It Begins and Ends with Testing

Sean Fenske, Editor-in-Chief, MDT

Medical devices differ so dramatically it barely seems appropriate that they fit under one “all encompassing” label. A manufacturer developing orthopedic implants does not have very much in common with a patient monitoring device manufacturer. Both are providing a device to help enhance the level of healthcare a person has access to and, as such, that person’s quality of life, but beyond that, the similarities are few and far between. That is, except for testing. Regardless of the indication, the technology, or the manufacturing process, all medical devices face thorough testing regimens to ensure they function as designed. There’s no room for error with any medical device, whether a low-tech orthopedic knee brace or a life saving pacemaker. The patient relying on the device they are using needs it to work perfectly.

Subjective Testing

That great variety of medical device technologies, however, makes for challenges in ensuring that the proper tests are being performed on each device. There are, of course, standards that need to be followed, but there is certainly the opportunity for those standards to have a level of interpretation that is subjective. Two testing labs will not necessarily test a device in the same manner, explains Dawn A. Lissy, president of Empirical Testing Corp. [1], a testing service partner for medical device OEMs.

“There’s also some latitude in the standards that allow test labs to take in their setups, which again means your results may vary from test to test and lab to lab,” Lissy says. “For example, one type of device may call for three different static tests and three dynamic tests. Someone with less experience may not know which standard static tests are best suited for that particular device, so they may not be testing appropriately (i.e., testing more than is needed for regulatory approval based on that type of device). That means the client is not getting the most for his or her time and money, and it may lead to setbacks as well.”

Materials Testing

Finished device testing is just one piece of the puzzle however. By the time those tests are performed, there have likely already been a number of tests accomplished in the design and engineering phase—or, at least, there should have been to help ensure a successful outcome. Starting with the base material components, testing at this stage can eliminate redesigns later in the development cycle, saving time and money.

“Testing early in the design phase can help identify materials that may have some unexpected risk factors or that lose key material properties when used. Identifying potential problems early can mean that time and effort is not wasted on a material that has to be redesigned and then retested,” states Lisa Olson, vice president of testing and service development for WuXi AppTec [2], a company uniquely

positioned to support product development from concept to commercialization, with industry leading comprehensive testing programs that help ensure regulatory submission success. “Further, some choices in materials and additives will impact the amount of testing that has to be done in the future. Colorants are a prime example. Not all colorants have been tested for specific medical device applications, though they may be on the GRAS list (Generally Recognized as Safe). What seems a simple design choice in the beginning could possibly have significant implications at the point of regulatory review.”

Feasibility Testing

Once material testing has been accomplished and the “proper” components have been identified, a device manufacturer can have feasibility testing performed to ensure they are “on the right path” with a device design. Lissy explains, “Feasibility testing is frequently used to make sure you’re going to hit the minimum criteria before you pay for and wait on a full battery of tests. It lets you know if a device is on the right track and can save you significant time and money if you uncover an issue early that you can correct before a full battery of tests. The full range of testing may require as many as 50 devices, eight to 12 weeks of work and $20,000 to $50,000. For feasibility testing, you can often test eight to 12 specimens over a shorter period of time for a lower cost and ‘gut-check’ acceptance criteria. It’s like a preview of the full range of tests. Yes, it’s an additional commitment of time and money, but it’s often well worth it because it can save a company considerable time and money (manufacturing more test specimens than are needed, extra unnecessary testing, etc).”

Budgeting for Testing

As mentioned, regardless of the type of medical device, a testing program is going to be required to ensure safety and reliability. Therefore, budgeting the proper amount of time and money for this process is a critical aspect when working out the timeline for the project.

As medical device manufacturers deal with increasing budgetary constraints, they are looking to cut costs wherever possible. Looking at testing, however, can lead to disaster. Olson expands on this, “Many OEMs have significant budget constraints and design their testing programs to meet the budget rather than to answer all of the pertinent safety questions. Many studies can be designed to be cost effective and answer safety questions.”

Also addressing the financial aspect of device testing, Lissy explains the benefit of working with a reputable testing partner. “If a manufacturer is working with an experienced, reputable testing lab, that lab will stop the testing process as soon as it’s clear there’s an issue that requires further work from the manufacturer. Some labs will continue to run a full battery of tests even if an early test reveals a fault or problem that will prevent approval.”

Conclusion

As testing is a critical element of product development, device manufacturers need to be sure they either have the proper staff on hand to adequately fulfill their testing needs or they need to spend the time in selecting a testing partner who is

not only fully capable of handling the actual testing protocols, but also has their interests in mind.

Full Responses
To see the full responses of the participants, view these links:

With a Testing Partner, Experience Matters [3]- Dawn A. Lissy, President, Empirical Testing Corp.
Medical Device Testing…Smartly [4]- Lisa Olson, Vice President—Testing and Service Development, WuXi AppTec

Links:
[1] http://www.empiricaltesting.com/
[2] http://www.wuxiapptec.com/
[3] http://www.mdtmag.com/blogs/2013/08/testing-partner-experience-matters-roundtable-q
[4] http://www.mdtmag.com/blogs/2013/08/medical-device-testing…smartly