propharma

CASE STUDY

bringing a device from concept to market

A medical device start-up company wanted to bring their device to the global market starting with the US and EU. The client enlisted the assistance of Propharma MedTech to navigate the complex regulatory environments.

The first step was to determine the risk classification of the device, which was the highest risk classification in both the US and EU. This risk determination required the support of clinical data and robust bench testing. Researching public information on similar devices further shaped the initial testing plan and regulatory requirements.

A comprehensive quality system was developed to comply with both the FDA regulations and ISO 13485. In parallel, PPM engaged with the FDA and a selected Notified Body to discuss the test plan, clinical data support, and submission timelines. The biggest challenge revolved around the clinical data required to support the respective submissions. Clinical data from a site in Europe was available along with several publications. Moreover, a vast amount of clinical data was published on a similar marketed device to use as a comparator. PPM devised a strategy and negotiated with FDA on the useof Real World Evidence (RWE) to demonstrate safety and effectiveness of the device. A similar strategy was also employed for satisfying the requirements for CE Marking. PPM also worked extensively with test houses, suppliers, and contract manufacturers.

Less than 3 years after submitting to the FDA and Notified Body the company had an approved PMA and CE Marking to allow entry into both the US and EU markets. Other international markets followed including Canada and Australia.

challenge

Medical Device start-up wants to globally market their device in the US and EU. The device is the highest risk classification in both markets.

Challenges Observed:

- Extensive regulatory, testing, and clinical requirements
- No established quality management system or controls
- Strategize utilizing RWE to demonstrate safety and effectiveness

solution

- Engaged with FDA and selected Notified Body to strategize testing, clinical data, and submission timelines
- Developed comprehensive QMS in compliance with FDA regulations and ISO 13485
- Collected and analyzed patient data from OUS registry to demonstrate safety and performance

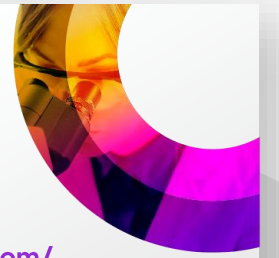
results

- FDA approved the PMA using RWE to demonstrate safety and effectiveness
- The Notified Body granted CE Marking to allow sale in the EU and EU Member States
- Facilitating the use of RWE saved the company millions of dollars in conducting a prospective randomized trial

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle



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