

## **Contract versus In-House Testing: How do you decide which is right for your test?**

Once you have determined that your device requires mechanical testing, you are faced with the decision of whether to do the testing in-house or to outsource it to a contract test lab. Sometimes this is not an easy decision, as each option has its advantages and drawbacks. Let's review some of the criteria that influence your decision:

### **1. Complexity.**

For example, the test could be basic materials characterization, feasibility for proof of concept, full device fatigue-to-success for FDA submission or supplementary data needed based on device performance in patients. The extent of testing can range from small to extensive requiring varying levels of expertise based on the type of testing. The test could be standardized and easy to perform, or new and complicated requiring specialty expertise.

### **2. Urgency.**

Some testing can be done when your team has the time, while other tests are driven by strict deadlines and project schedules. When time is critical, you need to know that deadlines will be met. As you choose a lab for testing, you should think about its capacity as well. If you have many devices that need to be tested, the lab you choose needs to have adequate capacity to run many devices in parallel to provide more data points. If high frequency tests are needed, you will also need test machines that can run at accelerated frequencies to reduce testing time as much as possible. Time to market is paramount.

### **3. Quality.**

Data and results are important as they form the basis of business decisions. In fact, some testing data are so critical that their accuracy can have a direct impact on business viability. For high importance testing, the requirement for quality is key and provides reassurance to both internal (e.g., management) and external (e.g., FDA) stakeholders.

### **4. Cost.**

The costs of performing the testing in-house and outsourcing are typically calculated and directly compared. Outsourcing costs are easily obtained by requesting quotations from contract test labs. In-house testing costs usually have more parameters to consider:

- Will equipment and accessories (such as fixtures, sensors, etc.) need to be purchased?
- Will parts need to be machined?
- What are the costs of using facilities and equipment?
- What are the costs of technicians' and/or engineers' time spent training with and calibrating the equipment; setting up and performing the test; and performing data analysis and report writing?

In addition to these more obvious costs, other factors need to be considered such as schedule delays and their financial impact. The impact of testing errors and repeat tests should also be considered.

**5. Confidentiality.**

Your intellectual property is a significant component of your competitive advantage. The device design, test protocol, and data generated need to be kept confidential. Does the test lab you are considering have a quality policy that deals directly with confidentiality?

**6. Management preferences.**

You and your management team may have a preference on where the testing should take place. Perhaps you have invested significant capital in an in-house lab or you have worked with a particular contract test lab for a long period of time and trust their services.

With these considerations, it quickly becomes clear that the decision to test in-house or outsource is not always an easy one to make. Below are some guidelines and tips on when it makes sense to do testing in-house and when it might be a good idea to outsource tests.

**Go with in-house testing if:**

- Time is not critical and you have some breathing room.
- You have internal staff with enough experience with the required equipment and in developing the required fixturing.
- Your staff is familiar with developing testing protocols.
- You have enough test equipment capacity to meet your timeline.
- Outsourcing tests is perceived as cost-prohibitive, and you are working within a fixed, limited budget.

**Choose working with a contract test lab if:**

- Specialty expertise is needed. When your device and/or test protocol are unique and so complicated that true expertise is needed, you should work with a group of specialists that has already either tested your device or has tested device designs that are similar to it.
- Expedited testing is critical, and the test lab has the staff and equipment to perform your test in a timely manner.
- Quality is absolutely required, and you need to work with an accredited lab that the FDA has experience with.
- The quotation from the test lab has been thought through and communicated so that there are no surprises once the testing has started.
- The test lab has an accredited quality program that deals with the confidentiality of your device head-on.
- The testing facility is conveniently located in a metropolitan area and promotes effective communication with an open door policy that welcomes visits to review their test needs both before and after the test is started.

As you work on collecting input for your decision, make sure you shop around for a contract test lab to obtain quotations. Assess their expertise and capabilities with a phone consultation or site visit, obtain references, and evaluate their quality accreditations, reputation and reliability.

MDT specializes in medical device contract testing and has expertise in materials characterization, fatigue & durability and corrosion testing. Here are the top benefits of working with MDT:

- Reputation- over 26 years of experience in the industry.
- Quality- ISO17025 Certified and A2LA Accredited.
- Equipment inventory- The largest inventory of fatigue equipment available.
- Capabilities- Broad expertise in developing tests for many medical devices.

With our certifications, extensive equipment base, and broad experience in the medical device testing area, MDT is an ideal partner for your contract testing needs. Please contact us today with your testing requirements. We look forward to working with you.