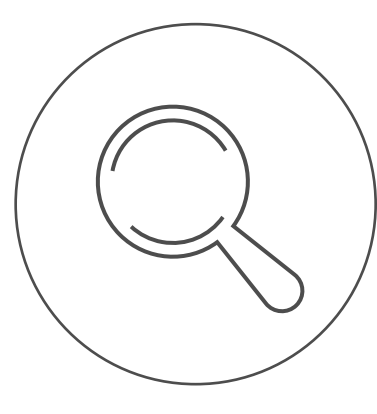


A well-founded regulatory roadmap for tapping into the U.S. market

Case Study

The Company

A leading manufacturer of laboratory centrifuges and incubators that caters to virtually every application need in the medical, chemical, and technical fields. From manual centrifuges to robot-operated models, the product range includes all standard and specialty models. With its solutions—which can also be custom-designed as needed—the company is committed to simplifying daily operations in medical practices and laboratories.

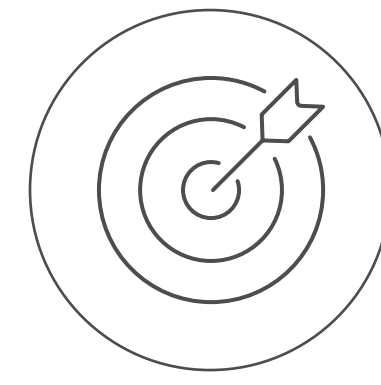


Overview

The company aimed to enter the U.S. market with its innovative blood refrigerators and freezers and needed a regulatory strategy that would meet both the company's internal and legal requirements.

We worked closely with the client and, through a structured process, developed a precise product classification, selected the appropriate approval pathway, identified relevant standards and regulations, and ensured compliance with QMSR requirements. By providing a precise and solution-oriented regulatory roadmap, the company was able to efficiently plan the next steps and thus lay the foundation for a successful market launch in the U.S.

- ✓ Comprehensive regulatory strategy
- ✓ Detailed preparation for the pre-submission meeting with the FDA
- ✓ A clearly structured and well-founded roadmap for market launch



Challenge

The client planned to enter a new, strategically important market – namely the United States – with its innovative blood refrigerators and freezers.

To do so, the company first needed to identify regulatory hurdles early on and address them systematically. The initial goal of the project was to develop a tailored regulatory strategy that would meet both the company's specific requirements and the legal requirements for the distribution of blood refrigerators and freezers in the U.S.



Solution

Using a structured approach, our FDA experts worked with the company to develop a comprehensive regulatory strategy for entering the U.S. market.

Through written documents and interactive workshops, key topics such as correct product classification, the identification of applicable standards and requirements, the selection of the appropriate regulatory pathway (e.g., 510(k)), and the requirements for the quality management system in accordance with QMSR.

Subsequently, our team provided specific recommendations for a pre-submission meeting with the FDA and developed a realistic estimate of the time and cost required for the entire approval project. The approach was practical, solution-oriented, and always carried out in close coordination with the company.

AN OVERVIEW OF THE SOLUTION

- ✓ Development of a comprehensive regulatory strategy
- ✓ Development of product classification
- ✓ Identification of appropriate standards and requirements
- ✓ Selection of the appropriate approval pathway
- ✓ Definition of the requirements for the quality management system
- ✓ Preparation of a realistic estimate of time and cost



Result

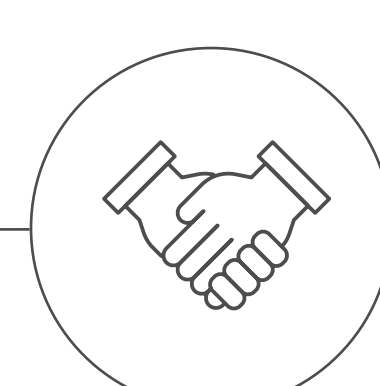
The company received a clearly structured, well-founded regulatory roadmap covering all relevant aspects of its planned market launch in the U.S.

Thanks to our expert guidance and the precise development of the strategy, the company was able to plan its next steps with confidence and focus.

This laid the foundation for an efficient approval process – a crucial step toward successfully establishing the innovative blood refrigerators and freezers in the U.S. market.

Conclusion

We developed a clearly structured regulatory roadmap that laid the groundwork for an efficient approval process—a crucial step toward successfully establishing a presence in the U.S. market.



Would you like to work with us?

[CONTACT](#)