Quest Advanced® Pharma Solutions

In vitro diagnostics (IVD) solutions

Selecting a lab partner for your 510(k) submission: **9 Key Considerations**

Any IVD manufacturer who has submitted a 510(k) knows there are countless hurdles to overcome when submitting a premarket notification to the FDA. One major hurdle is the predicate device study.

by Greg Baschkopf, Sr. Director, IVD and Innovation

Predicate device studies
Development and validation of new diagnostic tests

As you are no doubt aware, IVD manufacturers typically need to perform predicate device studies during the development and validation of new diagnostic tests. A predicate device study involves comparing the performance of a new test to that of a previously approved or cleared device that serves as a reference or "predicate" for the new device. The purpose of this study is to demonstrate that the new test is substantially equivalent to the predicate device in terms of performance, safety, and effectiveness.

Having performed countless predicate device studies on behalf of IVD clients, here are **9 key considerations** we believe make Quest Diagnostics your lab partner of choice.

Working with Quest Diagnostics ensures that your predicate device study is **conducted with the highest level of accuracy, precision, and quality.**

Our team of experts has the knowledge and experience needed to help you **achieve your goals, and we're committed to providing you with the best possible service.**

9 key considerations when selecting **a lab partner for your 510(k) submission**

1 Lab director with Principal Investigator (PI) qualifications

Regulatory bodies such as the FDA require that a qualified PI oversee the conduct of device studies. Our lab directors ensure that your predicate device study is designed and conducted to the highest standards of quality, and according to regulatory requirements.

2 Project management

When working with Quest, every project has a dedicated project manager to ensure that your study runs smoothly. Our project managers have extensive experience in device trial management and can help you navigate the various stages of the study, from protocol development and site selection to data analysis and reporting.

3 Expertise in regulatory requirements

Our team of regulatory experts has extensive experience in the regulatory requirements for predicate device studies. We can help you design a study that meets the relevant regulatory guidelines and requirements, ensuring that your study is conducted in a way that will satisfy the regulatory authorities.

4 Access to a diverse range of samples

As the largest independent clinical diagnostics lab in the country, we have access to a diverse range of samples from various therapeutic areas. We can help you secure the samples needed for your predicate device study, including access to nearly unlimited remnant samples.

5 Access to a broad range of instruments

We have a vast array of state-of-the-art diagnostic instruments and technologies that can be used to support your study. Our instrumentation includes platforms for immunoassays, molecular diagnostics, hematology, and microbiology, among others, and we regularly invest in new technologies to ensure that our laboratory remains at the forefront of diagnostic innovation.

6 Technical expertise

Our team of 650+ MDs and PhDs has deep expertise across all diagnostic technology platforms and therapeutic areas. We have experience in the relevant analytical methods and instrumentation used for IVD tests, allowing us to accurately and precisely perform tests and troubleshoot technical issues.

7 Quality management system

We have a robust quality management system in place, including procedures for equipment maintenance, calibration, and validation, as well as documentation of all procedures and results. This helps ensure that the study is conducted according to relevant standards and guidelines.

8 Scalability

Whatever instrumentation is needed to support your study, chances are that we already have it in-house along with the personnel needed to support it. Our lab space is also ample and available to accommodate any special needs your study may require, regardless of size and technical specifications.

9 Communication and collaboration

We pride ourselves on our ability to communicate effectively with our clients throughout the study and are open to collaboration and feedback. This helps ensure that any issues or concerns are addressed in a timely manner, and that the study is conducted in a manner that meets your needs.

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Contact us today to learn more about how Quest can help you with your predicate device study.

Pharma.QuestDiagnostics.com

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